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BIOBANKING: HOW THE LACK OF A COHERENT POLICY ALLOWED THE VETERANS ADMINISTRATION TO DESTROY AN IRREPLACEABLE COLLECTION OF LEGIONELLA SAMPLES

HEARING

BEFORE THE

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

COMMITTEE ON SCIENCE AND TECHNOLOGY

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

SEPTEMBER 9, 2008

Serial No. 110–120

Printed for the use of the Committee on Science and Technology

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BIOBANKING: HOW THE LACK OF A COHERENT POLICY ALLOWED THE VETERANS ADMINISTRATION TO DESTROY AN IRREPLACEABLE COLLECTION OF LEGIONELLA SAMPLES

TUESDAY, SEPTEMBER 9, 2008

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
Washington, DC.

The Subcommittee met, pursuant to call, at 10:00 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Brad Miller [Chairman of the Subcommittee] presiding.

BART GORDON, TENNESSEE
CHAIRMAN

RALPH M. HALL, TEXAS
RANKING MEMBER

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Subcommittee on Investigations and Oversight

Hearing on

Biobanking: How the Lack of a Coherent Policy Allowed the Veterans Administration to Destroy an Irreplaceable Collection of Legionella Samples

Tuesday, September 9, 2008
10:00 a.m. – 2:00 p.m.
2318 Rayburn House Office Building

WITNESS LIST

PANEL I

Dr. Victor Yu
Professor of Medicine, University of Pittsburgh

Dr. Janet Stout
Director, Special Pathogens Laboratory

Dr. David Snydman
Chief, Division of Geographic Medicine and Infectious Diseases, and Attending Physician in Infectious Diseases, Department of Medicine, Tufts Medical Center

PANEL II

Dr. Jim Vaught
Deputy Director, Office of Biorepositories and Biospecimen Research, National Cancer Institute

Dr. Janet K.A. Nicholson
Senior Advisor for Laboratory Science, Coordinating Center for Infectious Diseases, Centers for Disease Control and Prevention

PANEL III

Mr. Michael Moreland
Director, Veterans Integrated Services Network 4, Department of Veterans Affairs

Dr. Mona Melhem
Associate Chief of Staff and Vice President, Clinical Support Service Line Pittsburgh Healthcare System, Department of Veterans Affairs

Dr. Ali Sonel
Associate Chief of Staff (Research), VA Pittsburgh Healthcare System

Dr. Steven Graham
Director, Geriatric Research, Education and Clinical Centers, VA Pittsburgh Healthcare System

Ms. Cheryl Wanzie
Chief Technologist, VA Pittsburgh Healthcare System

HEARING CHARTER

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

Biobanking: How the Lack of a Coherent Policy Allowed the Veterans Administration to Destroy an Irreplaceable Collection of Legionella Samples

TUESDAY, SEPTEMBER 9, 2008
10:00 A.M.–2:00 P.M.
2318 RAYBURN HOUSE OFFICE BUILDING

Purpose

On December 4, 2006, a set of biological materials that was a primary support for work on *Legionella,* the bacterium causing Legionnaire's Disease, was destroyed at the Veterans Administration (VA) Medical Center in Pittsburgh, Pennsylvania. This occurred even as the process to transfer the collection to a University of Pittsburgh laboratory for further use in research was underway. It was also the last act of an acrimonious process that had seen the closure of its host, the Special Pathogens Laboratory (SPL), some four months earlier. The closure of this lab puts all hospital patients, especially the elderly, severely sick children—all those with compromised immune systems—at greater risk because this was one of the top hospital infection laboratories in the Nation.

The purpose of this hearing is to make public the findings of a Subcommittee investigation of this case. The Subcommittee's findings highlight the need for improved policies on biospecimen management.

Witnesses

Panel I

Dr. Victor Yu, *Professor of Medicine, University of Pittsburgh*

Dr. Janet Stout, *Director, Special Pathogens Laboratory*

The collection of materials destroyed at Pittsburgh was the work of Doctors Yu and Stout, who have, during the last three decades, become world-recognized experts in identifying Legionnaire's Disease. Dr. Stout is widely recognized for her work in developing methods to keep *Legionella* out of water supplies at hospitals and nursing homes. Dr. Yu has an international reputation for his work on infectious diseases in hospitals, of which Legionnaires' Disease is a common type. Dr. Stout had a meeting scheduled the morning after the destruction of the collection (December 5, 2006) to remove personal identifying data from the specimens, a necessary step prior in the transfer process.

Dr. David Snydman, *Chief, Division of Geographic Medicine and Infectious Diseases, and Attending Physician in Infectious Diseases, Department of Medicine, Tufts Medical Center*

Dr. Snydman has collaborated with Dr. Yu on infectious disease research, and will provide an expert perspective on the value of the lost materials. He was also instrumental in bringing the loss of the collection to the attention of the scientific community, and calling for an independent review of the actions by administrators at the Veterans Administration Pittsburgh Healthcare System (VAPHS).

Panel II

Dr. Jim Vaught, *Deputy Director, Office of Biorepositories and Biospecimen Research, National Cancer Institute (NCI)*

Dr. Vaught has been directly involved in the development of biospecimen management policies in his position at the NCI, helping to develop the "best practices" guide published by the Institute in June 2007. He was assigned to the task force that assisted in a review and update of National Institutes of Health (NIH) policies in 2006. He has also been participating as an NIH representative on an Office of Science and Technology Policy working group on scientific collections that is finishing a draft report on the state of all federal scientific collections.

Dr. Janet K.A. Nicholson, *Senior Advisor for Laboratory Science, Coordinating Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC)*

CDC is a federal agency that faces questions of biospecimen management constantly, as the collection of those materials is critical to the identification of disease. Dr. Nicholson will testify on her agency's methods for dealing with the issues raised by the collection and proper management of biospecimens. She will also discuss the policies governing operations at the CDC's major central repository, CASPIR.

Panel III

Michael Moreland, *Director, Veterans Integrated Services Network 4, Department of Veterans Affairs*

At the time the collection was destroyed, Mr. Moreland was the Director of the VAPHS (he was in the process of being promoted to lead the VA's regional office). Mr. Moreland oversaw the decision to close the SPL and instituted a Board of Investigation to examine allegations of financial impropriety against Dr. Yu. He is alleged, though there is no written record, to have personally ordered the destruction of the collection.

Dr. Mona Melhem, *Associate Chief of Staff and Vice President, VAPHS Clinical Support Service Line*

Dr. Melham supervises the clinical activities at the Pittsburgh VA Healthcare System, which include the Clinical Microbiology Laboratory at the hospital. It was Dr. Melhem's direct order that led to the abrupt destruction of the collection at the Special Pathogens Laboratory on December 4, 2006.

Dr. Ali Sonel, *VAPHS Associate Chief of Staff (Research)*

In his position, Dr. Sonel is responsible for the management and conduct of research by staff at VAPHS. Dr. Sonel assumed the position on September 1, 2006, soon after the SPL was closed. He was overseeing efforts to assist Dr. Stout to move the collection from the SPL to the Department of Microbiology and Molecular Genetics of the School of Medicine at the University of Pittsburgh when the collection was destroyed without his knowledge.

Dr. Steven Graham, *Director, VAPHS Geriatric Research, Education and Clinical Centers*

Dr. Graham preceded Dr. Sonel as head of research at VAPHS, and was involved in the process that led to SPL's closure. He served as a member of the Board of Investigation convened by Mr. Moreland. He was cited by Dr. Melhem as having approved the destruction of the collection, but has denied it.

Ms. Cheryl Wanzie, *VAPHS Chief Technologist*

Ms. Wanzie supervises the technical operations of the VAPHS Clinical Microbiology Laboratory. She was one of those receiving Dr. Melhem's order to destroy the collection on December 4, and was in the Laboratory as the freezers were emptied into biohazard bags.

Background

On December 4, 2006, employees of the VAPHS' clinical microbiology laboratory, were ordered to destroy the collection of *Legionella* and other disease isolates and also water samples containing the *Legionella* bacteria that had been accumulated by Dr. Yu and Dr. Stout over the decades of their research on this disease. The order was given by Dr. Melhem at the same time Dr. Sonel was actively working to transfer the collection to a laboratory at the University of Pittsburgh for use in further research by Dr. Yu and Dr. Stout.

At that time, the Special Pathogens Laboratory had been closed for almost five months, and Dr. Yu was no longer with the VAPHS.

The destruction took place outside of any previous process that had been used to determine the disposition of biospecimens left behind by former researchers and without the knowledge of Dr. Sonel or the Research Compliance Committee, which would normally been involved. The collection was the life's work of Dr. Yu and Dr. Stout, and no one from the VAPHS has been able to provide a credible reason for such a precipitous act.

Building the Better Biobank

Collections such as the *Legionella* collection are more and more common as researchers study the evolution of both disease strains and treatment. The improving capability of tools for biological analysis is allowing researchers to make greater strides in understanding the workings of human biology at ever finer detail. Coupled with ever more powerful computers, this allows studying amounts of data that could never have been contemplated in the past. With the completion of the "draft" of the human genome, so-called "personalized medicine" appeared on the horizon: medical treatments could be devised to meet a patient's unique condition.

These changes are reflected in the development of biobanks: places where traditional human biospecimens such as blood and tissue are matched to databases with medical records, genomic sequence data and other information. Bringing these together helps with the identification of disease-causing genes or genetic variants. It can find connections between outbreaks of infection and factors in the environment. Targets for new therapies can be found. The SPL collection was something of a prototype biobank, and much of its value resided in the ability to match a particular biospecimen to its clinical history. That the collection included biospecimens extending back more than two decades also allowed comparative study to learn how organisms were changing in response to efforts to control or eradicate them.

One of the principal values of a properly-run biobank is the control of quality, allowing researchers to be confident that the information they use (and the results they obtain) are accurate. This requires rigorous control over biospecimens from the moment of collection and equally careful handling of the patient-specific medical information associated with it. Today's hearing is concerned, not just with the events at the VAPHS, but with the collection management policy aspects related to the physical biospecimens.

The Federal Government has supported, either with work at agencies like the National Institutes or Health the Centers for Disease Control and Prevention or by external research grants, the collection of millions of biospecimens. Many are in freezers in thousands of disparate laboratories, mostly of interest to a particular researcher for a specific project. It is not easy to find firm policy governing these valuable materials. The loss of the SPL collection, where materials of continuing scientific value were destroyed on the order of just one person, highlights the need to bring greater discipline to biospecimen management.

There have been scattered efforts to address the need for improved policies in biospecimen management. The hearing today will discuss efforts at NIH and CDC to update their policies to serve as models for discussion. This includes the question of destroying materials; while no scientist likes to lose a piece of data, it sometimes is necessary when freezers fill up or the collection's champion retires and no one is interested in carrying on that line of work. Best practice today argues that efforts should be made to find an alternative home for those materials, a process that had been successfully underway with the SPL *Legionella* collection. It also expects that there will be some evaluation of the continuing value of the materials before deciding on destruction. The biospecimens at the heart of tomorrow's biobanks need robust protection, unlike the fate of SPL's collection.

The SPL Environment

The 1976 outbreak of Legionnaires' Disease at the Philadelphia American Legion convention immediately raised concerns at the Veterans Administration, as it attacked precisely the same populations in VA hospitals across the country. VAPHS did much to lead the effort to find out about the disease. The Clinical Microbiology Laboratory found a way to grow *Legionella* bacteria in laboratories, and Doctors Yu and Stout traced the source of infection to water systems. The Special Pathogens Laboratory was originally established as a focus for continued *Legionella* studies and testing for both VA and non-VA health care facilities. The work of Doctors Yu and Stout figured prominently in a review of Legionnaires' Disease risk at VA facilities by the Department's Inspector General last year and the institution of a new protocol.

SPL's expertise was shared with other VA facilities and outside entities. Although initially funded by the VA's central office, in keeping with VA policy in the mid-1990s, Dr. Yu proposed to recover testing costs by billing for services. This was approved, and the billing system was set up through the Veterans Research Foundation of Pittsburgh. Congress had allowed the creation of these non-profit entities to manage outside contributions for research at VA facilities. The revenues were used to pay the salaries of Lab employees (except for Dr. Stout, who was a VA microbiologist). By the time the SPL was closed, it was billing about $500,000 per year. For the most part, so far as documents show, there was little concern about the Lab's activities at the Foundation until 2006.

While the decision to close the SPL is not the focus of this hearing, it cannot be completely divorced from the discussion. The chaotic events of July 2006, during which Dr. Yu was told to close the lab in two days, then received a 10-day extension, after which the doors were locked and access denied, confused the status of the *Legionella* collection. It became clear that there were gaps in the system of research oversight at the VAPHS. Some administrators assert, based on incomplete, largely post-hoc investigations, that these biospecimens were not collected as part of approved research protocols, nor were they properly maintained and identified—therefore they had no scientific value despite their role in numerous peer-reviewed articles and VA's treatment practices. Doctors Yu and Stout firmly state that they had appropriate approvals and that the collection was properly cataloged.

But what is evident is that the research structure at the VAPHS—which was supposed to have been in charge of the collection, had opposed its destruction and was ready to transfer it to Dr. Yu—was deliberately kept out of the loop. What is also evident is that administrators at a major VA hospital system had allowed personal animosities and goals to overcome its own processes. No federal health facility should be allowed to function in this manner. A Subcommittee staff report describes the situation in greater detail.

Chairman MILLER. Good morning. This hearing will come to order. Today's hearing is *"Biobanking: How the Lack of a Coherent Policy Allowed the Veterans Administration to Destroy an Irreplaceable Collection of Legionella Samples."*

The Subcommittee staff for the Investigation and Oversight Subcommittee conducted an extensive investigation into the handling of an irreplaceable collection of *Legionella* samples at the Veterans Affairs Pittsburgh Healthcare Clinic. The purpose of this hearing is to make public the findings of the Subcommittee's investigation into this case and to highlight the need for a uniform national policy on biospecimen management.

On December 4, 2006, late in the afternoon, two employees of the clinical microbiology laboratory at the Veterans Affairs Pittsburgh Healthcare Clinic, the VAPHS, were ordered by Dr. Mona Melhem, the Associate Chief of Staff for Clinical Services, to go to the Special Pathogens Laboratory and destroy the research collection of Dr. Victor Yu and Dr. Janet Stout. Dr. Melhem said her orders came from Michael Moreland, then the system's Director.

The two employees commandeered the help of three other employees, and within three hours a collection that had taken three decades to build was gone. Drs. Yu and Stout are international experts in the detection, treatment and control of *Legionella,* a bacterium that causes a kind of severe pneumonia called Legionnaires' disease, and their laboratory was internationally acclaimed. Dr. Yu was known for his work on other infectious pneumonias and antimicrobial resistance. According to Dr. David Snydman of Tufts Medical Center, one of our witnesses today, this collection was used to develop new diagnostic tests and therapies and to study resistance and mechanisms of disease transmission.

The destruction of the research collection was the culmination of an acrimonious series of events that included the closing of the nationally acclaimed laboratory, the firing of Dr. Yu and the attempted firing of Dr. Stout.

As an impartial audience—there is no real partisanship to any of this—the most troubling part of the story is that the destruction of this one-of-a-kind collection occurred less than an hour after Dr. Melhem learned that formal steps were being taken the following day to transfer the collection to the University of Pittsburgh, where Drs. Yu and Stout were then affiliated so their research could go on, and the destruction of this collection occurred after Dr. Melhem made a false statement to the system's Chief of Staff and the head of the research office telling him that the collection could not be transferred because it had already been destroyed on the orders of the medical center's Director. That false statement kept the head of the research office from effectively intervening to try to save the collection.

Months of investigation by the Subcommittee have not revealed any credible reason for the destruction of the collection. Dr. Melhem said that a former research official had approved the destruction months before. That official denies giving such approval. She also claims that the decision was made in July without ever informing Dr. Stout or Dr. Yu, both of whom were then still on staff. Dr. Moreland can't remember giving her such orders on December 4 and seems unclear about his understanding of the dif-

ference between the research specimens that we are concerned with today and clinical specimens that were being processed by the laboratory on the day that it closed. Both Dr. Melhem and Mr. Moreland are now taking the position that the collection wasn't really a research collection and did not have to be preserved. This is despite the fact that dozens of peer review papers have come out of the laboratory in its 25 years of existence, and statements made to Dr. Yu that he would be able to continue his research, even if the lab closed.

Mr. Moreland's testimony came in late yesterday. The Subcommittee has made two very comprehensive document requests concerning the closure of the Special Pathogens Laboratory and the destruction of its research collection, and we received many documents, voluminous documents, but in his testimony, Mr. Moreland refers to a technical review regarding biohazards at the lab, disposal acts done in July of 2006, and a December 2006 determination that not a single one of the samples in question were collected, or was collected, as part of any previously approved research effort. The Committee has never received any documentation of any of those assertions. Either they do not exist, the documents do not exist, or they have not been provided, but in any case, the testimony is very troubling.

Mr. Moreland and other witnesses from the Pittsburgh VA should remember that their testimony today is under oath and it is simply not credible that important technical decisions were made entirely based upon conversations with no documentation.

I cannot imagine the circumstances under which a federal health agency official would unilaterally order the destruction of a human tissue collection without receiving the approval of the agency's research office and the Research Compliance Committee. I cannot imagine why that official would apparently make false statements during the destruction to keep the associate director for research at the center in the dark until the destruction was complete. It stuns me that in the time since those actions, neither Pittsburgh nor national VA officials have taken formal action to discipline the managers involved in this case or establish clear policy on the destruction of biomedical collections to make sure that this will never happen again.

All of us may pay a price for this conduct, veterans most of all, because the Nation lost one of its leading research labs on hospital infectious diseases, and while the researchers can relocate and start their work again, the research samples can never be wholly reconstituted. Those who are in hospitals, the elderly, severely sick children or anyone else with compromised immune systems are those most at risk.

The work of Dr. Yu and Dr. Stout cannot be recovered entirely. However, we can protect the work of thousands of other professionals at the VA and other federal agencies or institutions that result in the collection of biological samples, biological collections funded by taxpayer money. Those collections should not be subject to similar mishandling simply at the caprice of a powerful administrator. It is time for the Office of Science and Technology Policy to start an interagency effort to create a core set of policies for the

handling, maintenance and disposition of such specimens, and I do intend to introduce that legislation shortly.

[The prepared statement of Chairman Miller follows:]

PREPARED STATEMENT OF CHAIRMAN BRAD MILLER

The Subcommittee staff of the Subcommittee on Investigations and Oversight conducted an extensive investigation into the handling of an irreplaceable collection of *Legionella* samples at the Veterans Affairs Pittsburgh Healthcare System. The purpose of this hearing is to make public the findings of the Subcommittee investigation of this case and to highlight the need for a national uniform policy on biospecimen management.

On December 4, 2006—late in the afternoon—two employees of the clinical microbiology laboratory at the Veterans Affairs Pittsburgh Healthcare System (VAPHS) were ordered by Dr. Mona Melhem, the Associate Chief of Staff for clinical services, to go to the Special Pathogens Laboratory and destroy the research collection of Dr. Victor Yu and Dr. Janet Stout. Dr. Melhem said her orders came from Michael Moreland, then the system's Director.

The two employees joined by three others took less than three hours to bag up a biomedical sample collection that represented almost three decades of research by Dr's Yu and Stout. It was bagged, burned and gone. Drs. Yu and Stout are international experts in the detection, treatment and control of *Legionella,* a bacterium which causes a type of severe pneumonia called Legionnaires' disease, and their laboratory was internationally acclaimed. Dr. Yu was also known for his work on other infectious pneumonias and antimicrobial resistance. According to Dr. David Snydman of Tufts Medical Center and one of our witnesses today, this collection was used to develop new diagnostic tests and therapies and to study resistance and mechanisms of disease transmission.

The destruction of the research collection was the culmination of an acrimonious series of events that included the closing of the nationally acclaimed laboratory, the firing of Dr. Yu, the system's long-time Chief of Infectious Disease, and the attempted firing of Dr. Stout.

As an impartial audience, the most troubling part of this story is that the destruction of this one-of-a-kind collection occurred less than an hour after Dr. Melhem learned that formal steps were being taken, on the following day, to transfer the collection to the University of Pittsburgh, where Drs. Yu and Stout were affiliated. And the destruction of this collection occurred after Dr. Melhem made a false statement to the system's Chief of Staff and the head of the research office, telling them that the collection could not be transferred because it had already been destroyed on the orders of the medical center's Director. That false statement kept the head of the Research Office from effectively intervening to try to save the collection.

I will leave many details to my written statement, but summarize by saying months of investigation by the Subcommittee have not revealed any credible reason for this rash and malicious act. Dr. Melhem says she received direction to destroy the collection; the people she cites deny it or don't recall doing so. There is a claim this isn't "research" collection, despite the fact that dozens of peer-reviewed papers have come out of the laboratory in its 25 years of existence, and statements made to Dr. Yu in July that he would be able to continue his research even if the lab closed.

The policies for collection management at the Pittsburgh VA—and perhaps the entire VA system—are unclear, and the organizations in place to oversee research appear to have been short-circuited. We also found that there were years of neglect by the board of the Veterans Research Foundation of Pittsburgh, which was handling the Special Pathogens Laboratory's funds, but paid little attention to it until a few months before its abrupt decision to close the lab. The institutional failure to establish and follow clear procedures spilled over into the decision-making process for closing the lab. It appeared that the most important thing to the Pittsburgh VA hierarchy in the summer of 2006 was to close the lab and rid itself of Dr. Yu and Dr. Stout by whatever means necessary.

I want to make one comment about Mr. Moreland's testimony which came in late yesterday. The Subcommittee has made two very comprehensive document requests concerning the closure of the Special Pathogen Laboratory and the destruction of its research collection, and we have received many documents. Yet in his testimony, Mr. Moreland makes reference to a "technical" review regarding biohazards at the lab; disposal acts done in July of 2006; and a December 2006 "determination" that not a single one of the samples in question were collected as part of any previously approved research efforts. The Subcommittee has never received any documentation

of any of these claims. Either they do not exist or they have not been provided, but either way, this testimony is very troubling.

Mr. Moreland and other witnesses from the Pittsburgh VA should remember that they are giving their testimony under oath. The Subcommittee will take it very seriously if they cannot provide documentation of their statements.

Scientists from several other agencies and institutions have been contacted by the Committee staff and, while their own policies may be based more on habit and common sense than actual guidance, all of them indicated that such an act would not have occurred in their agency. A much more common practice is to determine if any other researchers at the institution are interested in the collection and, if not, ask the departing researcher if he or she wants to take the collection. If no one wants the collection and its long-term value to the originating institution is deemed minimal, it may be offered to outside researchers who have worked in the field. If there is absolutely no interest, the collection is destroyed. The Pittsburgh VA's actions were so out of the norm that more than 200 infectious disease researchers have called for an independent investigation.

I cannot imagine the circumstances under which a federal health agency official would unilaterally order the destruction of a human tissue collection without receiving the approval of the agency's research office and the Research Compliance Committee. I cannot imagine why that official would, apparently, make false statements during the destruction to make it keep the Associate Director for Research at the Center in the dark until the destruction was complete. It disappoints me that in the time since those actions, neither Pittsburgh nor national VA officials have taken formal action to discipline the managers involved in this case or establish clear policy on the disposition of biomedical collections to make sure that this could never occur again.

The work of Dr. Yu and Dr. Stout cannot be recovered. However, we can protect the work of thousands of other professionals at the VA and other federal agencies or institutions that result in the collection of biological collections funded by taxpayer money. These collections should not be subject to similar mishandling simply because they run afoul of a powerful administrator. It is time for the Office of Science and Technology Policy to start an interagency effort to create a core set of policies for the handling, maintenance and disposition of such specimens. I intend to introduce that legislation shortly.

Chairman MILLER. I now yield to my distinguished colleague, Representative Rohrabacher, for an opening statement.

Mr. ROHRABACHER. I thank you very much, Mr. Chairman, and I am sorry that I have a bit of a cold today. Maybe I could seek advice from the panel on what to do. If you have one of those things to cover my face, that might be an appropriate situation.

So often here in Washington, D.C., when we take a look at a serious problem, we find that politics and bureaucracy has really screwed things up, and this may or may not be the case here. In this case, we might be looking at a situation where individuals were wrong. People who held power made wrong decisions, and people who make wrong decisions should be held accountable or it will not encourage other people who hold positions of authority to take their job as seriously as their jobs dictate. If it's not an individual flaw or a situation where we have a situation where an individual has made wrong decisions, we may find in this case that the system itself is flawed.

I want to congratulate the Chairman for the work he has done on this issue to see if we can come down to find out exactly what is at the heart of this issue and what caused this to happen and what can be done to correct the situation. We need to hear the details to see if it is a flaw in the system, if it can be corrected, and if it is a personnel situation where bad decisions were made for whatever reason, that those people are held accountable. Our policy on biobank issues certainly deserves our attention in relation to looking over this particular issue.

I would suggest that we should be very careful, however, to make sure that when we are proposing changes or what should be the reaction of the government to this incident that we be careful not to introduce politics and bureaucracy in a negative way into a system that may well be making mistakes because people within the system just made flawed decisions. Maybe people were kept in positions of authority for too long, maybe perhaps a situation where the people themselves did not have the proper oversight, so we really have to take a look where an individual, he or she did something wrong but we can't use that as an excuse to alter the system in a way that might make it less effective in the future if we haven't targeted the reforms in the right way.

So I am very open-minded to this, and if we can make it better, we will, and as the Chairman stated, there is no politics in a situation like this. We work together to try to see what we can come up with that will correct a flawed situation or hold people accountable for the decisions they have made.

With that, thank you very much, Mr. Chairman. I look forward to the hearing.

Chairman MILLER. Thank you, Mr. Rohrabacher.

Any additional opening statements submitted by Members will be included in the record.

[The prepared statement of Ms. Johnson follows:]

PREPARED STATEMENT OF REPRESENTATIVE EDDIE BERNICE JOHNSON

Mr. Chairman, the flippant destruction of a biobank of *Legionella* concerns me greatly, as a nurse.

As you may know, this bacterium causes a serious lung infection. It was so named in 1976 when many people attending a convention of the American Legion became sickened by it.

The Centers for Disease Control report that between 8,000 and 18,000 people are hospitalized each year with Legionnaires' disease in the United States. Elderly people are especially vulnerable to it.

Legionnaires' disease can have symptoms like many other forms of pneumonia, so it can be hard to diagnose at first. Signs of the disease can include: a high fever, chills, and a cough.

The disease can be very serious and can cause death in up to five percent to 30 percent of cases.

The *Legionella* bacteria are found naturally in the environment, usually in water.

The bacteria grow best in warm water, like the kind found in hot tubs, cooling towers, hot water tanks, large plumbing systems, or parts of the air-conditioning systems of large buildings.

People get Legionnaires' disease when they breathe in a mist or vapor (small droplets of water in the air) that has been contaminated with the bacteria.

Mr. Chairman, I understand that in 2006, a set of biological specimens was destroyed at the Veterans Administration Medical Center in Pittsburgh, Pennsylvania.

This represented a hostile act that was part of the shut-down of the lab at the VA Medical Center.

The collection was intended to be transferred to the University of Pittsburgh, so that important research on Legionnaire's disease could continue.

This recklessness is a disservice to the American public and is an ignorant waste of taxpayer dollars.

In addition, the closure of the Special Pathogens Laboratory (SPL) is detrimental to public health because the lab was one of the top hospital infection laboratories in the Nation.

The circumvention of appropriate decision-making processes will have the ultimate effect of harm to public health.

I want to commend the Chairman and staff for seeking the perspectives of scientists who were in the Special Pathogens Laboratory.

Researchers will be able to underscore the value of the specimens that were discarded, and the consequences of that action on our nation's public health.

Thank you, Mr. Chairman. I yield back.

Panel I:

Chairman MILLER. It is now my pleasure to introduce our first panel of witnesses today. First is Dr. Victor Yu, a professor of medicine at the University of Pittsburgh. Dr. Janet Stout is the Director of the Special Pathogens Laboratory. Dr. David Snydman is the Chief of the Division of Geographic Medicine and Infectious Diseases and attending physician in infectious diseases at the Department of Medicine at the Tufts Medical Center. I suspect that is not what he says at cocktail parties that his job is.

You will all have five minutes for your oral testimony. Your written testimony will be included in the record. When you complete your testimony, we will begin with questions. Each Member will have five minutes to question the panel. It is the practice of the Committee, because we are an Investigations and Oversight Subcommittee, to take testimony under oath. Do any of you have any objection to being sworn in, to swearing an oath? All the witnesses nodded their heads that they did not. The Committee also provides that you may be represented by counsel. Are any of you represented by counsel at today's hearing? All three of witnesses also nodded their heads no. If you would now please stand and raise your right hand. Do you swear to tell the truth and nothing but the truth? All three of the witnesses said that they did so swear.

Actually, if we could begin with Dr. Stout today. Dr. Stout, could you begin?

STATEMENT OF DR. JANET E. STOUT, DIRECTOR, SPECIAL PATHOGENS LABORATORY; RESEARCH ASSOCIATE PROFESSOR, DEPARTMENT OF CIVIL AND ENVIRONMENTAL ENGINEERING, UNIVERSITY OF PITTSBURGH

Dr. STOUT. Thank you. Members of the Committee, first I want to thank you for holding the hearing. I am Dr. Janet Stout. I received both my Master's and Ph.D. degrees from the University of Pittsburgh Graduate School of Public Health. I am internationally recognized as an authority on Legionnaires' disease. I have authored book chapters and more than 80 publications in peer-reviewed journals. I spent 25 years at the Pittsburgh VA Medical Center as a microbiologist in the Special Pathogens Laboratory. My scientific achievements include identifying the drinking water, not air conditioning, as the real source for hospital-acquired Legionnaires' disease.

The VA Special Pathogens Laboratory was part of the VA microbiology laboratory and served as a national *Legionella* reference laboratory until its closure in 2006. The accomplishments of this laboratory are many. The collection of isolates and specimens housed in this collection played a major role in these accomplishments. From 1979 to 2006, we banked over 8,000 specimens from our studies on Legionnaires' disease and other infections. These specimens included isolates of *Legionella* and thousands of serum, respiratory and urine samples.

The role of this collection of microorganisms in our discoveries can be summarized as follows. We showed that Legionnaires' dis-

ease was acquired from hospital drinking water systems. *Legionella* isolates in our collection proved this association for hospitals across the United States. Our laboratory developed new and better ways to detect and treat this disease. Every antibiotic and *Legionella* diagnostic test in use today was tested in our laboratory. Our collection allowed new tests to fulfill FDA requirements for approval. These specimens were destroyed.

We developed advanced environmental and clinical methods which were not used by many laboratories. Less-experienced labs gave incorrect results and bad advice, placing patients at risk. For example, in 2005, one laboratory failed to diagnose a large outbreak of Legionnaires' disease in a nursing home. Using our collection, we showed that the urine antigen test used by that laboratory gave false negative results. The specimens that allowed us to make this discovery were destroyed. I therefore caution the Pittsburgh VA, who is performing *Legionella* testing for free for other VA laboratories, that this testing is being done by untrained and inexperienced technicians.

Our collection included isolates from every hospital using our laboratory. Having these isolates available in the future would establish whether or not the hospital was the actual source of infection or the patient acquired the disease elsewhere. These isolates were destroyed.

We demonstrated the development of resistance by *Legionella* to a commonly used water disinfection method. This observation was only made possible by comparison of historical isolates to present-day isolates. The specimens that allowed us to make this discovery were destroyed.

We showed that the risk of illness to patients could be predicted. Other scientists have requested our specimens for study in their laboratories to study disease-causing traits and evaluate new antibiotics. These specimens are no longer available to the scientific community for study. They were destroyed.

Our research was supported by the VA Merit Review System, the U.S. Environmental Protection Agency and industry. The VA Merit Review study was an IRB-approved study involving 20 VA institutions across the United States. The results of this study were published in 2007 in the journal *Infection Control and Hospital Epidemiology*.

We also showed that patients get Legionnaires' disease from drinking water in their own homes. This was an EPA-funded, IRB-approved study. All of the isolates and specimens collected during the Merit Review and EPA studies were destroyed.

We collected these isolates for research purposes and the research was approved. Dr. Yu will provide the Committee with documentation to support this point.

What did we do to save the collection? I wasn't concerned about the transfer of the collection from the VA because I knew other VA investigators had transferred their collections when they left the VA. The research office even told us that they had recently gone through this process with one of their VA physicians. In August 2006, we first expressed our concern for the safety of the collection. In an e-mail from Dr. Yu to Dr. Graham, Dr. Yu stated, "I fear the vindictiveness of the Administration may imperil this irreplaceable

collection." We were reassured by Dr. Graham when he responded, "Of course I don't want to see valuable specimens destroyed." In response, Dr. Yu and I obtained the assistance of Dr. Tim Mietzner at the University of Pittsburgh and we requested the transfer of these materials to his laboratory at the University of Pittsburgh. From August through December 2006, I actively engaged the research office in my attempt to transfer the collection to the university. VA administration was copied on these e-mails. I was never asked by anyone to provide any information on the contents of the collection and there was never any indication that the disposition of the collection was in question or that the collection was in danger of being destroyed.

On December 4, 2006, Dr. Sonel notified the VA administration that I was to meet with the research compliance officer in the laboratory the next day to begin the transfer. Later on that same day, Dr. Sonel informed me via an e-mail that he was asked by the front office to put this process on hold. He said he or someone from the front office will be contacting me about this request. No one from the VA ever contacted me and I did not know that the collection had been destroyed. Only after an inquiry from Senator Specter and Rick Earl, a reporter, did the VA publicly admit to destroying the collection. For me as a scientist, and for veterans and the American public, the loss is incalculable.

In protest, a petition was published in the April issue of Clinical Infectious Diseases and signed by over 250 scientists worldwide. They requested that an investigative committee review the actions of the Pittsburgh VA Healthcare System regarding the closure of the laboratory and the destruction of the scientifically valuable collection of microorganisms.

The petition signatories and I thank you for your time today and your effort in fulfilling this request. Thank you.

[The prepared statement of Dr. Stout follows:]

PREPARED STATEMENT OF JANET E. STOUT

Members of the Committee, first I want to thank you for holding this hearing.

I am Dr. Janet Stout. I have a Ph.D. in infectious disease microbiology and I am a Research Associate Professor at the University of Pittsburgh Department of Civil and Environmental Engineering. I received both my Masters and Ph.D. degrees from the University of Pittsburgh, Graduate School of Public Health.

I am internationally-recognized as an authority on Legionnaires' disease. I have authored book chapters and more than 80 publications in peer-reviewed journals including the *New England Journal of Medicine,* the *Journal of the American Medical Association* (See Stout CV in Section 8 of written testimony).

I have lectured on Legionnaires' disease at national microbiology, infection control and engineering conferences, at the European Working Group on *Legionella* Infection and in 2009, I will speak at the International *Legionella* Symposium in Paris France.

I spent 25 years at the Pittsburgh VA Medical Center as a microbiologist in the Special Pathogens Laboratory.

My scientific achievements include identifying drinking water—not air conditioning—as the real source for hospital-acquired Legionnaires' disease. This finding was a major paradigm shift and unraveled the epidemiology of hospital-acquired Legionnaires' disease, and was published in the *New England Journal of Medicine* and in the *Lancet.*

I have worked with State and local public health agencies in developing guidelines for the prevention of hospital acquired Legionnaires' disease. This work provided the foundation for guidelines for the Health departments in the States of Maryland and New York, and the countries of Spain, Italy, Taiwan, the Netherlands, Denmark, and France, and the VA Healthcare System.

In 2005, I was asked by the VA Medical Inspector General to assist him in devising a new VA *Legionella* prevention Directive, which was issued nationwide in February 2008.

The Special Pathogens Laboratory

The VA Special Pathogens Laboratory was part of the VA microbiology laboratory and served as a national reference laboratory until its closure in 2006. As a microbiologist in this unit, I performed clinical and reference laboratory testing for VA and non-VA institutions (See Stout position description Section 5 of written testimony).

I was among the many students, physicians and scientists that worked in this "Center of Excellence" and whose accomplishments were highlighted in the VA "Vanguard" in 1996, on the occasion of the 20th anniversary of the discovery of Legionnaires' disease (See "Medical Advances May/June 1996).

The collection of isolates and specimens housed in this laboratory played a major role in those accomplishments and resulted in more than 200 publications on Legionnaires' disease.

The Collection

A scientifically valuable collection of microorganisms was destroyed. In order to fully understand the impact of this action, I will describe its scientific relevance and how we were the guardians of the collection until its destruction in 2006.

I was trained to catalogue isolates and specimens, place them in plastic freezer vials at -70°C and maintain a detailed record so others could retrieve the isolates for future study (See Section 4 of written testimony—Bacterial Stock Maintenance). I maintained the collection in the Special Pathogens Laboratory at the VA Medical Center in Pittsburgh, PA. Information about the isolates was recorded in a log book and typed into an electronic file on the lab computer.

From 1979 to 2006, we banked over 8000 specimens from our studies on Legionnaires' disease and other infections. The specimens included isolates of *Legionella, Staphylococci, Pseudomonas, Klebsiella, Enterococci, Streptococci* and *Candida* species and thousands of serum, respiratory and urine samples. **They were all were destroyed.**

The role of this collection of microorganisms in our discoveries can be summarized as follows:

1. We showed that Legionnaires' disease was acquired from hospital drinking water systems. *Legionella* isolates in our collection proved this association for hospitals in Pittsburgh and across the U.S.
2. Our laboratory developed new and better ways to detect and treat this disease. Every antibiotic and *Legionella* diagnostic test in use today was tested in our laboratory. Our collection allowed new tests to fulfill FDA requirements for approval (See requests from scientist in Section 7 of written testimony). **These specimens were destroyed.**
3. We developed advanced environmental and clinical methods. Less experienced laboratories often gave incorrect results and advice, placing patients at risk. For example, in 2005 one laboratory failed to diagnose a large outbreak of Legionnaires' disease in a nursing home. Using our collection, we showed that the urine antigen test used by the laboratory gave *false negative* results. **The specimens that allowed us to make this discovery were destroyed.**
4. Isolates from every hospital using our lab were stored in our freezer. Having these isolates available in the future would establish whether or not the hospital was the actual source or the patient acquired the disease elsewhere. **These isolates were destroyed.**
5. We demonstrated the development of resistance by *Legionella* to a commonly-used water disinfection method—copper-silver ionization. This observation was *only* made possible by comparison of historical (frozen) isolates to present day isolates. **The specimens that allowed us to make this discovery were destroyed.**
6. We showed that the risk of illness to patients could be predicted. Other scientists have requested our specimens for study in their laboratories to study disease-causing traits and evaluate new antibiotics. **These isolates are no longer available to the scientific community for study—they were destroyed.**

7. Our research was supported by the VA Merit Review System, the U.S. Environmental Protection Agency, and industry. The VA Merit Review study was an IRB approved study involving 20 VA institutions across the U.S. The results of that VA Merit Review-funded study were published in 2007 in the journal *"Infection Control and Hospital Epidemiology."*
8. We also showed that patients get Legionnaires' disease from the drinking water in their own homes. This was an EPA-funded IRB-approved study.

All of the isolates and specimens collected during the Merit Review and EPA studies were destroyed.

Did We Collect These Isolates For Research Purposes and Was the Research Approved?

Dr. Yu and the other VA infectious disease physicians participated in approved research activities that involved the collection and storage of microorganisms and specimens in the Special Pathogens Laboratory (See Section 5). When the lab closed in July 2006, we had an active R&D approved study that was in effect through December 2006 entitled *"Various Studies Examining Treatment, Prevalence and Eradication of Legionella"* ID: 00137.

What Did We Do to Save the Collection?

Initially, I was not concerned about the transfer of the collection from the VA. I knew that other VA investigators had left the VA and taken their collections of specimens with them. The VA Research office even told us that they had recently gone through this process with one of the VA physicians.

July 2006—During a meeting in the Special Pathogens Laboratory in July, Sue Mietzner, a microbiologist in our lab, showed Dr. Melham the freezer where our collection was stored and told her of its importance. She also showed her the location of the computer file describing the isolates. The handwritten log book containing all the isolate identification information was also left in the laboratory. I was never asked to provide any information on the contents of our collection.

August 2006—I first expressed my concern for the safety of the collection in an e-mail to Dr. Yu on August 12, 2006. In response, Dr. Yu immediately sent an e-mail to Steven Graham, the head of Research requesting his assistance in protecting the collection. In this e-mail Dr. Yu stated "I fear the vindictiveness of the administration . . . may imperil this irreplaceable collection."

We were reassured by Dr. Graham when he responded: "Of course I don't want to see valuable specimens destroyed, but these specimens are biohazards so we must follow accepted procedures in order to transfer them. We recently went through this process in regard to Dr. VonKammens samples at Highland Drive."

He told us that the collection "must be moved to an institution approved to handle biohazards. They must sign a materials transfer agreement and have an approved biosafety program."

In response, Dr. Yu and I obtained the assistance of Dr. Timothy Mietzner, Professor of Molecular Genetics and Molecular Biology at the University of Pittsburgh and on August 21st we requested the transfer of these materials to his laboratory at the University of Pittsburgh.

More assurances came from Dr. Sonel, who replaced Dr. Graham as head of Research in September of 2006. In an e-mail to me on October 5th, he stated "We will work with you to facilitate the transfer."

August and December 2006—There were numerous e-mails between me and the Research office to affect the transfer of the collection, which included sending the Material Transfer form to the Research office. I actively engaged the Research office in my attempt to transfer the collection to the University of Pittsburgh. VA Administration was copied on these e-mails.

Throughout this time, there was never any indication that the disposition of the collection was in question or that the collection was in danger of being destroyed.

Dr. Sonel notified the Pittsburgh VA Administration on December 4th that I was to meet the Research Compliance Officer on December 5th in the Special Pathogens Laboratory to begin the process of transferring the collection to the University.

In response to this information, and less than 24 hours before I was to start the transfer of the collection they destroyed our collection on December 4th, 2006.

The Pittsburgh VA administration failed to preserve and protect this valuable scientific resource.

Were We Notified of this Action?

Dr. Sonel sent me an e-mail on December 4th informing me that he "was asked by the front office to put this process on hold. I or someone from the front office will be updating you soon regarding this request. I apologize for any inconvenience that this may have caused."

No one from the VA has *ever* contacted me regarding the destruction of our collection.

For me as a scientist, and for Veterans and the American public—The loss is incalculable.

A petition was published in the April 2008 issue of the medical journal *"Clinical Infectious Diseases"* (CID 2008;46:1053–9) and signed by over 250 scientists. They requested that an investigative committee review the actions of the Pittsburgh VA Healthcare System regarding the closure of the Special Pathogens Laboratory and the destruction of a scientifically valuable collection of microorganisms.

The petition signatories and I thank you for your time and effort today in fulfilling this request.

The Special Pathogens Laboratory

The Special Pathogens Laboratory has existed as a special microbiology laboratory at the University Drive VA since 1981. The initial funding and FTE's for the unit were provided by VA Central Office in response to endemic hospital-acquired Legionnaires' disease at the hospital. Thereafter, the Special Pathogens Laboratory has been funded through the clinical microbiology laboratory (a microbiology sub account) as well as by grant and industry support.

The Special Pathogens Laboratory is a diagnostic, training, and clinical research laboratory, varied in scope of operations and a nationally recognized *Legionella* resource/reference center. The microbiologists assigned to the Special Pathogens Laboratory are responsible for day-to-day patient care testing, research projects and laboratory functions. This includes the teaching and training of students, clinical research and *LegionelIa* resource/reference laboratory testing for VA and non-VA facilities.

Dr. Stout is an internationally recognized microbiologist who is an expert on the microbiology and epidemiology of Legionnaires' disease. Dr. Stout has assisted public health agencies such as the Centers for Disease Control and Prevention as well as State and local health agencies in *Legionella* outbreak investigations. The VA Medical Inspector General contacted Dr. Stout in 2006 to assist in the development of a Legionnaires' disease prevention plan for the VA nationwide. She has over 70 peer-reviewed publications.

Closing of the Special Pathogens Laboratory

The Special Pathogens Laboratory has been active for approximately 25 years, and in that time has become internationally recognized as a *Legionella* reference center. The closure of the laboratory was swift and disorganized—the culmination of an inquiry that denied Dr. Victor Yu (the Chief of Infectious Diseases and Microbiology) a fair appeal.

It was within this atmosphere of chaos that I was repeatedly informed by Dr. Melhem that all *Legionella* testing functions of the lab were to be transferred to the clinical microbiology laboratory. Only one person in this lab has limited ability to perform *Legionella* clinical testing and no one in this lab has the capability to perform *Legionella* environmental testing.

This decision by Dr. Melhem and Mr. Moreland was made despite Dr. Yu's repeated requests for a review of the decision by VA Central office. In addition, one reason given by Dr. Melhem for the speed of the closure was the imminent demolition of Building 2—the building which houses the Special Pathogens Laboratory. When asked about this, Engineering service could not verify this assertion.

I was required to meet with Dr. Gutkin and Cheryl Wanzie to coordinate the move of equipment and *Legionella* testing supplies so that this testing would be performed in Building 1 the clinical microbiology laboratory. We agreed that this would be done on July 25th. July 19th, I was asked to meet with Dr. Melhem—Dr. Muder and Cheryl Wanzie were present at this meeting. Dr. Melhem informed us that the equipment and supplies would be moved within the next two hours! Again she repeated the statement that Building 2 was set to be demolished as a justification for the hurried pace. I was directed to move all clinical specimens from our -70° freezer into a freezer that was being moved (that day) to the clinical laboratory. This required the removal and transfer of specimens from one freezer into the other. It is important to note that as a *Legionella* reference laboratory, we maintain a collection

of specimens and isolates in these freezers that are of historical significance and are irreplaceable.

Board of Investigation

Also within this same time period on July 19th, I was contacted by David Cord to appear at a Fact Finding Administrative Board of Investigation to testify as a witness. Mr. Cord noted that I was "not the subject of the investigation, but testifying as a witness." I was to appear that afternoon.

It was at this time that I experienced cardiac-related symptoms and called a friend to take me to my doctor's office. Upon arrival at the office, the staff advised me to go to the emergency room (ER). I went directly to the ER of West Penn Hospital. After undergoing several tests, I was told that they wanted to admit me for additional tests, including a cardiac stress test. After consultation with the ER physician, I agreed to arrange for the testing the next day, and I signed out Against Medical Advice (AMA).

Both Mr. Cord and Mr. Bonner were notified of my medical situation and that my appearance at the board would need to be rescheduled. They were also made aware of my scheduled leave for July 21 and July 24th.

Given that we were informed that access to the laboratory and our materials would be restricted, I asked the laboratory staff to pack our things. These files were removed to preserve our research. They were then placed in the custody of my attorney.

The laboratory service secretary and time keeper (Lorraine Paternoster) was notified on July 20th of my ER visit via voice mail before 7 a.m. on July 20th. I requested four hours of sick leave for July 19th (12:30–4:30 p.m.) and eight hours of sick leave for July 20th.

Thursday, July 20th, I went to my doctor's office to make arrangements for the cardiac stress test. Given that I was scheduled off to annual leave for Friday the 21st and Monday the 24th, I left Pittsburgh to attend to my previously scheduled personal matter.

Cheryl Wanzie attempted to reach me on Thursday, but failed to do so before I left Pittsburgh. She left a voice mail message at my home stating that she was informing me that she had canceled my annual leave and that I was considered absent without leave (AWOL).

Upon my return to work on July 25th, I called Mr. Cord expecting to be interviewed at the "Board of Investigation" that day—given the apparent urgency displayed the week before.

Instead I was told that my testimony was scheduled for Monday August 2nd. I explained to Mr. Cord that I was scheduled off on annual leave from Monday July 31st to Thursday August 3rd. I suggested that I testify any time between July 25–28, but because Dr. Graham was out of the office on vacation we had to wait until his return. I requested that my testimony be scheduled for Friday August 4th or that we have Dr. Graham attend the meeting via conference call. Mr. Cord arranged to have my testimony scheduled for 10 a.m. on Friday August 4th.

I was notified on August 24, 2006 that the VA Pittsburgh Healthcare System—University Drive Division proposed to remove me from my position as a GS–11 Microbiologist with the Department of Veterans Affairs for "Misuse of Government Property: Failure to Safeguard Confidential and Privacy Act protected Data in Violation of VA PHS Privacy Policy, MCM RI–17."

This action against me by the Agency was challenged with the assistance and representation of the AFGE Union President Robert Bonner and attorney George Love, Esq. The proposed termination was ultimately not upheld by the Administration. Instead they imposed a 30-day suspension—without pay. This action is also being challenged through the merit System Protection Board (MSPB).

Upon completion of the 30-day suspension, I returned to the VA Pittsburgh Healthcare System—University Drive microbiology section on December 13, 2006. I was immediately presented with a "Performance Improvement Plan," (PIP) which claimed that my performance was unsatisfactory in several critical areas. The items listed in the PIP were complete fabrications. Interestingly, the PIP was signed by the microbiology supervisor, but he emphasized that he had not participated in writing it. He was, however, responsible for implementing it.

In addition, the new position description that was created for me prior to my return to duty was never reviewed by the Union—per the AFGE contract.

As mentioned previously, the Special Pathogens Laboratory was an internationally-recognized *Legionella* reference laboratory. We maintained a collection of specimens and isolates in the lab freezers that are of historical significance and are irreplaceable. Despite our inquiries for the transfer of this collection to the University, Dr. Melhem ordered the destruction of this irreplaceable collection of research mate-

rial. This was done despite recommendations to the contrary from Dr. Robert Muder—the Chief of Infectious Diseases. We were never informed that this action was to be taken.

1 Background and Overview by Dr. Stou

2 Destruction of the SPL Collection of Isolates and Specimens – the Petitio

3 Documents Related to the Request to Transfer the Collection

4 Procedure for Storing Bacterial in the Special Pathogens Laboratory

5 The Functions of the Special Pathogens Laboratory – Janet E. Stout, Ph.D. PD & Research Documents

6 Documentation of Legionella-related Isolates and Specimens

7 Examples of Use of the Collection and Requests by Scientists

8 Stout CV and Relevant Publications

www.Legionella.org
The Legionella experts
Home Page

University of Pittsburgh
School of Medicine
Department of Medicine

January 17, 2007

Dr. Rajiv Jain
Dr. Steven Graham
Dr. Frederick DeRubertis
VA Medical Center
University Drive C
Pittsburgh, PA 15240

Dear Drs. Jain, Graham and DeRubertis:

We are writing this letter to protest and express our outrage and sorrow over the destruction of valuable and irreplaceable research material that is critical to future research efforts. This includes developing new laboratory tests for atypical pathogens, new media for identification of *Legionella*, assessment of new antibiotics for Legionnaires' disease and correlation of virulent isolates with proposed models of pathogenesis. Before release to physicians and microbiology labs worldwide, all FDA-approved lab tests and antibiotics used for diagnoses and therapy for Legionnaires' disease were tested in the Special Pathogens Laboratory using these materials

Consequences of the Action

This treasure trove of research material includes the most comprehensive set of *Legionella* isolates worldwide, including rare species isolated from fewer than 10 patients. The pathogenesis of *Legionella* is now being elucidated using new molecular methods. Our collaboration with basic scientists has been predicated on the use of isolates from this collection that are known to be virulent to patients and from environmental isolates that are not linked to disease.

Moreover, the collection included environmental isolates from the Pittsburgh VAMC and other VAMCs nationwide. It included isolates collected from patient homes in ongoing studies supported by the American Legion, Environmental Protection Agency, and 5 US state departments of health. Retrieval of these isolates allowed assessment of the success
of disinfection measures over time. It also allowed identification of the environmental source using molecular methods if patients contracted Legionnaires' disease in the future. The greatest harm from this action will be to patients from our VAMC and other VAMC's as *Legionella* outbreaks continue to affect VA patients because they have the highest risk factors for the disease -smoking, alcohol use, and age.

How Could This Have Happened?

We have now been informed that the Pittsburgh VA Healthcare System Administration ordered the destruction of the entire collection of isolates.

It is important to note that repeated requests were made to the Administration to transfer these precious and irreplaceable research materials to a suitable laboratory at the University of Pittsburgh. The first of these requests for assistance in transferring the materials was made by Dr. Yu on August 12, 2006 to Dr. Steven Graham (cc: Dr. DeRubertis and Dr. Robert Muder). He expressed his deep concern over the safety of our frozen collection. We subsequently made arrangements with a qualified investigator at the University of Pittsburgh (Dr. Timothy Mietzner) to house the isolates and communicated with the Research Department regarding the necessary steps and proper procedure for accomplishing the transfer. After Dr. Graham stepped down as the ACOS for Research and Dr. Sonel took over, Dr. Stout pursued this with Dr. Sonel. Dr. Sonel replied on October 5, 2006 and cc'd Dr. Melhem, Dr. Jain and Nicholas Squeglia. He stated that "We will work with you to facilitate the transfer". Dr. Stout was then directed to work with Barbara Strelec to deidentify the material prior to transfer. Dr. Stout was scheduled to meet with her on December 4, 2006 when Ms. Strelec abruptly cancelled the meeting -- citing direction from Dr. Sonel. It appears that Drs Melhelm and Sonel disregarded approved scientific practice and the direction of the Chief of Infectious Diseases by destroying the collection before the transfer could be arranged. This shameful behavior is unprofessional and barbaric. It will cause harm to VA patients at this facility. Janet Stout's research career has been severely damaged.

Under whose authority was the destruction of this scientifically and medically-important collection approved and when did this occur?

An investigation into this matter by the scientific community, congressional leaders monitoring the issue of Special Pathogens Lab closure, and the VA Inspector General should be conducted to prevent this from happening to another VA investigator.

Sincerely,

Victor L. Yu, M.D. and Janet E. Stout, Ph.D.

PS: Our collection included over 4,000 organisms, including *Klebsiella, Staphylococcus aureus, Candida* species, *Streptococcus* species, Enterococcus species, *Cryptococcus neoformans, Stenotrophomonas maltophilia,* and *Pseudomonas aeruginosa.* These microorganisms are also the property of numerous international scientists who entrusted us with the responsibility of keeping the collection intact in one laboratory with the proviso that we would provide unfettered access to these organisms. Was the entire treasure trove of these microorganisms also destroyed?

University of Pittsburgh

School of Medicine
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February 2, 2007

Dr. Rajiv Jain
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Dr. Frederick DeRubertis
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Dear Drs. Jain, Graham and DeRubertis:

We still need to verify the status of the collection of non-Legionella isolates. These isolates were accumulated from multiple observational studies and were the property of over 40 international collaborators.

We need an immediate answer to whether you have destroyed the entire collection for the following reason: A virulent Klebsiella has been seen in Taiwan that causes an invasive syndrome of liver abscess and endopthalmitis with high mortality rate. We were the first to demonstrate that it was a Taiwan phemenonon not seen in Europe, North America, South America, or Australia. At least 11 suspected cases have now been reported in the US, but confirmation is lacking. Klebsiella isolates from California, New York, and Barcelona from bacteremic patients with liver abscesses have been sent to us for storage and safekeeping. We injected these isolates in a mouse model of Klebsiella in a VA IRB-approved protocol, These 3 Klebsiella isolates killed mice similar to the Taiwan isolates in storage, and, in contrast, to Klebsiella from other continents which were avirulent in mice. Our collaborators from Taiwan have recently developed new methods of subtyping based on capsular serotype and presence of virulent factors. They have requested our 3 isolates to confirm the fact that the virulent Klebsiella has now reached Spain and the US. If we were able to confirm that the Taiwan isolates have indeed made it to the US, it would have immediate public health implications. Were over 400 Klebsiella isolates from 6 continents and the 3 Klebsiella isolates from US and Spain destroyed as were the legionella isolates?

If not, then it is imperative that the entire collection of microorganisms including the Klebsiella isolates should now be transferred to the University of Pittsburgh as planned months ago.

If Drs Sonel and Melhem indeed destroyed the entire collection, it becomes your responsibility to uncover the truth of why this despicable action could have occurred. On the other hand, if you stonewall or attempt to whitewash our inquiry, this irresponsible action would be consistent with your vindictive and unethical response to our attempts to save the Special Pathogens Lab. Eventually the truth would be revealed and besmirch all of you. As of now, your silence adds to the complicity of the entire Pittsburgh VA administration.

Victor L. Yu , MD and Janet E Stout, PhD

VIEWPOINTS

Destruction of Isolates from the Pittsburgh Veterans Affairs Laboratory

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The Pittsburgh Veterans Affairs hospital administration closed the research laboratory directed by Victor Yu and Janet Stout and destroyed isolates collected as part of a series of clinical studies over 25 years. This article discusses the implications and protests such destruction as an affront to science and scientific study. A petition signed by 243 individuals accompanies this article.

The Pittsburgh Veterans Affairs (VA) Special Pathogens Laboratory, headed by Victor Yu, MD, and Janet E. Stout, PhD, was terminated by the Pittsburgh VA administration in July 2007, under protest from Dr. Yu. During the administrative dispute, the collection of clinical specimens and microbiological isolates obtained by investigators from around the world were destroyed. These materials were collected as part of numerous prospective observational studies and infection control–related studies. For almost 30 years, Drs. Yu and Stout set the standards for our understanding of the epidemiology of *Legionella* infection, as well as for our understanding of the control of environmental *Legionella* infection.

Dr. Yu also established a series of national and international collaborations to elucidate our understanding of the microbiological and clinical management issues of bacteremia due to many different organisms. These studies were seminal in many respects. They changed our understanding of the relationship between appropriate and inappropriate therapy, the relationship between the MICs of isolates and outcome, the molecular epidemiology of relapse and reinfection, and the relatedness of strains throughout the world. The studies are far too numerous to articulate in detail or even to list here in total, but they include studies of the major pathogens that confound us today, including *Staphylococcus aureus*, *Pseudomonas aeruginosa*, extended-spectrum β-lactamase–producing *Klebsiella pneumoniae*, *Enterobacter* species, *Stenotrophomonas maltophilia*, *Enterococcus* species, *Bacteroides fragilis*, *Streptococcus pneumoniae*, and *Candida* species. The concept was simple: observe the clinical presentation of bacteremia or fungemia, and follow outcomes while correlating the microbiology to the outcome. The studies were all prospective, and the isolates were collected and sent to a central laboratory for more-definitive analysis. Each of the studies emanating from this collection has changed our knowledge base and has contributed significantly toward optimal treatment of patients with these infections. Moreover, the careers of a number of prominent academicians were launched when they coordinated these large-scale studies and had the opportunity to analyze the data as trainees.

Capturing the isolates and making sure they were sent to the laboratory was an important and difficult task—especially for fastidious organisms like *S. pneumoniae* and *Bacteroides* species. Given the international component, as well the requirements for sending specimens across national borders, these studies were difficult to perform. All studies were approved in accordance with local institutional review board requirements, and permits were obtained from regulatory authorities. Nevertheless, the number of studies and important insights total >100 peer-review articles (see References [online only] for selected articles) and have provided important information that correlates outcome with the use of certain antibiotic classes, as well as levels of susceptibility. Some of the studies challenged prevailing dogma and helped provide data for the Clinical and Laboratory Standards Institute.

All of these isolates, many of which were still being studied, were destroyed. The samples were incinerated without warning or notification to Drs. Yu and Stout, such

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that it became an irrevocable action. These isolates were accrued purely for the advancement of science, and the beneficiaries of these studies were the patients infected with these microbes. Moreover, these isolates and samples would have proven to be invaluable in the future, because having these strains would enable comparison over time, for changes in pathogen virulence, antimicrobial susceptibility correlation with outcome, and changing genetic diversity, as well as the development of new molecular tests. Their destruction can by no means be considered to be justifiable. Add your name to the petition or review details at the Call for Inquiry Web site (http://www.legionella.org/vaspl.asp). It is in this context that this petition is being published.

PETITION FOR VA ACCOUNTABILITY

We, the undersigned, respectfully request that VA Central Office convene an investigative committee to review the actions of the Pittsburgh VA Healthcare System regarding the closure of the Special Pathogens Laboratory and the destruction of a scientifically valuable collection of microorganisms.

The collection of microorganisms was created and preserved by Victor L. Yu, MD and Janet E. Stout, PhD over a 25-year period in the Special Pathogens Laboratory in Pittsburgh. The entire collection was incinerated without informing Drs. Yu and Stout. This action was taken despite efforts by Drs. Yu and Stout to appropriately transfer the collection to the University of Pittsburgh.

The collection contained stored patient sera, urine samples from patients infected by unusual *Legionella* species and respiratory tract specimens yielding rare *Legionella* species dating back to 1979. Among the several thousand *Legionella* isolates destroyed were environmental and patient isolates from 20 VA hospitals experiencing outbreaks of hospital-acquired Legionnaires' disease. For some of us, *Legionella* isolates from our VA hospital were among those destroyed.

These *Legionella* isolates and specimens were being stored for future epidemiologic investigation; providing an invaluable resource for elucidating the source of Legionnaires' disease at VA Medical Centers. As importantly, emergence of resistance of *Legionella* to disinfectants has been reported by us and the storage of the original isolates from each hospital allows documentation of this possibility in the event of failure of disinfection. Finally, molecular fingerprinting would allow individual VA hospitals to ascertain the source of the infecting *Legionella* in VA patients should future outbreaks occur.

Among the isolates in the collection were several thousand well-characterized microorganisms from multinational observational studies. These disease-causing strains of *Pseudomonas aeruginosa*, *Enterobacter* species, *Enterococcus* species, *Bacteroides fragilis*, *Stenotrophomonas maltophilia*, *Klebsiella* species, *Candida* species and *Cryptococcus neoformans* were also destroyed.

This unique collection of specimens and isolates were being used to develop new diagnostic tests, new therapies, and to study resistance and mechanisms of disease transmission. The results of these studies benefited veterans nationwide.

To remove the appearance of impropriety, we request that an outside scientific body with no relationship to the VA be convened to ascertain the appropriateness of this action.

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Scientists Call for Inquiry into Destruction of Microbes in VA Special Pathogens Laboratory

233 scientists and physician researchers from 27 countries have collectively expressed outrage over the destruction of an irreplaceable collection of microbes numbering in the thousands. The collection included Legionella bacteria (the cause of Legionnaires' disease) and many other species of pathogens causing disease in humans including antibiotic resistant strains of Pseudomonas, Klebsiella, fungi, etc. The scientific collection had been accumulated over 25 years from numerous international studies by Victor L. Yu M.D., Professor of Medicine, University of Pittsburgh, Janet E. Stout Ph.D., Director, Special Pathogens Laboratory and scientific researchers throughout the world.

Members of the infectious disease community have now petitioned congress and the Department of Veterans Affairs Healthcare System to conduct an independent investigation of the Pittsburgh VA administration and its role in the destruction of these valuable research materials. Dr. David Snydman , Chief of Infectious Diseases, Tufts University Boston, MA and Dr. Elias Anaissie, Chief, Division of Cancer Supportive Care, University of Arkansas Medical Center, Little Rock, AK headed the petition drive. The signatories of the petition included physicians and researchers from 30 states and 27 countries. Interestingly, the largest single contingency was 47 VA physicians from 31 VA healthcare facilities. Some of these VA investigators participated in a recently published study of hospital-acquired Legionnaires' disease authored by Drs. Yu and Stout. As a result of this study, the VA is now revising its policy regarding the prevention of this waterborne disease. The Pittsburgh VA administration destroyed all the Legionella isolates, including those collected from patients and water sources from this VA-supported study. According to one signatory, this action "is just appalling ignorance and irresponsibility". Dr. Anaissie stated "The destruction of this treasure trove of pathogens is a scientific disaster. The tragedy is that the actions of those that gave the order for destruction are completely ignorant about the seriousness of this breach of trust and the implications for all patients – including VA patients."

In a letter to Sen. Arlen Specter, the Pittsburgh VA justified the action by stating that the specimens were unlabelled, a claim that Drs. Yu and Stout reject. Dr. Yu noted that "These specimens were shared with other scientists from around the world, something impossible to do if they were not meticulously catalogued." Moreover, the Pittsburgh VA Research Department was ready to release the collection to a laboratory at the University of Pittsburgh. Drs. Stout and Yu were assured that the VA would facilitate the transfer. Only later was it disclosed that the collection had been destroyed without even informing Drs. Yu and Stout. "I am grateful to my colleagues for their support. Hopefully, an investigation will prevent this from ever happening to another VA investigator" said Yu.

Letters

Preservation of Culture Collections

The article by Jenkins and Cypess on the loss of biologically valuable scientific collections (*Microbe*, September 2007, p. 427) is timely, important, and a painful reminder of the destruction of our collection of microorganisms. Our collection included the most extensive and well-characterized collection of *Legionella* strains in the United States (more than 3,000 isolates) and hundreds of other medically important pathogens. The non-*Legionella* strains included isolates from clinical studies of illnesses (bacteremia and pneumonia) due to *Pseudomonas aeruginosa*, *Enterobacter* species, *Bacteroides fragilis*, *Stenotrophomonas maltophilia*, *Klebsiella* species, *Candida* species, *Cryptococcus neoformans*, *Streptococcus pneumoniae*, and *Enterococcus* species. Most isolates had an annotative pedigree of a wealth of clinical information that included clinical manifestations, underlying diseases, ancillary laboratory data, geographic location, antibiotics received, severity of illness scores, and clinical outcome over time. This additional information made the collection even more valuable than a mere collection of microorganisms.

We would like to share with you the circumstances surrounding this tragic occurrence in the hope that mechanisms can be put in place to prevent future losses of medically important collections. The main theme of the article by Jenkins and Cypess was the regrettable loss of thousands of pathogens because the logistical and financial burdens of maintaining the collections proved too difficult for the institutions holding the collections. Unlike the problems mentioned in the ASM article, our loss occurred at the Pittsburgh VA Medical Center as part of a dispute involving the untimely closure of the Pittsburgh Special Pathogens Laboratory.

Investigators at the Special Pathogens Laboratory were the guardians of this collection and maintained this collection for over 20 years—sharing strains with other scientists worldwide. Financial resources for maintaining the collection were not an issue, and the investigators had arranged for the transfer of the collection to the University of Pittsburgh.

How such a tragedy could have been averted is uncertain since the collection was deliberately destroyed without notifying the investigators, Dr. Victor L. Yu and Janet E. Stout. This scenario is even more horrifying since it required the tacit consent of physician researchers in the administrative hierarchy of the Pittsburgh VA Medical Center. Administrators at both VA Central Office and the Pittsburgh VA Medical Center have not provided an appropriate explanation for this scientifically unconscionable act.

A commentary regarding this tragic loss and a petition drive is in press at Clinical Infectious Diseases. The petition signatories include over 250 physicians and scientists from around the world who have called for an investigation into this senseless loss of scientifically-valuable materials. If you wish to see greater details of this issue or express your concern, please go to www.legionell.org/vaspl.usp.

Victor L. Yu
Janet E. Stout
University of Pittsburgh
Special Pathogens Laboratory
Pittsburgh, Pa.

Lymerix® Risks Revisited

Phillip Baker and Stanley Plotkin (*Microbe*, October 2007, p. 473) attempt to reassure us about the safety of Lymerix®, the ill-fated Lyme vaccine. Their effort is far from reassuring.

Baker cites the limited FDA adverse events monitoring for Lymerix®, which was approved in 1998 based on initial Phase III results and withdrawn in 2002 before adequate Phase IV safety data could be obtained (L. E. Nigrovic and K. M. Thompson, Epidemiol. Infect. 135:1–8, 2007; M. S. Hanson and R. Edelman, Expert Rev. Vaccines 2:683–703, 2003). Baker's reliance on incomplete safety monitoring raises the specter of Vioxx®, which was approved by the FDA in 1999 based on safety data from more than 5,000 treated patients and then withdrawn three years later after Phase IV studies revealed serious cardiovascular complications in a more diverse population. Based on legal action aimed at Lymerix®, it is likely that Phase IV studies would have shown significant risks in a broader population if the Lyme vaccine had not been withdrawn by the manufacturer (C. D. Rose, P. T. Fawcett, and K. M. Gibney, J. Rheumatol. 28:2555–2557, 2001; N. Latov, A. T. Wu, R. L. Chin, H. W. Sander, A. Alaedini, and T. H. Brannagan, J. Periph. Nerv. Syst. 9:165–167, 2004).

Baker describes the potential negative effect of LFA-1 crossreactivity with the OspA subunit of Lymerix®, but this molecular mimicry was shown to be "irrelevant" as a mechanism of arthritis in Lyme disease (Hanson and Edelman, Expert Rev. Vaccines 2:683–703, 2003; R. B. Stricker, Clin. Infect. Dis. 45:149–157, 2007). His argument that the complication rate should have been higher based on this discredited disease model is both irrelevant and incendiary for the hundreds of patients who reported arthritic and neurologic complications from the vaccine (Nigrovic and Thompson, Epidemiol. Infect. 135:1–8, 2007). The bottom line is that the mechanism of Lymerix® toxicity is unknown, and pretending to understand the unknown is unacceptable.

Baker and Plotkin both argue that the immunological response to natural infection with the Lyme spirochete, *Borrelia burgdorferi*, should be different from the response to a subunit vaccine, implying that the latter could not cause the same arthritic and neurologic complications. This peculiar view is contradicted by a

07 Specter to Bennett (VA)

ARLEN SPECTER
PENNSYLVANIA

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AGING

United States Senate

WASHINGTON, DC 20510-3802
specter.senate.gov

March 12, 2007

Gloria Bennett
Director, Congressional and Legislative Affairs
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Dear Director Bennett:

I am writing once again in connection to the VA's decision to close the Special Pathogens Laboratory located at the Pittsburgh VA Medical Center. I appreciate the Department's responsiveness to my previous inquiries.

According to Dr. Victor L. Yu, former Chief of the Infectious Disease Section, and Dr. Janet Stoudt, former Director of the Special Pathogens Laboratory, prior to its closure, the Special Pathogens Laboratory was home to a valuable collection of microorganisms, which included a comprehensive set of Legionella isolates. Dr. Yu and Dr. Stout have asserted that this collection would allow for scientific advancement of patient care initiatives including the development of new diagnostic tests, evaluation of new antimicrobial therapy, and ongoing epidemiologic investigations for Legionnaires' disease.

Dr. Yu and Dr. Stoudt have informed my office that following the Laboratory's closure, they attempted to work with the VA to facilitate the transfer of this collection to a suitable lab at the University of Pittsburgh. However, they have told my office that the VA is no longer cooperating with this effort and that they now suspect the collection has been destroyed. Dr. Yu and Dr. Stoudt have stated that the collection's destruction would represent a major loss for the scientific and medical communities. Accordingly, I would appreciate a response from appropriate VA officials to the following:

- Was this collection of microorganisms (Legionella, Klebsiella, Streptococcus, Staphylococcus, Pseudomonas, Bacteroides, fungi, respiratory specimens, blood samples, etc.) destroyed?

- If the collection was not destroyed, is the VA willing to have the collection of research material transferred to the University of Pittsburgh? I have been informed that the University is willing to accept the collection because of its scientific value.

- If the collection has been destroyed, please provide a specific explanation for this action. Please include an explanation as to whether this action has the potential to negatively impact patient care or safety.

Thank you for your consideration of this request. Should you have any questions for my staff, please contact Mr. Charles Fitzpatrick of my Washington office at (202) 224-2026.

Sincerely,

Arlen Specter

AS/cf

WPXI.com

Did Break-Through Cures End Up In Trash?

Lab Closes After 25 Years

POSTED: 4:48 pm EDT March 13, 2007
UPDATED: 7:29 pm EDT March 14, 2007

Related To Story

Video: 25 Years Of Research Gone

PITTSBURGH -- A Target 11 investigation has uncovered shocking details about the destruction of an entire collection of rare specimens at the Veteras Affair Hospital in Pittsburgh.

This comes at a time when the VA and the Army are under fire for patient care at the Walter Reed Army Hospital in Washington.

The special pathogens lab at the VA Hospital in Pittsburgh was on the cutting edge of scientific research.

Scientists tracked infectious diseases, specializing in legionnaires, a type of pneumonia.

They were the first to locate the organism in drinking water and they identified antibiotics to cure the illness and treatments to kill the bacteria.

Through the years, they created a collection of thousands of specimens.

Last summer, after 25 years of research the lab was abruptly shut down.

A statement from the VA to Target 11 said the "research function was no longer supported by any research projects."

The VA would not elaborate.

Scientists were given 48 hours to move out.

They said they were not allowed to finish critical tests on samples from other hospitals to find the source of legionnaires disease.

Dr. Janet Stout thought she had convinced the VA to allow her to transfer the entire collection of specimens to a lab at the University of Pittsburgh.

Instead the entire collection of more than 3,000 samples was destroyed by the VA.

The VA refused to talk on camera instead issuing a statement that the specimens were incinerated.

They wouldn't say why and the doctors haven't been told either.

Target 11 contacted Sen. Arlen Specter earlier this week and Tuesday his office said that they have sent a request for information to administrators with the Pittsburgh VA.

Doctors said they are in the process of attempting to set up another lab for legionnaires disease research.

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nature news

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News

Researchers protest destruction of bacteria collection

Petitioners call for investigation after hospital destroys nearly 10,000 samples.

Heidi Ledford (/news/author/Heidi-Ledford/index.html)

A group of nearly 250 researchers is requesting an investigation into the destruction of thousands of samples from an infectious disease lab at the Veterans Affairs Medical Center in Pittsburgh, Pennsylvania. The collection — which contained nearly 10,000 specimens — was the product of more than 20 years of work and included many different strains of infectious bacteria, some of them very rare.

Bacterial collections can help to trace the origins of new infectious agents.

BARRY DOWSETT / SCIENCE PHOTO LIBRARY

"They were priceless," says David Snydman, an infectious disease expert at Tufts Medical Center in Boston, Massachusetts. Snydman had collaborated with the curators of the collection on several projects, and lost samples from patients with pneumococcal meningitis collected from sites around the world. "This is like a book burning," he says.

The specimens were destroyed after the medical centre closed down their Special Pathogens Laboratory, headed by Victor Yu, in July of 2006. Yu and colleagues were planning to move the samples to a new home, but the collection was meanwhile destroyed by the hospital as part of the closure.

Snydman and 242 others have now signed a petition, published in the April issue of *Clinical Infectious Diseases* 1(#B1), asking that an independent review committee investigate what led to the repository's destruction.

Unknown fever

The lab specialized in testing samples for *Legionella* bacteria, the agent that causes a deadly form of pneumonia called Legionnaire's disease.

pathogens. The collection contained samples of an emerging strain of Klebsiella pneumonia that was originally discovered in Asia, but has since been found around the globe. And it also held specimens taken from patients diagnosed with 'fever of unknown origin'. These samples could one day have been used to trace the origins of new infectious agents, Yu says.

Yu and his colleague, Janet Stout, have since reopened the Special Pathogens Laboratory at the nearby University of Pittsburgh, but say there is no way to replace the full contents of their archive.

Mystery destruction

Exactly why the hospital chose to destroy the samples remains a mystery. Hospital representatives declined to comment when contacted by *Nature News* , but did tell WTAE, a local television news station, that the hospital incinerated samples that were not clearly labeled to protect the safety of hospital patients and staff.

Stout and Yu chafe at this explanation. Stout says the samples were "meticulously catalogued", though the identity of the infectious agent in some samples was not known. She says she was coordinating with hospital administrators to transfer the samples to the University of Pittsburgh, where she and Yu are now faculty members.

Both researchers say they were not alerted in any way that their samples were in danger. "No one from the administration ever discussed this with Yu or I," says Stout. There were no complaints, she says, that the samples were still in storage at the medical centre. Stout only learned of the destruction when she consulted an attorney to help negotiate the terms under which she would leave the hospital after the lab was closed. She wanted to be sure that she could take her strains with her, and had her attorney contact the hospital's lawyers. "They told him we can't do that because they've already been destroyed," she says. "That's how I found out."

Quick exit

Discussions over whether the lab would be closed culminated in a decision that left Yu only 48 hours to shut down the lab. "On Wednesday they handed the notice to me," says Yu. "On Friday they padlocked the lab."

Yu protested that there were samples in the lab that needed to be tested so that his clients could be told whether their water was contaminated. Yu appealed to hospital administrators and US congressmen for more time. This won him two weeks to finish the lab work, but did not win him any friends in the hospital's administration, he says.

ENT
5823/25093680/1;;~sscs=%3fhttp://www.nature.com/nphys/focus/quantum-phase-transition:

Yu's colleagues note that he is no stranger to controversy. Yu has clashed with the US Centers for Disease Control and Prevention in the past over *Legionella* testing standards. The agency advises hospitals to test their water only after a patient has been diagnosed with Legionnaire's disease; Yu thinks water should be tested once a year to prevent infections before they strike.

[illegible] is done, says Stout. "What happened to Yu and I is one thing. But the

figure out how this can never happen again."

References

1. Snydman, D. R. , Anaissie, E. J. , and Sarosi, G. A. *Clinical Infectious Diseases* 46, 1053-1059 (2008).

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Important Bacteria Cultures Destroyed (http://washingtonindependent.com/view/important-bacteria)
Scientists wonder why the VA killed the collection of Legionnaire's disease samples.

By **Arthur Allen** (http://washingtonindependent.com/person/12673-artallen) 03/17/2008
Let's say your 48-year-old husband has just been diagnosed with Legionnaire's disease in a hospital intensive care unit. You learn that the bacteria causing this disease spread in water supplies, and you have a hot tub at home where your teen-age kids are currently splashing about. How do you find out whether the hot tub was the source of your husband's infection?

Until recently, you sent water samples to the Special Pathogens Lab at the Veterans Administration hospital outside Pittsburgh. That's what Lynn Winn, of Orange, Calif., did in July 2006. But she never got the results, because the VA closed down the lab without processing her samples.
Six months later, in what infectious disease specialists around the world are calling a tragic, inexplicable act of vandalism, the VA incinerated the lab's library of 4,000 microbe cultures, including the world's most important collection of legionella bacteria, collected over a period of nearly 30 years.

No one seems to understand the point of this deliberate destruction. "My theory is that this was essentially a vindictive act," sayd Dr. Victor L. Yu, who headed the lab. The VA has said the samples weren't properly labeled. But Yu and his colleagues flatly deny that, and it seems hard to believe. VA spokesmen in Washington and Pittsburgh did not return several phone calls and emails seeking explanations.

A murky turf war seems to lie behind the closing of the pathogens lab, which was unusual because its influence extended well beyond the Veterans Administration health-care system. (For exhaustive details and background, go **here**). Yu has been at odds with the Centers for Disease Control in the proper way to detect

Colleagues of Yu and his partner, Dr. Janet Stout, described the destruction of the collection as a calamity on a scale with the burning of a library of rare books or a museum full of prized artworks. They said it would damage research into Legionnaire's and other illnesses; the collection also included strains of Pseuodomonas, Enterococcus, Klebsiella and many other pathogenic bacteria. Isolates of these bacteria could have been used to compare changes in virulence and antibiotic resistance, and to help fingerprint new outbreaks of disease.

"This was a tragic event, and it seems to me both stupid and egregious," says Dr. William Bonnez, a physician and researcher at the University of Rochester Medical Center. "This was a collection that had taken years to collect and provided insight into all sorts of things—the evolution of bacteria and bacterial resistance, the genes that allow these germs to survive in the environment and in people."

This story of destruction emerged in the April 1 edition of the journal Clinical Infectious Diseases, released on line last week, which included a **petition** (http://www.journals.uchicago.edu/doi/abs/10.1086/528853) signed by 250 infectious disease specialists. They demanded that the Veterans Administration convene an investigation of the Pittsburgh VA Healthcare System's decision to close the lab and wreck its collection of microorganisms. "These isolates were accrued purely for the advancement of science," the petitioners write, "And the beneficiaries of these studies were the patients."

Kate Kelly, spokeswoman for Sen. Arlen Specter (R-Pa), said he has conducted an inquiry into the episode but, for the moment, had no further details.

Following the closure of the lab, Yu got into an ugly battle with the administration, which locked him out. The VA destroyed the microbe library in December 2006, without even notifying Yu or Stout. Both scholars had joint appointments at the University of Pittsburgh, and have moved their operations there.

Infectious disease doctors view Yu and Stout as the go-to experts on Legionnaire's disease and the bacteria that causes it. Legionnaire's bacteria sicken an estimated 20,000 Americans each year, mostly the old and immunocompromised, often in hospitals, according to the Centers for Disease Control. About a quarter of the patients die. Sending samples to Drs. Yu and Stout, hospitals around the world were able to determine whether the bacteria afflicting their patients existed in the microbiological record, providing hints as to the disease's spread and the virulence of the particular strains they sent in.

"Many researchers depended upon them," said David Relman of the Stanford VA Hospital and Stanford University. "Given the amount of time they put in, and the value of these collections it seems incredibly shortsighted to terminate it. Its value was immense, almost unmeasurable, and it's very hard to replicate."

David Cowgill, spokesman for the Pittsburgh VA, said in 2006 that the lab was closed because it had performed commercial testing, which he said wasn't permitted in government buildings. In fact, the lab had for decades conducted tests for hospitals and for individuals, whom it did not charge. Its extensive links with doctors and hospitals around the world were part of what made the lab invaluable, supporters say. Cowgill did not respond to an email and two phone requests for comment on Friday.

Legionnaire's bacteria are named for a 1976 outbreak that killed 34 people and sickened 221 others attending an American Legion convention in Philadelphia. Though first discovered during that outbreak, the germ seems to be common and growing health threat.

The Pittsburgh lab's expertise was especially sought-after because legionella is a notoriously difficult bacteria to culture, and Legionnaire's disease often difficult to diagnose. Yu and Stout proved that the disease frequently spreads through undetected contamination of tap water.

In 2005, after a mysterious outbreak of pneumonia at a Toronto nursing home killed 17 people, samples were sent to Yu's laboratory, which confirmed legionella as the cause. Toronto doctors were unfamiliar with the intricacies of culturing the bacteria, and had failed to diagnose it.

Research by Yu, Stout and their colleagues has embroiled them in a scientific dispute with the Centers for Disease Control over the proper way to control legionella. Yu believes all hospitals should conduct routine examination of faucets and water coolers for legionella colonies. Most clusters of the disease, Yu and Stout believe, have broken out in hospitals that later turned out to have contaminated water.

The CDC's guidelines, however, do not encourage proactive water testing. Many hospitals that are colonized with high counts of legionella do not have cases of the

epidemiologist. Hicks maintains that decontamination of water supplies does not provide lasting protection against legionella contamination; Yu claims that such treatments do exist.

Most of Western European and some Asian countries now require hospitals to proactively check for legionella in their water, and Stout and Yu have attacked CDC for failing to follow suit. "We think this long-overdue approach should be adopted," Stout told a Pittsburgh newspaper last year. "How much longer do we have to wait and how many more lives will be lost?"

In the **study** (http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=&db=pubmed&orig_db=PubMed&term=stout%20je%2C%20muder%20rr%20role that reinforces this conviction most strongly, Stout and Yu's team found high levels of legionella bacteria in six of 20 VA hospitals over a three-year period. Five of the six hospitals had cases of Legionnaire's disease during the study; none of the 14 "clean" ones did.

A few years later, one of the "clean" VA hospitals, in Phoenix, found cases of Legionnaire's disease. Yu's lab processed water from that hospital and found that 65 percent of the samples contained legionella. That was the last piece of work his team did at the VA. Administrators sent in security guards to keep his employees from finishing samples sent in by other hospitals or individuals—including Winn's hot tub waters.

"We were given 48 hours to shut down a lab that had been open for 25 years," says Yu. "How could they shut this lab down? It was the legionella reference lab for the entire world."

In response to the results Yu sent it, the Phoenix hospital installed a water treatment program, and since has been legionella-free.

"So," said Yu, "we proved our point."

Yu and Stout now operate a lab across town. Their library, and its precious volumes of killer bugs, is gone forever.

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Janet Stout

From:	Janet Stout [jes20micro@gmail.com]
Sent:	Thursday, August 23, 2007 9:31 AM
To:	Victor Yu; Gunner Lyslo; Jaclynn Shannon; Sue Mietzner; jrihs@specialpathogenslab.com
Cc:	Frank Canonica
Subject:	Fwd: FW: Re: A recent study about monitoring hospital water

---------- Forwarded message ----------
From: LF Muscarella, PhD <editor@myendosite.com>
Date: Aug 23, 2007 9:10 AM
Subject: FW: Re: A recent study about monitoring hospital water
To: Janet Stout <jes20micro@gmail.com>

-----Original Message-----
From: LF Muscarella, PhD [mailto:editor@myendosite.com]
Sent: Thursday, August 23, 2007 9:04 AM
To: 'myendosite@lists.iqnection.com'
Subject: Re: A recent study about monitoring hospital water

Dear Subscribers:

I bring to your attention an article that discusses a recent study about monitoring hospital water to help predict hospital-acquired Legionnaires' disease risk. This article can be read at:
<http://www.sciencedaily.com/releases/2007/08/070822110545.htm>

One of the researchers of this study states that: "Our study provides much-needed evidence to support a national policy change to include routine environmental surveillance of health care facility water systems along with stringent clinical monitoring of patients," said Dr. Stout, who estimates that 39,000 people have died of Legionnaires' since 1982. "We think this long overdue approach should be adopted by infection control and infectious disease practitioners nationwide."

These comments are well-taken and would seem to support my recommendation to periodically monitor the water used to rinse endoscopes, to reduce the risk of healthcare-acquired infections associated with, in particular, bronchoscopy and ERCP (upper GI endoscopy). Refer to a related article I wrote in "CHEST":

<http://www.chestjournal.org/cgi/content/full/126/3/1001-a>

I support future studies to determine whether hospital water contaminated with, for example, Pseudomonas aeruginosa and used to reprocess and rinse bronchoscopes and ERCP endoscopes, among others, is associated with an increased risk of healthcare-acquired respiratory infections including pneumonia. Morbidity and mortality linked to endoscopes rinsed with filtered water contaminated with Pseudomonas aeruginosa have been reported and are discussed, for example, in the following article I wrote:

<http://www.journals.uchicago.edu/ICHE/journal/issues/v23n7/230704/230704.te
xt.html> OR the article beginning on page 3 of this link:

Samples of the rinse water would be taken at several sites including the healthcare facility's tap and just prior to entering the automated endoscope reprocessor or liquid processing system. The water inside the reprocessor or processing system that terminally rinses the endoscopes after chemical immersion and just prior to their use would, of course, be sampled and of greatest importance.

It is understood that AAMI, which is now addressing the topic of the quality of the water used to rinse reusable instruments, would adopt and include in its to-be-completed technical information report (TIR-34) the importance to patient safety of monitoring the bacterial quality of the water, not just leading up to, but also inside, the AER or processing system and in terminal contact with the instruments, especially if the rinse water were claimed to be "sterile" (or "bacteria-free").

Remember to stop by and visit: www.myendosite.com <http://www.myendosite.com/> for dozens of articles I wrote on the topics of infection control, disease transmission, disinfection, sterilization, and instrument (and endoscope) reprocessing, among others.

Regards,

Larry

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Janet Stout <jes20micro@gmail.com>

(no subject)

Paola Borella <borella.paola@unimore.it> **Thu, Mar 22, 2007 at 11:16 AM**
To: Arlen Specter <scott_boos@specter.senate.gov>, Arlen Specter <stan_caldwell@specter.senate.gov>, Michael Doyle <alan.smith@mail.house.gov>, Tim Murphy <Michael.Baxter@mail.house.gov>, "Deyton, Lawrence R., MSPH, MD" <lawrence.deyton@va.gov>, "Hamerschlag, Arthur" <arthur.hamerschlag@va.gov>

Dear Sir:
As a research group devoted to the investigation of Legionella we are very concerned about this information " *We regret to inform you that the Pittsburgh VA administration has destroyed our frozen collection of Legionella isolates, stored patient sera, urine sample from patients infected by unusual Legionella species and respiratory tract specimens yielding rare Legionella species".*

It is difficult for us (and for any research group in any field) to understand the reason for the VA to take this action that may compromise some of the ongoing and future investigations in the field of Legionella. If confirmed we will consider this action as unethical and irresponsible since it represents a tremendous loss of one of most valuable Legionella collections in the world. We would like to extend our full support to the V.L. Yu and co workers in any decision they consider against this tragic event.

Prof. Paola Borella
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Prof. Paola Borella, MD, Full Professor of Hygiene
Director School of Specialization in Hygiene and Preventive Medicine
Dipartimento di Scienze di Sanità Pubblica
Via Campi 287,
41100 Modena, Italy

Tel +39(059) 2055474, Fax +39(059) 2055483

Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

Phoenix VA (Peterson) - Letter of support for VA Lab

Victor Yu <victorlyu@gmail.com> **Fri, Sep 1, 2006 at 2:23 PM**
To: "Peterson, Rick C" <Rick.Peterson@va.gov>
Cc: Janet Stout <jes20micro@gmail.com>

Got it. Thanks, Victor L Yu MD

On 9/1/06, **Peterson, Rick C** <Rick.Peterson@va.gov> wrote:
Dr. Yu,

I would like to thank you for processing the Legionella water samples from the Phoenix VAMC in July, 2006. I know that pressure existed to not process these environmental samples. And, I understand that the dedicated staff of the Special Pathogens Laboratory worked without pay on these specimens to fulfill their public health mission.

Fortunately you were able to get them done. The results we received were important for the healthcare of our veteran patients . 65% of our water samples were positive. These results have confirmed that the recent addition of copper/silver ionization to our domestic water system was the right thing to do.

The staff of the Pittsburgh VA Special Pathogens Lab has worked with us every step of the way in our fight to rid our water system of Legionella. Not only with lab analysis but with development of a treatment strategy. Your Lab has brought deserved prestige to the DVA Healthcare System and improved our care of the veteran patients at the Phoenix VAMC.

With the help of you and Dr. Stout, our facility is on the way to significantly reducing the odds of an outbreak of Legionnaire's Disease.

> Thanks to you and your group.

> Rick Peterson
> Plumbing and Mechanical Supervisor
> Phoenix VA Medical Center
> (602) 277-5551 ext 7122

--
Victor L Yu MD
Professor of Medicine
University of Pittsburgh
VA Medical Center
Pittsburgh, PA

Telephone:
Office secretary: 412-688-6179

1 Background and Overview by Dr. Stou

2 Destruction of the SPL Collection of Isolates and Specimens – the Petitio

3 Documents Related to the Request to Transfer the Collection

4 Procedure for Storing Bacterial in the Special Pathogens Laboratory

5 The Functions of the Special Pathogens Laboratory – Janet E. Stout, Ph.D. PD & Research Documents

6 Documentation of Legionella-related Isolates and Specimens

7 Examples of Use of the Collection and Requests by Scientists

8 Stout CV and Relevant Publications

Dates of Inquiries for Transfer of Isolates from the Special Pathogens Laboratory to the University of Pittsburgh

Date	From	To	Cc
8-12-06	Janet E. Stout, Ph.D.	Victor L. Yu, M.D.	---
8-12-06	Victor L. Yu, M.D.	Steven H. Graham, M.D.	F. DeRubertis, M.D. Robert Muder, M.D.
*8-15-06	Steven H. Graham, M.D.	Victor L. Yu, M.D.	
8-15-06	Victor L. Yu, M.D.	Janet E. Stout, Ph.D.	Robert Muder, M.D.
8-17-06	Janet E. Stout, Ph.D.	Victor L. Yu, M.D.	Tim Mietzner, Ph.D.
8-21-06	Victor L. Yu, M.D.	Steven H. Graham, M.D	Janet E. Stout, Ph.D.
10-1-06	Janet E. Stout, Ph.D.	Ali Sonel, M.D.	------
10-5-06	Ali Sonel, M.D.	Janet E. Stout, Ph.D.	------
10-5-06	Janet E. Stout, Ph.D.	Ali Sonel, M.D.	------
**10-5-06	Ali Sonel, M.D.	Janet E. Stout, Ph.D.	N. Squeglia, M. Melhem, M.D. R. Jain, M.D.
10-5-06	Janet E. Stout, Ph.D.	Tim Mietzner	-----
10-9-06	Tim Mietzner, Ph.D.	Janet E. Stout, Ph.D.	-------
11-7-06	Barbara Strelec	Janet E. Stout, Ph.D.	A. Sonel, M.D.
11-9-06	Janet E. Stout, Ph.D.	Barbara Strelec	A. Sonel, M.D.
11-10-06	Barbara Strelec	Janet E. Stout, Ph.D.	------
11-15-06	Janet E. Stout, Ph.D.	Barbara Strelec	-------
11-20-06	Barbara Strelec	Janet E. Stout, Ph.D.	-------
11-21-06	Janet E. Stout, Ph.D.	Barbara Strelec	-------
11-26-06	Janet E. Stout, Ph.D.	Barbara Strelec	------

11-28-06	Barbara Strelec	Janet E. Stout, Ph.D.	------
11-29-06	Janet E. Stout, Ph.D.	Barbara Strelec	-------
12-4-06	Barbara Strelec	Janet E. Stout, Ph.D.	-------
12-4-06	Janet E. Stout, Ph.D.	Ali Sonel, M.D.	------
***12-4-06	Ali Sonel, M.D.	Janet E. Stout, Ph.D.	N. Squeglia, B. Strelec

*Dr. Graham states "Of course I don't want to see valuable specimens destroyed…"

** Dr. Sonel states "We will work with you to facilitate the transfer"

*** Dr. Sonel states " I was asked by the front office to put this process on hold".

UNIVERSITY OF PITTSBURGH OFFICE OF RESEARCH (OR)
SUBMISSION FORM FOR THE EVALUATION OF AN
INCOMING MATERIAL TRANSFER AGREEMENT (MTA)

SUBMIT THIS COMPLETED FORM AND SUPPORTING DOCUMENTS TO THE OFFICE OF RESEARCH WITH ANY MTA FOR UNIVERSITY REVIEW AND SIGNATURE

University Principal Investigator Name/Title: Timothy A. Mietzner/Associate Professor of Molecular Genetics and Biochemistry.	Company/Institution Providing Materials: **VA Hospital of Pittsburh, Oakland Branch**
University Department Contact for MTA: Mary Lou Bendetti, Senior Administrator, Department of Molecular Genetics and Biochemistry (412-648-9570).	Company/Institution Contact for MTA: Name: Dr. Janet Stoudt, PhD Email: jes20micro@gmail.com
University Location/Lab(s) where Material will be housed: University of Pittsburgh BST1 room W1105; a card access secured room. The -70 freezer is marked "Mietzner".	List *ALL* Material being provided under this MTA: **Legionalla stock collection of approximately 3000 historical isolates dating from 1980 to the present. This collection is (i) the only one in existence, and (ii) represent a "bacterio-paleological" movement toward increased Legionella disease to toxic metals. These isolates will be stored in the top-half of the Mietzner -70 freezer.**

General:

Does this MTA reference a specific scope of work?
☐ Yes, attach a copy of the referenced scope of work
☒ No, attach a brief summary of the research and the intended use of the Material in the research.

What is the intended use of the Material in your research?
☐ Control
☒ Tool
☐ Other: _____ (If *Other*, Provide answers to below two questions)
Will the Material be modified?
☐ Yes ☐ No
Will the Material/modified Material become incorporated into a new research material?
☐ Yes ☐ No

Will the Material be used in experiments involving other materials obtained from a third party under another agreement (e.g., license, Sponsored Research, MTA)?
☐Yes, explain_____
☒No

What other agreement/ funds will be applicable to the research involving the Material? *(list all that apply)*
☐ Sponsored Research Agreement/Government or Other Grant *(list applicable proposal/project number(s))*:
_____
_____
_____
☐ License Agreement/Option *(list Company/companies)*:
_____
_____
☐ Other:
_____
_____
☒ None

Is any of the Material published?
☒ Yes ☐ No ☐ Not Aware

Are there alternative sources to obtain the Material?
☐ Yes ☒ No

Compliance:

Will the Material be used in animals, or is the Material a live animal?
☐ Yes, provide the appropriate IACUC approval letter. *(Note: OR provides the IACUC approval letter and MTA to DLAR for review/approval)*
☒ No

Is the Material of direct human origin, or will the Material be used in human subjects?
☐ Yes, provide the appropriate IRB letter of approval or exemption. If the letter does not name you, append explanation/approval from the named person
☒ No
☐ Not Aware

Does the Material include Human embryonic stem cell lines?
☐ Yes, provide an RPF training module VI certificate of completion for each investigator and a copy of the approval of the research by the ESCRO
☒No

Is the Material potentially infectious to humans or animals?
☒Yes, explain These bacteria, if aerolized, can caulse lung infection in immunocompromiseed individuals.
☐No

Does the Material involve recombinant DNA, or is any of the Material hazardous?
☐ Yes, attach ☐IBC or ☐EHS approval letter
☒ No

Does the Material require Radiation Safety Office approval?
☐ Yes, provide RSO approval letter
☒ No

Is the Material on the federal Select Agent list?
☐ Yes, provide safety officer approval
☒ No

Does the Material require handling at Biosafety level (BSL) designation?
☒ Yes, indicate level: ☐BSL 1 ☒BSL 2 ☐BSL 3
☐ No

University Principal Investigator Name/Title:	Company/Institution Providing Materials:
Timothy A. Mietzner/Associate Professor of Molecular Genetics and Biochemistry.	**VA Hospital of Pittsburh, Oakland Branch**
University Department Contact for MTA:	Company/Institution Contact for MTA:
Mary Lou Bendetti, Senior Administrator, Department of Molecular Genetics and Biochemistry (412-648-9570).	Name: Dr. Janet Stoudt, PhD Email: jes20micro@gmail.com
University Location/Lab(s) where Material will be housed:	List *ALL* Material being provided under this MTA:
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To the best of my knowledge, the answers to the questions are true, complete and accurate. I have read the referenced MTA and agree to comply with its terms and conditions. I am a University of Pittsburgh faculty member authorized to oversee the transfer and use of materials named above.

Principal Investigator:_____ **Date:**_____

Melhem, Mona F

From: Squeglia, Nicholas L
Sent: Friday, July 21, 2006 2:27 PM
To: Nealon, Patricia A; Sundin, Melissa A; Melhem, Mona F; Graham, Steven H
Cc: Moreland, Michael E
Subject: RE: Building 2

I will be glad to help in any way I can.

From: Nealon, Patricia A
Sent: Friday, July 21, 2006 1:45 PM
To: Sundin, Melissa A; Melhem, Mona F; Graham, Steven H; Squeglia, Nicholas L
Cc: Moreland, Michael E
Subject: RE: Building 2

Please include Nick who might be able to help with this.

From: Sundin, Melissa A
Sent: Friday, July 21, 2006 1:23 PM
To: Melhem, Mona F
Cc: Nealon, Patricia A
Subject: Building 2

Mona -
I have been requested to begin on Monday to ensure there are no biohazards in B2. I'm assuming anything left by the Special Pathogens lab that is not to remain. However, there may be items left that Pathology/Clinical Support still requires.

As such this really isn't something for Steve Baker alone. He can inspect the laboratories but cannot dispose/remove items unless cleared.

I'm assuming that Cheryl Wanzie will be taking this lead and Steve can assist.

Please confirm and I will direct Steve to contact Cheryl.

---

thanks

Melissa Sundin
VP, Facilities Management Service Line
VA Pittsburgh Healthcare System
University Drive C
Pittsburgh, PA 15240
Phone (412) 688-6138
Fax (412) 688-6899

The administration in such haste to close down this lab of excellence and the movement of our equipment and freezers has now endangered this extraordinary collection.

Steve and Fred, you are the only MDs and scientists who have the ability to ensure the safety of these isolates. The administration is now acting recklessly without conscience. How can you safeguard these isolates?

Victor L. Yu , MD
Professor of Medicine
University of Pittsburgh
Chief, Infectious Disease Section
VA Medical Center
Pittsburgh, PA

Victor L Yu MD (111E-U)
Infectious Disease Section
VA Medical Center
University Drive C
Pittsburgh, PA 15240

Direct: 412-688-6643
Secretary: 412-688-6179
Direct Fax: 412-688-6507
Cell ph: 412-901-7707
Home: 412-343-7429

---------- Forwarded message ----------
Date: Sat, 12 Aug 2006 10:24:36 -0400
From: Janet E Stout <jes20ebsol@gmail.com>
To: Victor L Yu <vly@pitt.edu>
Subject: Re: My research equipment

Dr. Yu;

I am deeply concerned about the safe keeping of our stock cultures in the -70 freezer in building 2. This repository of isolates represents 30 years of work and includes isolates that were collected for study over many years. In addition to our own research, we have assisted other investigators over the years by providing these unique and well characterized isolates to them for their investigations.

If the freezer were to be unplugged or the proper operation of this freezer not monitored, these irreplaceable scientific materials would be lost.

Can we get some assurance from Dr. Graham that our work will be safeguarded until these issues are resolved?

Janet

On 8/10/06, Victor L Yu <vly+@pitt.edu> wrote:
>
> Steve
>
> As we discussed, now thatthe VA Special Pathogens lab has been
> destroyed, the research projects underway, and the services that we
> provide to other hospitals including VAMCs needs to be continued.
>
> I request assistance in moving equipment and supplies purchased
> through my VRF funds elsewhere.
>
> Please acknowledge receipt of this email.
>
> Victor L. Yu , MD
> Professor of Medicine
> University of Pittsburgh
> Chief, Infectious Disease Section
> VA Medical Center
> Pittsburgh, PA
>

From: "Victor L Yu" <vly+@pitt.edu>
Subject: RE: Invaluable isolates for research (fwd)
Date: Tue, August 15, 2006 12:56 pm
To: "janet stout" <jes20@pitt.edu>,jes20ebsol@gmail.com
Cc: "muder robert" <rmuder1@aol.com>

JES

What do you suggest???

Victor L Yu MD (111E-U)
Infectious Disease Section
VA Medical Center
University Drive C
Pittsburgh, PA 15240

Direct: 412-688-6643
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Date: Tue, 15 Aug 2006 13:53:41 -0400
From: "Graham, Steven H" <Steven.Graham@va.gov>
To: Victor L Yu <vly@pitt.edu>
Subject: RE: Invaluable isolates for research

Of course I don't want to see valuable specimens destroyed, but these specimens are biohazards so we must follow accepted proceedures in order to transfer them. We recently went through this process in regards to VonKammens samples at HD.

In order to move such specimens, they must be moved to an institution approved to handle biohazards. They must sign a materials transfer agreement and have an approved biosafety program.

Any transfers of equipment of samples will have to be approved by the board.

-----Original Message-----
From: Victor L Yu [mailto:vly+@pitt.edu]
Sent: Saturday, August 12, 2006 3:58 PM
To: Graham, Steven H
Cc: DeRubertis, Frederick R; muder robert
Subject: Invaluable isolates for research

Steven

Included in the freezers is a treasure trove of isolates including Pseudmonias aeruginosa, Staph aureus, Klebsiella pneumoniae, Enterobacter species, Candida species, Streptococcus pneumoniae and Cryptococcus species collected by collborative research teams over the past 30 years,

The legionella isolates are the most ocmplete set of isolates of not omly Legionella pneumophila but also of 8 other rare legionella speices taken from patients throughout the world. They are now the basis of for devising the new molecular tests for legionella diagnosis.
Moreover, hundreds of hospitals with legionella outbreaks are relying on us for storage of these isolates. For example one hospital in southwestern Us had a repeat outbreal of Legionnaires' disease. Because the clinical isolates and environmental isolates had been svaed since the 1990's, we wer eable to demonstrate that this was a recurrent outbreak in which the original isolates had emerged resistant to the disinfectant used for the wqater supply.

> Let me know your thoughts on this and the outcome of your meeting with Dr.
> Rinaldo.
>
> Sue is in Mississippi and happy tonight. She is picking up her email if
> you have any questions.
>
> T
>
> _____
>
> From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
> Sent: Thu 8/17/2006 12:30 PM
> To: Victor L Yu
> Cc: Mietzner, Timothy
> Subject: RE: Invaluable isolates for research (fwd)
>
>
>
> -
> Dr. Yu ;
> Tim Mietzner at the University Molecular Genetics and Biology Dept. has
> offered to accept our isolates. This department is approved to handle
> biohazards and has an approved biosafety program. I'm sure Tim would
> sign a materials transfer agreement. I have copied Tim on this message.
>
> Janet
> _____
> JES
>>
>> What do you suggest???
>>
>> Victor L Yu MD (111E-U) Direct: 412-688-6643
>> Infectious Disease Section Secretary: 412-688-6179
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>> Subject: Invaluable isolates for research
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>> Steven

From: "Victor L Yu" <vly+@pitt.edu>
Subject: Safeguarding our research isolates
Date: Mon, August 21, 2006 10:58 am
To: steve.graham@va.gov
Cc: "janet stout" <jes20@pitt.edu>

Dear Steve

We wish to proceed with the transfer of isolates to the University of Pittsburgh. Please send us the proper forms and we will fill them out. Please proceed with obtaining approval from the "board".

This is a legitimate scientific matter, and we are hopeful that the political and bureaucratic issues which have so dominated the unfortunate closing of the Special Pthgoens Lab will not be a problem.

Regards, Victor Yu

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> southwestern Us had a repeat outbreal of Legionnaires' disease. Because the clinical isolates and environmental isolates had been saved since the 1990's, we wer eable to demonstrate that this was a recurrent outbreak in which the original isolates had emerged resistant to the disinfectant used for the water supply.

From: "Sonel, Ali F" <Ali.Sonel@va.gov>
Subject: RE: Material Transfer Agreement- Special Pathogens Lab isolates
Date: Mon, October 2, 2006 7:58 am
To: jes20@pitt.edu
Cc: "Squeglia, Nicholas L" <Nicholas.Squeglia@va.gov>

Dr. Stout,
Do any of the isolates contain any reference numbers that could link it to human subjects? We could only consider releasing isolates that do not contain such identifiers.

If they are only isolates without any direct or indirect linkage to human subjects, we could schedule a time for you to visit and identify what you would like to remove.

AFS

-----Original Message-----
From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
Sent: Sunday, October 01, 2006 11:26 PM
To: Sonel, Ali F
Subject: Material Transfer Agreement- Special Pathogens Lab isolates

Dr. Sonel;
I had some discussion with Dr. Graham regarding the transfer of our frozen collection of isolates to the University. Now that he has stepped down and you have taken over as ACOS for research, I would like to move this request forward.

Would you please tell me where I can obtain the material transfer forms and what other steps are necessary to accomplish this?

Sincerely,

Janet E. Stout, Ph.D.

Download this as a file

From: "Sonel, Ali F" <Ali.Sonel@va.gov>
Subject: RE: Material Transfer Agreement- Special Pathogens Lab isolates
Date: Thu, October 5, 2006 10:16 am
To: jes20@pitt.edu
Cc: "Squeglia, Nicholas L" <Nicholas.Squeglia@va.gov>,"Melhem, Mona F" <Mona.Melhem@va.gov>,"Jain, Rajiv VAPHS" <Rajiv.Jain@va.gov>

We will work with you to facilitate the transfer. However more definitive deidentification would be needed than taping over identifiers.

In terms of the paperwork, please check with the laboratory that will be receiving them in terms of what documentation they would need from us in order to accept the transfer. While we would assist in any providing information needed from us, ultimately you would be responsible to complete the required paperwork.

-----Original Message-----
From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
Sent: Thursday, October 05, 2006 11:03 AM
To: Sonel, Ali F
Subject: RE: Material Transfer Agreement- Special Pathogens Lab isolates

Dr. Sonel;
The majority of the isolates are environmental in origin. Among any clinical isolates, the majority have been deidentified. I would be willing to over label any that would need to be further deidentified. Obviously my future research depends on this collection and I would appreciate every professional courtesy in facilitating this transfer.

It is my understanding that some documentation will be needed from the institution/laboratory that will house the isolates. Please provide whatever information we need to accomplish this.

Thanks.

Janet

Dr. Stout,
> Do any of the isolates contain any reference numbers that could link
> it to human subjects? We could only consider releasing isolates that
> do not contain such identifiers.
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If the freezer were to be unplugged or the proper operation of this freezer not monitored, these irreplaceable scientific materials would be lost.

Can we get some assurance from Dr. Graham that our work will be safeguarded until these issues are resolved?

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> _____
>
> From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
> Sent: Thu 8/17/2006 12:30 PM
> To: Victor L Yu
> Cc: Mietzner, Timothy
> Subject: RE: Invaluable isolates for research (fwd)
>
>
>
> -
>
> Dr. Yu ;
> Tim Mietzner at the University Molecular Genetics and Biology Dept. has
> offered to accept our isolates. This department is approved to handle
> biohazards and has an approved biosafety program. I'm sure Tim would
> sign a materials transfer agreement. I have copied Tim on this message.
>
> Janet
> _____
> JES
>>
>> What do you suggest???
>>
>> Victor L Yu MD (111E-U) Direct: 412-688-6643
>> Infectious Disease Section Secretary: 412-688-6179
>> VA Medical Center Direct Fax: 412-688-6507
>> University Drive C Cell ph: 412-901-7707
>> Pittsburgh, PA 15240 Home: 412-343-7429
>>
>> ---------- Forwarded message ----------
>> Date: Tue, 15 Aug 2006 13:53:41 -0400
>> From: "Graham, Steven H" <Steven.Graham@va.gov>
>> To: Victor L Yu <vly@pitt.edu>
>> Subject: RE: Invaluable isolates for research
>>
>> Of course I don't want to see valuable specimens destroyed, but these
> specimens are biohazards so we must follow accepted procedures in order to
> transfer them. We recently went through this process in regards to
> VonKammens samples at HD.
>>
>> In order to move such specimens, they must be moved to an institution
> approved to handle biohazards. They must sign a materials transfer
> agreement and have an approved biosafety program.
>>
>> Any transfers of equipment of samples will have to be approved by the
> board.
>>
>>
>> -----Original Message-----
>> From: Victor L Yu [mailto:vly+@pitt.edu]
>> Sent: Saturday, August 12, 2006 3:58 PM
>> To: Graham, Steven H
>> Cc: DeRubertis, Frederick R; muder robert
>> Subject: Invaluable isolates for research
>>
>> Steven
>>

From: "Sonel, Ali F" <Ali.Sonel@va.gov>
Subject: RE: Material Transfer Agreement- Special Pathogens Lab isolates
Date: Mon, October 2, 2006 7:58 am
To: jes20@pitt.edu
Cc: "Squeglia, Nicholas L" <Nicholas.Squeglia@va.gov>

Dr. Stout,
Do any of the isolates contain any reference numbers that could link it to human subjects? We could only consider releasing isolates that do not contain such identifiers.

If they are only isolates without any direct or indirect linkage to human subjects, we could schedule a time for you to visit and identify what you would like to remove.

AFS

-----Original Message-----
From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
Sent: Sunday, October 01, 2006 11:26 PM
To: Sonel, Ali F
Subject: Material Transfer Agreement- Special Pathogens Lab isolates

Dr. Sonel;
I had some discussion with Dr. Graham regarding the transfer of our frozen collection of isolates to the University. Now that he has stepped down and you have taken over as ACOS for research, I would like to move this request forward.

Would you please tell me where I can obtain the material transfer forms and what other steps are necessary to accomplish this?

Sincerely,

Janet E. Stout, Ph.D.

Download this as a file

From: "Sonel, Ali F" <Ali.Sonel@va.gov>
Subject: RE: Material Transfer Agreement- Special Pathogens Lab isolates
Date: Thu, October 5, 2006 10:16 am
To: jes20@pitt.edu
Cc: "Squeglia, Nicholas L" <Nicholas.Squeglia@va.gov>,"Melhem, Mona F" <Mona.Melhem@va.gov>,"Jain, Rajiv VAPHS" <Rajiv.Jain@va.gov>

We will work with you to facilitate the transfer. However more definitive deidentification would be needed than taping over identifiers.

In terms of the paperwork, please check with the laboratory that will be receiving them in terms of what documentation they would need from us in order to accept the transfer. While we would assist in any providing information needed from us, ultimately you would be responsible to complete the required paperwork.

-----Original Message-----
From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
Sent: Thursday, October 05, 2006 11:03 AM
To: Sonel, Ali F
Subject: RE: Material Transfer Agreement- Special Pathogens Lab isolates

Dr. Sonel;
The majority of the isolates are environmental in origin. Among any clinical isolates, the majority have been deidentified. I would be willing to over label any that would need to be further deidentified. Obviously my future research depends on this collection and I would appreciate every professional courtesy in facilitating this transfer.

It is my understanding that some documentation will be needed from the institution/laboratory that will house the isolates. Please provide whatever information we need to accomplish this.

Thanks.

Janet

Dr. Stout,
> Do any of the isolates contain any reference numbers that could link
> it to human subjects? We could only consider releasing isolates that
> do not contain such identifiers.
>
> If they are only isolates without any direct or indirect linkage to
> human subjects, we could schedule a time for you to visit and identify

> what you would like to remove.
>
> AFS
>
> -----Original Message-----
> From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
> Sent: Sunday, October 01, 2006 11:26 PM
> To: Sonel, Ali F
> Subject: Material Transfer Agreement- Special Pathogens Lab isolates
>
>
> Dr. Sonel;

Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

Material Transfer Agreement- Special Pathogens Lab isolates

jes20+@pitt.edu <jes20+@pitt.edu> **Mon, Oct 9, 2006 at 10:39 AM**
To: jes20micro@gmail.com

---------- Original Message ----------
Subject: RE: [Fwd: RE: Material Transfer Agreement- Special Pathogens Lab isolates] From: "Mietzner, Timothy" <mietzner@mgb.pitt.edu>
Date: Mon, October 9, 2006 10:25 am
To: jes20@pitt.edu

Janet,

Attached is the incoming MTA that I need to fill out from Pitts end. If you fill out as much info as possible and send it back to me, I will complete.

Let me know a good day this week to get the boxes of tagged material, preferably this week (Friday would be best).

My lab can submit material to autoclave for you, however one of our two autoclaves are down and you would have to let me know the number of items that you intend to submit for me to confirm that we can do this.

T

From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
Sent: Thu 10/5/2006 12:05 PM
To: Mietzner, Timothy
Subject: [Fwd: RE: Material Transfer Agreement- Special Pathogens Lab isolates]

Hi Tim;
I'd like to move ahead with this transfer. Dr. Sonel says that the receiving lab would have the burden of telling us what documentation is needed to make the transfer. I don't know if this is a run around, but can you update me on this?

Also Sue said that the stuff we marked for taking can be removed. Can we schedule that for a time that is convenient for you?

One last request- if needed, can we use your autoclave for media prep

JAnet

---------- Original Message ----------
Subject: RE: Material Transfer Agreement- Special Pathogens Lab isolates
From: "Sonel, Ali F" <Ali.Sonel@va.gov>
Date: Thu, October 5, 2006 11:16 am
To: jes20@pitt.edu
Cc: "Squeglia, Nicholas L" <Nicholas.Squeglia@va.gov>
"Melhem, Mona F" <Mona.Melhem@va.gov>
"Jain, Rajiv VAPHS" <Rajiv.Jain@va.gov>

We will work with you to facilitate the transfer. However more definitive deidentification would be needed than taping over identifiers.

In terms of the paperwork, please check with the laboratory that will be receiving them in terms of what documentation they would need from us in order to accept the transfer. While we would assist in any providing information needed from us, ultimately you would be responsible to complete the required paperwork.

-----Original Message-----
From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
Sent: Thursday, October 05, 2006 11:03 AM
To: Sonel, Ali F
Subject: RE: Material Transfer Agreement- Special Pathogens Lab isolates

Dr. Sonel;
The majority of the isolates are environmental in origin. Among any clinical isolates, the majority have been deidentified. I would be willing to over label any that would need to be further deidentified. Obviously my future research depends on this collection and I would appreciate every professional courtesy in facilitating this transfer.

It is my understanding that some documentation will be needed from the institution/laboratory that will house the isolates. Please provide whatever information we need to accomplish this.

Thanks.

Janet

Dr. Stout,
> Do any of the isolates contain any reference numbers that could link it to human subjects? We could only consider releasing isolates that do not contain such identifiers.
>

human subjects, we could schedule a time for you to visit and identify

> what you would like to remove.
>
> AFS
>
> -----Original Message-----
> From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
> Sent: Sunday, October 01, 2006 11:26 PM
> To: Sonel, Ali F
> Subject: Material Transfer Agreement- Special Pathogens Lab isolates
>
>
> Dr. Sonel;
> I had some discussion with Dr. Graham regarding the transfer of
> our frozen collection of isolates to the University. Now that he has
stepped down and you have taken over as ACOS for research, I would like
to move this request forward.
>
> Would you please tell me where I can obtain the material transfer
> forms and what other steps are necessary to accomplish this?
>
> Sincerely,
>
> Janet E. Stout, Ph.D.
>

MTA_IncomingForm.doc
58K

Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

RE: MTA - VA Hospital of PGH

Mietzner, Timothy <mietzner@mgb.pitt.edu> **Wed, Oct 18, 2006 at 4:11 PM**
To: "Bowler, Mary Beth" <bowler@mgb.pitt.edu>
Cc: Janet Stout <jes20micro@gmail.com>

Janet,

Mary Beth Bowler in our office has signature on the incoming MTA. We can share these documents with Doctor Sonel. The VA should have an outgoing MTA that has to be signed off on.

Tim

Message from the VA:

> > > Hi Tim;
> > > I'd like to move ahead with this transfer. Dr. Sonel says that the
> > > receiving lab would have the burden of telling us what documentation is
> > > needed to make the transfer. I don't know if this is a run around, but
> > > can you update me on this?

From: Bowler, Mary Beth
Sent: Wed 10/18/2006 1:17 PM
To: Mietzner, Timothy
Subject: FW: MTA - VA Hospital of PGH

Tim,
Do you have the MTA agreement or do you need to contact the VA?

Mary Beth
412/383-6912 (phone)
412/624-8997 (fax)

From: Micco, Gina
Sent: Wednesday, October 18, 2006 11:59 AM
To: Bowler, Mary Beth; Mietzner, Timothy
Subject: MTA - VA Hospital of PGH

Hi all,

The Office of Research is in receipt of the Incoming MTA Submission Form. However, we do not have an MTA for Dr. Mietzner with the VA. Please send us 2 original MTA to be signed by Allen DiPalma. Contact me with questions.

Thank You,

Gina M. Micco

Clinical and Corporate Research Secretary

Office of Research, University of Pittsburgh

350 Thackeray Hall

412-624-7419

412-624-7414 (fax)

gmicco@offres.pitt.edu

Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

Material Transfer Agreement Form

Janet Stout <jes20micro@gmail.com> **Thu, Oct 19, 2006 at 12:57 PM**
To: "Mietzner, Timothy" <mietzner@mgb.pitt.edu>
Bcc: jes20micro@gmail.com, Sue Mietzner <smmietzner@yahoo.com>, Victor Yu <victorlyu@gmail.com>

Tim;
Would you please have the Material Transfer Agreement faxed to the attention of Dr. Sonel at (412) 365-4263. Would you also have a hard copy mailed to me at my home address:

Janet E. Stout, Ph.D.
3213 Fox Run Road
Allison Park, PA 15101

Thanks so much for your help with this!

Janet

---------- Forwarded message ----------
From: Sonel, Ali F <Ali.Sonel@va.gov>
Date: Oct 19, 2006 12:31 PM
Subject: RE: Material Transfer Agreement Form Completed
To: Janet Stout <jes20micro@gmail.com>
Cc: "Squeglia, Nicholas L" <Nicholas.Squeglia@va.gov>

Please send me a copy and we can get back toyou after we have had a chance to review it. You can fax it to my attention at (412) 365-4263.

Gmail BETA

Janet Stout <jes20micro@gmail.com>

RE: MTA - VA Hospital of PGH

Mietzner, Timothy <mietzner@mgb.pitt.edu> **Thu, Oct 19, 2006 at 5:44 PM**
To: Janet Stout <jes20micro@gmail.com>

J,

Office phone: 412-648-9244
Fax: 412-624-1401

I will be back on Nov. 4. If you need to perform the transfer of organisms before then contact Dilhari at 412-648-8875. I can talk with you about the lecture when I get back.

T

From: Janet Stout [mailto:jes20micro@gmail.com]
Sent: Thu 10/19/2006 11:56 AM
To: Mietzner, Timothy
Subject: Re: MTA - VA Hospital of PGH
[Quoted text hidden]

Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

Material Transfer Agreement Form

Mietzner, Timothy <mietzner@mgb.pitt.edu> **Thu, Oct 19, 2006 at 5:50 PM**
To: "Bowler, Mary Beth" <bowler@mgb.pitt.edu>
Cc: Janet Stout <jes20micro@gmail.com>

Mary Beth,

Can you please Fax a copy of the MTA to Dr. Sonel and send a hard copy to Janet Stout?

Thanks,

Tim Mietzner

From: Janet Stout [mailto:jes20micro@gmail.com]
Sent: Thu 10/19/2006 12:57 PM
To: Mietzner, Timothy
Subject: Material Transfer Agreement Form
[Quoted text hidden]

Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

Material Transfer Agreement Form Completed

Janet Stout <jes20micro@gmail.com> **Thu, Oct 19, 2006 at 12:30 PM**
To: "Sonel, Ali F" <Ali.Sonel@va.gov>
Bcc: jes20micro@gmail.com, "Mietzner, Timothy" <mietzner@mgb.pitt.edu>

Dr. Sonel;
I now have the Material Transfer Agreement Form (MTA) completed. Should I have it faxed to you? If yes, please provide your tel. and fax numbers.

What is the next step?

Sincerely,

Janet E. Stout, Ph.D.

---------- Original Message ----------
Subject: RE: Material Transfer Agreement- Special Pathogens Lab isolates
From: "Sonel, Ali F" <Ali.Sonel@va.gov>
Date: Thu, October 5, 2006 11:16 am
To: jes20@pitt.edu
Cc: "Squeglia, Nicholas L" <Nicholas.Squeglia@va.gov>
"Melhem, Mona F" <Mona.Melhem@va.gov>
"Jain, Rajiv VAPHS" <Rajiv.Jain@va.gov>

We will work with you to facilitate the transfer. However more definitive deidentification would be needed than taping over identifiers.

In terms of the paperwork, please check with the laboratory that will be receiving them in terms of what documentation they would need from us in order to accept the transfer. While we would assist in any providing information needed from us, ultimately you would be responsible to complete the required paperwork.

-----Original Message-----
From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
Sent: Thursday, October 05, 2006 11:03 AM
To: Sonel, Ali F
Subject: RE: Material Transfer Agreement- Special Pathogens Lab isolates

Dr. Sonel;
The majority of the isolates are environmental in origin. Among any clinical isolates, the majority have been deidentified. I would be [illegible] any that would need to be further deidentified.

Obviously my future research depends on this collection and I would appreciate every professional courtesy in facilitating this transfer.

It is my understanding that some documentation will be needed from the institution/laboratory that will house the isolates. Please provide whatever information we need to accomplish this.

Thanks.

Janet

Dr. Stout,
Do any of the isolates contain any reference numbers that could link it to human subjects? We could only consider releasing isolates that do not contain such identifiers.

If they are only isolates without any direct or indirect linkage to human subjects, we could schedule a time for you to visit and identify

what you would like to remove.

AFS

-----Original Message-----
From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
Sent: Sunday, October 01, 2006 11:26 PM
To: Sonel, Ali F
Subject: Material Transfer Agreement- Special Pathogens Lab isolates

Dr. Sonel;
I had some discussion with Dr. Graham regarding the transfer of our frozen collection of isolates to the University. Now that he has stepped down and you have taken over as ACOS for research, I would like to move this request forward.

Would you please tell me where I can obtain the material transfer forms and what other steps are necessary to accomplish this?

Sincerely,

Janet E. Stout, Ph.D.

Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

FW: Transfrer agreement from the VA to Pitt

Mietzner, Timothy <mietzner@mgb.pitt.edu> **Tue, Nov 7, 2006 at 5:56 PM**
To: Ali.Sonel@va.gov
Cc: dilhari@hotmail.com, jes20micro@gmail.com

Dr. Sonel,

We are trying to transfer a strain collection from the VA (Janet Stoudt0 to Pitt (Timothy Mietzner). From the point of view of the VA this is an "outgoing" MTA and from the point of view of Pitt this is an "incoming" MTA. For Pitt to sign off on this we need to have the "incoming" agreement from the VA so that the receiving institution (pitt) can sign off on this. Please send Janet Stoudt the appropriate forms so that we can complete this transaction.

Tim Mietzner

From: Mietzner, Timothy
Sent: Tue 11/7/2006 4:47 PM
To: Ali.Sonel@va.gov
Subject: Transfrer agreement from the VA to Pitt

Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

FW: Transfrer agreement from the VA to Pitt

Sonel, Ali F <Ali.Sonel@va.gov> **Tue, Nov 7, 2006 at 6:12 PM**
To: mietzner@mgb.pitt.edu
Cc: dilhari@hotmail.com, jes20micro@gmail.com, "Squeglia, Nicholas L" <Nicholas.Squeglia@va.gov>, "Strelec, Barbara A" <Barbara.Strelec@va.gov>

I think Dr. Stout had indicated that she had the MTA to fax over for us to review. We have not yet received that. She should work with Barbara Strelec from the Compliance Office to coordinate this. Barbara has an email out to Dr. Stout.

Ali F. Sonel, M.D., FACC, FACP

Associate Chief of Staff for Research and Development

Director, Cardiac Catheterization Laboratories

VA Pittsburgh Healthcare System

Sent from my Blackberry
[Quoted text hidden]

Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

FW: Transfrer agreement from the VA to Pitt

Janet Stout <jes20micro@gmail.com> **Fri, Nov 10, 2006 at 1:30 AM**
To: "Sonel, Ali F" <Ali.Sonel@va.gov>
Cc: mietzner@mgb.pitt.edu, dilhari@hotmail.com, "Squeglia, Nicholas L" <Nicholas.Squeglia@va.gov>, "Strelec, Barbara A" <Barbara.Strelec@va.gov>
Bcc: jes20micro@gmail.com

Dr. Sonel;
I have not received any form for the "outgoing" transfer of the isolates to the University. If there is such a form, would you please have it sent to me as soon as possible? I believe that the form from the University for the "incoming transfer was faxed to you or someone in the Research office.
The e-mail from Barbara requested information about deidentifying the isolates. I will follow up with her next week about that process.

Thanks.

Janet
[Quoted text hidden]

Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

FW: Transfrer agreement from the VA to Pitt

Strelec, Barbara A <Barbara.Strelec@va.gov> **Mon, Nov 13, 2006 at 3:20 PM**
To: Janet Stout <jes20micro@gmail.com>

Dr. Stout,

We have not received a copy of the University's "incoming transfer" form referred to below. Could you please FAX it again to 412-365-4281? This comes directly into my office. We do have a copy of the VA Material Transfer Agreement. Can you please provide a FAX number to which I can send it? Also, we need to agree on how the specimens will be de-identified.

Thank you,

Barbara

Barbara Strelec
VA Pittsburgh Healthcare System
Research Education and Compliance Coordinator
7180 Highland Drive
Pittsburgh, PA 15206-1297
Phone (412) 365-4266
FAX (412) 365-4281

[Quoted text hidden]

Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

FW: Transfrer agreement from the VA to Pitt

Janet Stout <jes20micro@gmail.com> **Mon, Nov 13, 2006 at 3:32 PM**
To: "Mietzner, Timothy" <mietzner@mgb.pitt.edu>
Bcc: jes20micro@gmail.com

Tim;
Would you please send (fax) the "incoming" MTA to Barbara Strelec? She also requests a fax number to send the "outgoing" MTA. Her message to me is below:

Dr. Stout,

We have not received a copy of the University's "incoming transfer" form referred to below. Could you please FAX it again to 412-365-4281? This comes directly into my office. We do have a copy of the VA Material Transfer Agreement. Can you please provide a FAX number to which I can send it? Also, we need to agree on how the specimens will be de-identified.

Thank you,

Barbara

Barbara Strelec
VA Pittsburgh Healthcare System
Research Education and Compliance Coordinator
7180 Highland Drive
Pittsburgh, PA 15206-1297
Phone (412) 365-4266
FAX (412) 365-4281

Thanks!

Janet

[Quoted text hidden]

Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

FW: Transfrer agreement from the VA to Pitt

Mietzner, Timothy <mietzner@mgb.pitt.edu> **Wed, Nov 15, 2006 at 1:46 AM**
To: jes20micro@gmail.com

Janet,

Let me know if there are any more bumps in the road on this MTA.

T

From: Bowler, Mary Beth
Sent: Tue 11/14/2006 9:23 AM
To: Mietzner, Timothy
Subject: RE: FW: Transfrer agreement from the VA to Pitt

Normally, for "incoming" MTAs, the party who is supplying the material generates the MTA. We have a template for the "outgoing" MTA that I will fax Barbara Strelec. I think maybe she is trying to come up with a format and she can use the format that Pitt uses. I'll let her know to contact me with any questions.

Mary Beth
412/383-6912 (phone)
412/624-8997 (fax)

-----Original Message-----
From: Mietzner, Timothy
Sent: Monday, November 13, 2006 3:12 PM
To: Bowler, Mary Beth
Subject: FW: FW: Transfrer agreement from the VA to Pitt

Mary Beth,

Can you please Fax this MTA to Barbara Strelec.

Thanks,

Tim

-----Original Message-----
From: Janet Stout [mailto:jes20micro@gmail.com]
[Quoted text hidden]

Gmail

Janet Stout <jes20micro@gmail.com

Transfer of Isolates

Strelec, Barbara A <Barbara.Strelec@va.gov> **Tue, Nov 7, 2006 at 9:43 AI**
To: jes20@pitt.edu
Cc: "Sonel, Ali F" <Ali.Sonel@va.gov>

Good Morning Dr. Stout,

I am writing at the request of Dr. Sonel to help facilitate the transfer of your frozen collection of isolates from the Special Pathogens Lab to the University. As mentioned previously, the release is contingent upon the complete de-identification of the specimens. OHRP considers private information or specimens *not* to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. I understand that the majority of your specimens are de-identified and you agree to the complete de-identification of the remainder. Could you please forward information regarding how the identifiable specimens are labeled? It is necessary to establish a mutually agreed upon method of de-identification prior to the transfer. In addition, please forward a copy of the Materials Transfer Agreement and any other paperwork required for the transfer.

Thank you for your cooperation.

Sincerely,

Barbara Strelec
VA Pittsburgh Healthcare System
Research Education and Compliance Coordinator
7180 Highland Drive
Pittsburgh, PA 15206-1297
Phone (412) 365-4266
FAX (412) 365-4281

From: "Strelec, Barbara A" <Barbara.Strelec@va.gov>
Subject: RE: Transfer of Isolates
Date: Tue, November 28, 2006 8:46 am
To: jes20@pitt.edu

Good Morning Janet,

Yes, Tuesday the 5th at 10:00 AM still works for me. Please see the previous e-mail I sent. I will be out of the office until Friday and will check in with you then,

Thanks,

Barb

-----Original Message-----
From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
Sent: Sunday, November 26, 2006 3:46 PM
To: Strelec, Barbara A
Subject: RE: Transfer of Isolates

Barbara;
I have not received a response regarding a meeting for the 5th of December. Please let me know your availability or you can suggest an alternative day/time. Thanks.

Janet

Hi Barb;
> Can we meet on Tuesday the 5th at 10:00am? Please tell me again where
> you are located and your tel. no. In preparation for the meeting,
> please have your specific instructions for me in writing to facilitate

> our discussion. Thanks.
>
> Janet
>
> P.S. If you needd to reach me, my number is 412-719-0488
>
>
> ---
>
>
> Hi Janet,
>>
>> I was off for a few days, sorry for the delay. Yes, I think it would

>> be good to meet. This is also a short week, I am off Wednesday and Friday.
>> Next week I am attending a conference. Anytime the week of December
>> 4th would be good for me. I understand you are anxious to get the
>> specimens and will do what I can to expedite the process.
>>
>> Thanks,
>>
>> Barb
>>
>>
>>
>> -----Original Message-----
>> From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
>> Sent: Wednesday, November 15, 2006 4:25 PM
>> To: Strelec, Barbara A

Hi Barbara;
Do you want me to meet with you about the deidentification process

>> or should I write something and have you review it? If you wish to
>> meet with me, please give me a couple of days & times so that we can
>> find a time that works for both of us. Thanks.
>>
>> Janet
>>
>>
>> _____
>>
>>
>> Sounds good, I am working on things at this end. I hope we can
>> resolve
>>> this for you soon.
>>>
>>> Barbara
>>>
>>> Barbara Strelec
>>> VA Pittsburgh Healthcare System
>>> Research Education and Compliance Coordinator 7180 Highland Drive
>>> Pittsburgh, PA 15206-1297 Phone (412) 365-4266 FAX (412) 365-4281
>>>
>>>
>>>
>>> -----Original Message-----
>>> From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
>>> Sent: Thursday, November 09, 2006 11:08 PM
>>> To: Strelec, Barbara A
>>> Cc: Sonel, Ali F
>>> Subject: Re: Transfer of Isolates
>>>
>>> Barbara;
>>> I just got your message. I'll get this information to you next
week.
>>>
>>> Janet
>>> _____
>>>
>>>> Good Morning Dr. Stout,
>>>>
>>>> I am writing at the request of Dr. Sonel to help facilitate the
>>>> transfer of your frozen collection of isolates from the Special
>>>> Pathogens Lab to the University. As mentioned previously, the
>>>> release is contingent upon the complete de-identification of the
>>>> specimens. OHRP considers private information or specimens not to
>>>> be
>>
>>>> individually identifiable when they cannot be linked to specific
>>>> individuals by the
>>>> investigator(s) either directly or indirectly through coding
systems.
>>>
>>>> I understand that the majority of your specimens are de-identified
>>>> and
>>>
>>>> you agree to the complete de-identification of the remainder.
>>>> Could you please forward information regarding how the identifiable

>>>> specimens are labeled? It is necessary to establish a mutually
>>>> agreed
>>> upon method of
>>>> de-identification prior to the transfer. In addition, please
>>> forward
>>>> a copy of the Materials Transfer Agreement and any other paperwork
>>>> required for the transfer.
>>>>
>>>> Thank you for your cooperation.

Melhem, Mona F

From: Jain, Rajiv VAPHS
Sent: Tuesday, December 05, 2006 11:18 AM
To: Sonel, Ali F
Cc: Moreland, Michael E; Melhem, Mona F
Subject: RE: SPL Samples
Signed By: rajiv.jain@va.gov

Ali:
I sent you a response on the samples on the other e mail message...basically Drs Melhem and Gutkin are preparing a memo describing the process followed to move the samples or to dispose them. The excess equipment inventory can be distributed based on standard VA process. Both Drs Yu and Janet should be referred to Dr Melhem regarding any questions about the samples....

From: Sonel, Ali F
Sent: Monday, December 04, 2006 4:36 PM
To: Jain, Rajiv VAPHS
Cc: Moreland, Michael E; Melhem, Mona F
Subject: RE: SPL Samples

Thank you for the clarification and the update. I don't think we were ever made aware of the samples being destroyed. Since the activities that generated the samples included research, albeit unauthorized, our normal process would have been to involve the Research Compliance Committee prior to destroying specimens derived from human subjects as we have done in the past. In addition, a representative of the RCC has been present in the past to observe and verify sample or data destruction processes required by the RCC. The last I had spoken to Dr. Melhem in September, they were in the freezer in her lab during my visit there and I discussed with her our prior conversations regarding potential release of samples with certain safeguards.

As far as communicating this to her and/or Dr. Yu, who should relay her the message that the samples have been destroyed and they are not to have further access to any other inventory? Also, regarding any remaining equipment from the Special Pathogens Lab, I assume we can process them as excess inventory and assign them to other investigators.

Ali

From: Jain, Rajiv VAPHS
Sent: Monday, December 04, 2006 3:40 PM
To: Moreland, Michael E; Melhem, Mona F; Sonel, Ali F
Subject: RE: SPL Samples

Ali:
Based on Mona and Mr Moreland's comments we should deny any further access to Janet and others....there are no materials left for them to review...

They have already destroyed all the computerized documents and evidence that would have supported the VA in the latest decisions concerning the Special Pathogens labs, during their last visit (Janet and Dr Yu), under the pretext of "tagging" their equipment to be transported to the university.

was made to get rid of all the infectious agents in that lab, in preparation for it to be demolished.

From: Moreland, Michael E
Sent: Monday, December 04, 2006 3:22 PM
To: Jain, Rajiv VAPHS; Melhem, Mona F; Sonel, Ali F
Subject: RE: SPL Samples

My understanding was that the refrigerators were reviewed, there were samples, but that the samples were from work that was not authorized and was in fact redone outside the special path lab (i.e., the company that redid samples and completed in another lab and we paid for).....so, the samples and materials from the refrigerators was disposed of and the refrigerators returned to VA inventory.

From: Jain, Rajiv VAPHS
Sent: Monday, December 04, 2006 3:17 PM
To: Melhem, Mona F; Sonel, Ali F
Cc: Moreland, Michael E
Subject: RE: SPL Samples

That's interesting...so where are they going to go to look for samples if all freezers are in the lab...?

From: Melhem, Mona F
Sent: Monday, December 04, 2006 3:09 PM
To: Jain, Rajiv VAPHS; Sonel, Ali F
Cc: Moreland, Michael E
Subject: RE: SPL Samples

Per Mr Moreland's orders, all the freezers were cleaned out.
The freezers are turned in

From: Jain, Rajiv VAPHS
Sent: Monday, December 04, 2006 3:06 PM
To: Sonel, Ali F
Cc: Melhem, Mona F
Subject: RE: SPL Samples

Ali:
I am basically in agreement...have included Dr Melhem in case she would want someone from Lab to be there also...

From: Sonel, Ali F
Sent: Monday, December 04, 2006 2:34 PM
To: Jain, Rajiv VAPHS
Subject: SPL Samples

Dr. Jain,
I wanted to check with you to confirm that it is OK for Janet Stout and Sue Mietzner to complete their inventory under police supervision tomorrow. During this process, Barbara Strelec will also review their samples they have requested and we will proceed with releasing the samples that are deidentified. We will have them sign a statement that they will not use any serial number or another key to attempt to reidentify any subjects. Please let [illegible] this approach. Regards,

Ali

Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

FW: FW: QC isolates for media testing

Zhang Richard <richard_zhe@hotmail.com> **Mon, Jan 29, 2007 at 1:12 PM**
To: jes20ebsol@gmail.com, jes20@pitt.edu, jes20micro@gmail.com

From: "Vidic, Radisav" <Vidic@engr.pitt.edu>
To: "Zhang Richard" <richard_zhe@hotmail.com>
Subject: FW: FW: QC isolates for media testing
Date: Thu, 2 Nov 2006 11:33:59 -0500

Richard,

I am sending you this in case you did not yet get this information from Dr. Muder; it's OK to contact Nick and get your strains.

Dr. Vidic

-----Original Message-----
From: Squeglia, Nicholas L [mailto:Nicholas.Squeglia@va.gov]
Sent: Thursday, November 02, 2006 9:24 AM
To: Sonel, Ali F; Vidic, Radisav
Cc: Muder, Robert R
Subject: RE: FW: QC isolates for media testing

Dr. Muder,
Please ask Richard to contact me.
Thanks,
Nick

-----Original Message-----
From: Sonel, Ali F
Sent: Thursday, November 02, 2006 7:38 AM
To: 'Vidic@engr.pitt.edu'
Cc: Muder, Robert R; Squeglia, Nicholas L
Subject: Re: FW: QC isolates for media testing

We should be able to release the QC strains now.

Nick,
Please work with Richard to release the QC strains. Strains obtained from patient samples are not included in this request.

Ali F. Sonel, M.D., FACC, FACP

Associate Chief of Staff for Research and Development, VAPHS Director,
Cardiac Catheterization Laboratories, VAPHS Assistant Professor of
Medicine, University of Pittsburgh

Cardiology Office: 412-688-6191
Research Office: 412-365-4279
Fax: 412-688-6191

VA Pittsburgh Healthcare System
University Drive, 111C-U
Pittsburgh, PA 15240

Sent from my Blackberry

-----Original Message-----
From: Vidic, Radisav <Vidic@engr.pitt.edu>
To: Sonel, Ali F
CC: Muder, Robert R; Squeglia, Nicholas L
Sent: Mon Oct 30 17:42:45 2006
Subject: FW: FW: QC isolates for media testing

Dear Dr. Sonel,

I would like to point out that we are requesting access to only a few strains in the freezer of the Special Pathogens lab that will be used to check the quality of media that will be used in Richard's experiments. I would appreciate it if we can be granted access to about 10 QC strains (they are all either American Type Culture Collection (ATTC) or environmental in origin) to make the subcultures. We will remove the strains from the Special Pathogens Lab only to make the subcultures and will then return them to the freezer in the Special Pathogens Lab.

This way we will not have any additional delays in proceeding with Richard's experiments.

Best regards,
Radisav Vidic

> >
> >>From: "Muder, Robert R" <Robert.Muder@va.gov>
> >>To: "Zhang Richard" <richard_zhe@hotmail.com>
> >>Subject: FW:
> >>Date: Fri, 27 Oct 2006 11:09:17 -0400
> >>
> >>
> >>
> >>
> >>Robert R. Muder, MD
> >>
> >>-----Original Message-----
> >>From: Squeglia, Nicholas L
> >>Sent: Thursday, October 26, 2006 1:28 PM
> >>To: Muder, Robert R
> >>Subject: FW:

> >>
> >>FYI
> >>
> >>-----Original Message-----
> >>From: Sonel, Ali F
> >>Sent: Thursday, October 26, 2006 1:08 PM
> >>To: Squeglia, Nicholas L
> >>Subject: RE:
> >>
> >>There is a formal request for isolates that Dr. Stout sent and we
need to
> > review that next week before we can consider this item.
> >>
> >>
> >>Ali F. Sonel, MD, FACC, FACP
> >>
> >>Associate Chief of Staff for Research and Development Director,
Cardiac
> > Catheterization Laboratories
> >>
> >>VA Pittsburgh Healthcare System
> >>
> >>-----Original Message-----
> >>From: Squeglia, Nicholas L
> >>Sent: Thursday, October 26, 2006 11:29 AM
> >>To: Sonel, Ali F
> >>Subject: FW:
> >>
> >>FYI
> >>
> >>-----Original Message-----
> >>From: Muder, Robert R
> >>Sent: Thursday, October 26, 2006 10:13 AM
> >>To: 'Zhang Richard'
> >>Cc: Vidic@engr.pitt.edu; Squeglia, Nicholas L
> >>Subject: RE:
> >>
> >>
> >>Nick:
> >>
> >>Richard needs to get some Legionella strains for QC out of the
special
> > pathogens lab. Jack Rihs will need to go with him to locate them,
since
> > Jack is the only one who knows where they are. Thanks.
> >>
> >>Robert R. Muder, MD
> >>
> >>-----Original Message-----
> >>From: Zhang Richard [mailto:richard_zhe@hotmail.com]
> >>Sent: Tuesday, October 24, 2006 2:11 PM
> >>To: Muder, Robert R
> >>Cc: Vidic@engr.pitt.edu

> >>
> >>Dr.Muder,
> >>As a follow-up email, I am going to need subcultures of the following
> > isolates for quality control (QC) testing of the media. Would you please
> > request permission from Nick for Jack Rihs and me to go to the Special
> > Pathogens Lab to make subcultures of the QC strains?
> >>
> >>QC Strains
> >>1. L. pneumophila serogroup 1 (stock no. 20) 2. L. micdadei (stock no.
> > 594) 3. Candida albicans (stock no. 212) 4. E. coli (stock no. 210) 5.
> > S. aureus (stock no. 209) 6. P. aeruginosa (stock no. to be determined) 7.
> > M. gordonae (stock no.to be determined)
> >>
> >>Thanks.
> >>
> >>Richard
> >>

与世界各地的朋友进行交流，免费下载 Live Messenger; http://get.live.com/messenger/overview

Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

QC subs

Janet Stout <jes20micro@gmail.com> **Thu, Nov 2, 2006 at 5:43 PM**
To: Zhang Richard <richard_zhe@hotmail.com>
Cc: Sleepr zzz <sleeprzzz@aol.com>, Sue Mietzner <smmietzner@yahoo.com>
Bcc: jes20micro@gmail.com

Richard;
The list is the attached file that Sue sent in her message. You can go over this with Jack tomorrow. We did not know until today that you would be granted permission to remove the QC strains from the Special Pathogens lab and make the subcultures.
I would like you and Jack to make subcultures of the Special Pathogens QC strains in order to prepare a new freezer stock vial of each strain. These will be kept in a box in the micro -70 freezer until we can arrange for their transfer to Benedum. The original vials should be returned to the freezer in Special Pathogens when you have completed this process.
We used brucella broth and glycerol to suspend the growth from a full plate. Jack - if the micro lab does not have brucella broth, maybe we could use TSB? Our procedure is attached.

Janet

On 10/26/06, Sue Mietzner <smmietzner@yahoo.com> wrote:
[Quoted text hidden]

Bacterial Stock Maintenance.doc
25K

>>To: Squeglia, Nicholas L
>>Subject: RE:
>>
>>There is a formal request for isolates that Dr. Stout sent and we need to
> review that next week before we can consider this item.
>>
>>
>>Ali F. Sonel, MD, FACC, FACP
>>
>>Associate Chief of Staff for Research and Development Director, Cardiac
> Catheterization Laboratories
>>
>>VA Pittsburgh Healthcare System
>>
>>-----Original Message-----
>>From: Squeglia, Nicholas L
>>Sent: Thursday, October 26, 2006 11:29 AM
>>To: Sonel, Ali F
>>Subject: FW:
>>
>>FYI
>>
>>-----Original Message-----
>>From: Muder, Robert R
>>Sent: Thursday, October 26, 2006 10:13 AM
>>To: 'Zhang Richard'
>>Cc: Vidic@engr.pitt.edu; Squeglia, Nicholas L
>>Subject: RE:
>>
>>
>>Nick:
>>
>>Richard needs to get some Legionella strains for QC out of the special
> pathogens lab. Jack Rihs will need to go with him to locate them, since
> Jack is the only one who knows where they are. Thanks.
>>
>>Robert R. Muder, MD
>>
>>-----Original Message-----
>>From: Zhang Richard [mailto:richard_zhe@hotmail.com]
>>Sent: Tuesday, October 24, 2006 2:11 PM
>>To: Muder, Robert R
>>Cc: Vidic@engr.pitt.edu
>>Subject:
>>
>>Dr.Muder,
>>As a follow-up email, I am going to need subcultures of the following
> isolates for quality control (QC) testing of the media. Would you please
> request permission from Nick for Jack Rihs and me to go to the Special
> Pathogens Lab to make subcultures of the QC strains?
>>
>>QC Strains
>>1. L. pneumophila serogroup 1 (stock no. 20) 2. L. micdadei (stock no.

Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

[Fwd:] QC strains for Richard

jes20+@pitt.edu <jes20+@pitt.edu> **Wed, Oct 25, 2006 at 9:27 AM**
To: Jack Rihs <sleeprzzz@aol.com>

---------- Original Message ----------
Subject:
From: "Zhang Richard" <richard_zhe@hotmail.com>
Date: Tue, October 24, 2006 2:10 pm
To: Robert.Muder@va.gov
Cc: Vidic@engr.pitt.edu

Dr.Muder,
As a follow-up email, I am going to need subcultures of the following isolates for quality control (QC) testing of the media. Would you please request permission from Nick for
Jack Rihs and me to go to the Special Pathogens Lab to make subcultures of the QC strains?

QC Strains
1. L. pneumophila serogroup 1 (stock no. 20)
2. L. micdadei (stock no. 594)
3. Candida albicans (stock no. 212)
4. E. coli (stock no. 210)
5. S. aureus (stock no. 209)
6. P. aeruginosa (stock no. to be determined)
7. M. gordonae (stock no.to be determined)

Thanks.

Richard

与联机的朋友进行交流，请使用 Live Messenger;
http://get.live.com/messenger/overview

1 Background and Overview by Dr. Stou

2 Destruction of the SPL Collection of Isolates and Specimens – the Petitio

3 Documents Related to the Request to Transfer the Collection

4 Procedure for Storing Bacterial in the Special Pathogens Laboratory

5 The Functions of the Special Pathogens Laboratory – Janet E. Stout, Ph.D. PD & Research Documents

6 Documentation of Legionella-related Isolates and Specimens

7 Examples of Use of the Collection and Requests by Scientists

8 Stout CV and Relevant Publications

QUALITY CONTROL

Bacterial Stock Maintenance

Prepared by: Janet Stout, Ph.D.
Director, Special Pathogens Lab

_____
(Signature/Date)

Reviewed by: Victor L. Yu, M.D.
Chief, Microbiology Lab

_____
(Signature/Date)

Reviewed: _____ _____
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Revised: _____
_____

QUALITY CONTROL

Bacterial Stock Main

Freezer Stocks (-70°c and –20°C)

(1) Assign the next available number in both the –70°C and –20°C logbooks for new isolates.

(2) Enter isolate identification, source date frozen, and passage number from primary isolate.

(3) *Legionellaceae* isolates are streaked onto two (2) BCYE agar plates to obtain luxuriant growth and incubated for 2-3 days at 35-37°C.

(4) Other bacteria are streaked onto two (2) sheep blood agar plates and incubated 1 to 2 days at 35-37°C.

(5) Dispense 0.5 ml of a 15% glycerol in Brucella Broth (i.e., 1.5 ml glycerol in a 8.5 ml Brucella Broth) into 2 sterile microtubes.

(6) Suspend 2 blue loopfuls of growth from the surface of one plate into one tube of the 0.5 ml broth mixture; do the same with the second plate and tube.

(7) Store one tube at –70°C and the other tube at –20°C in the appropriate storage boxes in the freezers. Caution: Handle the –70°C components with gloves.

Working Stock Slants (2-8°C)

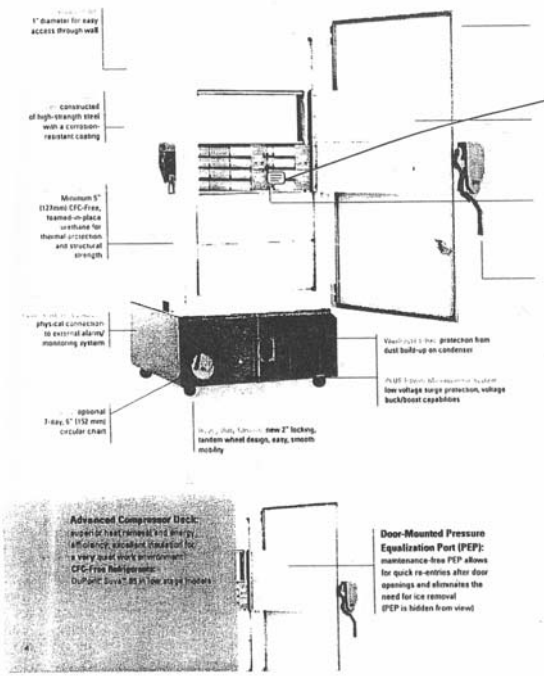
(1) Remove isolate from –20°C freezer and after partial thawing subculture to a plate medium using a .01 or .001 ml loop. Replace isolate in freezer as soon as possible.

(2) Incubate plate(s) 1 to 3 days at 35-37°C.

(3) Subculture to slanted media and incubate at 35-37°C 1 to 3 days.

(4) Store slants in refrigerator: NOTE: BCYE agar slants are used for *Legionell*a species and Tryptic Soy Agar slants for other bacteria ad yeast.

NOTE: The –70°C stock cultures are only to be used for working stock preparation when the –20°C freezer stock is non-viable; the –20°C freezer stock is replaced from the –70°C stock.



Summary of Comments on productPDF_1271.pdf

Page: 1

Author: Janet Stout
Subject: Note
Date: 9/1/2008 11:21:46 AM
Freezer capacity: Each box holds 81 vials (81 isolates); each rack holds 20 boxes; each shelf holds 4 racks = 6480 vials (81x20x4) per shelf x four (4) shelves = 25,920 vials

Thermo Scientific Racks and Accessories

You can depend on your Thermo Scientific freezer for the long-term protection of your valuable samples.

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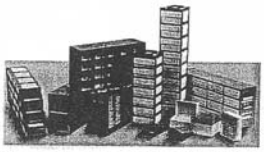
Forma Racks and Accessories.pdf **Revco Racks and Accessories.pdf**

Download our racks and accessories brochures for products sold **outside North America** by clicking below:

Forma International Racks and Accessories.pdf

If you would like a sales representative to contact you to discuss your racking needs, please fill out the following form and someone will contact you within 48 hours.



Economics Endanger Thousands of Biologically Valuable Collections

The deposit-storage-distribution approach is a cost-effective means for preserving, sharing valuable strains or other biological materials

Scott Jenkins and R. H. Cypess

Investigators searching for microorganisms, cell lines, and other biological materials to use in doing their research often obtain those materials from long-established, publicly available culture collections. While large, centralized service collections are well known in the scientific community, they are in the minority compared to the numbers of small, specialized collections that are housed within university research laboratories or private firms. These smaller, institutionally held collections may be the outgrowth of specific research programs of commercial interest or may embody the work of an individual researcher. While a comprehensive inventory of such culture collections does not exist, perhaps thousands of these small private collections are scattered in labs around the world.

Such specialized collections are valuable scientific resources, often containing unique strains and genetic material from diversified sources. Valuable though they might be, their continuing existence typically depends on the dedicated efforts of individual scientists. When those scientists retire or shift research directions, the institutions holding those collections—whether universities, research organizations, or corporations in the private sector—often prove unwilling or unable to assume the financial and logistical burdens of maintaining or even transferring these collections to other repositories.

However, funding for such activities is extremely limited, and this economic reality tends to overshadow the scientific value in preserving these collections. The scientific community thus stands to lose these resources because of such shortsighted financial considerations.

Summary

- Funding for preserving specialized culture collections, which are valuable scientific resources, continues to be scarce.
- Even specialized microbial collections without apparent industrial or medical relevance may contain untapped resources of incalculable importance.
- By following a cost-effective approach known as deposit-storage-distribution, endangered specimens can be cryopreserved, distributed upon request, and fully authenticated when resources are made available and when demand arises.
- While priorities should be established, members of the scientific community ultimately decide which biological materials to preserve.

Many Challenges in Estimating the Value of Such Endangered Collections

Evaluating any collection is painstaking, and involves a case-by-case, or sometimes a culture-by-culture approach. However, viewed more comprehensively, material held in specialized collections offer values ranging from interest within a particular field or research discipline to widespread interest among the broader scientific community.

U.K. microbiologist Peter Green chairs the Endangered Collections Committee of the World Federation of Culture Collections. "Whatever their origins of purpose, they are highly likely to be of scientific value," he says. Although many cultures

Scott Jenkins is Communications Specialist at ATCC (American Type Culture Collection) Manassas, Va., and R. H. Cypess is President and Chief Executive Officer of ATCC.

Case Studies Involving the Deposit-Storage-Distribution Model

ATCC has put the DSD model into practice. Examples include:

- **Naval Biosciences Laboratory (NBL) cell lines.** In 1982, the Naval Biosciences Laboratory (NBL) transferred 1,552 human and animal cell lines to ATCC along with annotative documents. Some of the human lines in the NBL collection were accessioned into the ATCC general collection. However, because NBL could not afford to characterize and distribute all its cell lines, ATCC placed them in storage for later distribution to the scientific community in an "as is" condition.
- **Oregon Collection of Methanogens (OCM).** The OCM consists of strictly anaerobic, methane-producing *Archaea* and other fastidious anaerobes, including type strains and other strains that are not well characterized. More generally, methanogens are important in geochemical cycling and played a key role in the geochemical history of earth. Earlier, OCM was supported by researchers who deposited strains there and others who paid modest fees to use those strains. Until his death in 2005, it was managed by microbiologist David Boone from the Biology Department at Portland State University. Before he died, Boone and David Emerson at ATCC drafted a grant seeking funds to transfer the collection to ATCC. The National Science Foundation subsequently approved and is funding this effort.
- **Cystic Fibrosis (CF) Collection.** In the mid-1990s, Chiron of Emeryville, Calif., sponsored a clinical trial evaluating aerosolized Tobramycin for treating respiratory infections in CF patients. The investigators collected over 3,000 clinical isolates, which were kept following the trial. When Novartis later purchased Chiron, officials at the Swiss-based company investigated options for transferring the CF collection. Novartis later agreed to use the DSD model and transferred the collection, mostly *Pseudomonas aeruginosa* strains, to ATCC, ensuring its availability to the research community.

held in specialized collections may also be held elsewhere, many such institutional collections contain organisms from specialized niches that may not be found elsewhere. In contrast to large, centralized collections, specialized institutional collections typically contain large numbers of strains from a relatively small number of taxa.

In the face of limited resources for maintaining and transferring any particular endangered collection, difficult decisions must be made about its potential value to the scientific community. Some collections in their entirety offer immediate usefulness, while others may have only a handful of strains or materials of immediate interest to the wider research community. Since the few key items in a collection cannot always be easily identified or even considered in a current scientific context, these valuable resources are in danger of being discarded.

Even when a collection does not seem to have immediate relevance to a large number of researchers, it may hide untapped resources of incalculable importance. The history of science is punctuated with cases in which biological material of unknown value was preserved for long periods before a novel application became apparent.

For example, University of Wisconsin scientist Thomas Brock discovered thermophilic bacteria in Yellowstone National Park hot springs in 1967, and soon deposited *Thermus aquaticus* (ATCC® 25104™) with the American Type Culture Collection (ATCC), now in Manassas, Va. That specimen was stored for nearly 20 years without notice until biologist Kary Mullis of Cetus Corporation screened a range of microbes in search of a heat-stable DNA polymerase for amplifying isolated DNA strands. The version of that enzyme in *Thermus aquaticus*—*Taq* polymerase—proved well-suited to the rapid heating and cooling required for what soon came to be called the polymerase chain reaction, or PCR, still one of the most powerful research tools in biotechnology.

Other similarly "rediscovered" microorganisms have proved useful years after they were set aside in culture collections. For instance, a diagnostic tool for systemic lupus erythematosus that is useful in resource-poor settings was developed using *Crithidia luciliae* (ATCC® 30258™), a protozoan isolated from a green bottle fly 20 years earlier. Several strains of *Staphylococcus aureus* that were stored at ATCC for many years came to be plentiful sources of protein A, which is used for purifying monoclonal antibodies.

Maintaining Collections Has Benefits Beyond the Blockbuster

Storing biological materials for possible use in commercial products that are developed several decades later is a high-risk, high-reward prospect. Indeed, the percentage of cultures in specialized collections that will have as large an impact as *Thermus aquaticus* is exceedingly small. However, the rewards for the scientific community and society can be enormous.

The possibility, however remote, that industrially or medically relevant uses will be discov-

ered for little-known cultures from an endangered collection may not, by itself, be extremely compelling to those in a position to preserve such collections. However, blockbuster commercial products are not the only desirable outcome in preserving endangered collections. The resources in small private collections also enable researchers to ask questions that would be difficult to study otherwise, and may increase the efficiency of scientific inquiry.

For example, some collections contain microorganisms from very specific geographic locations or collected from the same location at several different times, enabling exploration of questions involving spatial location or temporal and environmental properties. Other collections may contain a particular strain from a wide range of hosts, allowing researchers to investigate host-pathogen interactions. The pace of these and other scientific inquiries would suffer from the loss of such collections along with the expertise that was involved in isolating those strains. Moreover, losing type strains would require re-treading scientific ground to reconstruct useful taxonomies.

Species contained in small, specialized collections may fill holes for researchers working in the fields of evolutionary biology or microbial taxonomy. They may also be important to those working on biodiversity projects. The geographic and temporal specificity of some samples collected for defined research projects could later help infectious disease epidemiologists study disease histories. In addition, such specialized collections can be of enormous value for studying emerging diseases and the evolution of pathogenesis. Stored strains also can be helpful in investigating how microbes acquire specific traits, including antibiotic resistance.

For example, consider a recent project on antimicrobial resistance undertaken by scientists at the Food and Drug Administration (FDA) Center for Veterinary Medicine along with microbiologists at ATCC. In 2004, they began to compile data for a 50-year retrospective analysis of antibiotic resistance patterns among isolates of common bacteria, including strains of *Escherichia coli*, *Salmonella enterica* serovar Typhimurium, and *Campylobacter jejuni*. The research team focused on isolates collected from humans and agriculturally relevant animals during the five decades since antibiotics came into widespread use. They evaluated drug susceptibility by subjecting the isolates to a specially selected panel of antibiotic agents. This study would not have been possible without access to bacterial specimens from clinical and animal sources that the ATCC had accumulated over that extended period.

Large and small microbial collections are also important in other specialized areas. For instance, professionals working in the growing field of microbial forensics also are benefiting from access to small specialized collections, particularly those containing microbial flora from specific environments or geographic areas. These specimens could be of enormous value when screening samples of unknown origin. A recent colloquium on microbial forensics acknowledged the need to understand the population diversity and environmental background of pathogen strains when analyzing them for forensics purposes. Preserving endangered collections also will benefit the basic research underlying microbial forensics.

Deposit-Storage-Distribution Approach Proves Cost-Effective

The tallest hurdle to saving endangered culture collections is financial. Many organizations are reluctant to spend significant funds to maintain or transfer collections that their researchers assemble. For financial solvency, biological repositories that do not receive government subsidies (such as ATCC) operate as self-sustaining, nonprofit businesses. Therefore, it is challenging to transfer small collections to large, centralized biological resource centers without first assessing their worth. Meanwhile, an important mission of ATCC and other biological resource centers (BRCs) is to serve the scientific community by providing the widest possible array of relevant research materials.

One approach being taken by ATCC to avoid losing scientific resources is what it calls the deposit-storage-distribution (DSD) model. Typically, when ATCC accessions material into its general collection, it is responding to expressed interest from the research and development (R&D) community. ATCC invests significant resources to test the materials and to ensure their quality, viability, purity, and authenticity.

Although ATCC acknowledges that well-qualified biological resources are vital for research, the cost for developing and maintaining those resources prohibits broadening this ap-

proach to acquiring any and all materials that are housed in a diversity of small, specialized collections. The DSD model offers an economical means for assuring that valuable materials are not lost but, instead, will be made available for full authentication when scientific demand demonstrates a need for them.

For instance, ATCC can store otherwise endangered specimens by checking viability and placing them in cryopreservation tanks. This approach delays spending the resources associated with authentication testing and producing stocks for distribution until demand materializes. The same process is used with materials that are deposited in the ATCC patent and safe deposit services.

In practice, materials from an endangered collection are prepared for long-term storage, while the scientific community is made aware that a particular collection or group of strains is being transferred to the ATCC or a comparable centralized resource center, where it can be made available to all registered scientists. If a researcher requests a sample from the transferred collection, the material is distributed with the caveat that it was not subject to authentication testing. Of course in such cases ATCC or the comparable repository cannot vouch for quality or authenticity, as it does with other materials. Nonetheless, that material remains available for study. If necessary, that material could later be accessioned into the general collection and given a full workup.

Thus, the DSD approach allows small collections to be saved without large outlays. ATCC hopes that government agencies, universities, foundations, and private firms will help in preserving endangered collections by defraying some of the modest costs involved in transferring them to centralized culture collections or BRCs. The organization that deposits the materials can retain ownership rights to the materials and could realize financial returns if the materials are someday licensed for commercial use.

Involving Researchers in Setting Priority Criteria

Priorities need to be set when deciding which endangered collections to save. The highest priority goes to indexed and annotated collections that already are being used by the scientific community. In many cases, those collections are are being cited in peer-reviewed literature, are requested by other researchers, have an associated database, and might also be at least partly authenticated.

Ideally, members of the scientific community ultimately should decide which materials deserve high priority. This process can be managed through scientific advisory committees. For example, the Biodefense and Emerging Infections Research Resource Repository (BEI Resources) is operated by ATCC under contract from the National Institute of Allergy and Infectious Diseases (NIAID). Its scientific advisory committee recently recommended that NIAID acquire endangered collections of cultures relevant to biodefense and emerging infectious disease research. By following the recommendations from the scientific advisors and with funding from relevant institutions, ATCC will use the DSD model to ensure that these endangered collections are preserved.

ACKNOWLEDGMENTS

We thank the following people for their help in preparing this article: Frank Simione (ATCC), Dr. Marian McKee (ATCC), Dr. David Emerson (ATCC), and Dr. Peter Green (National Collection of Industrial and Marine Bacteria, U.K.)

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Biobanking in microbiology: From sample collection to epidemiology, diagnosis and research

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Abstract

Millions of biological samples, including cells of human, animal or bacterial origin, viruses, serum/plasma or DNA/RNA, are stored every year throughout the world for diagnostics and research. The purpose of this review is to summarize the resources necessary to set up a biobanking facility, the challenges and pitfalls of sample collection, and the most important techniques for separation and storage of samples. Biological samples can be stored for up to 30 years, but specific protocols are required to reduce the damage induced by preservation techniques. Software dedicated to biological banks facilitate sample registration and identification, the cataloguing of sample properties (type of sample/specimen, associated diseases and/or therapeutic protocols, environmental information, etc.), sample tracking, quality assurance and specimen availability. Biobank facilities must adopt good laboratory practices and a stringent quality control system and, when required, comply with ethical issues.
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Keywords: Biological bank; Cryopreservation; Freeze–drying; Sample preparation; Quality control

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1. Introduction: why biobanking

The majority of relevant studies on microbial pathogenesis, infectious disease etiology and epidemiology, and environmental microbiology are based on obtaining biological samples. Biobanking, intended as the process of collecting, treating, and long-term storing biological samples, represents an essential tool for biological, biomedical and industrial research and for laboratory diagnostics. The characteristics of an ideal specimen bank were described by Lee in 1990 [1] as having a secure funding source, a cryogenic storage facility, developed criteria for selection of the best samples to be stored; at the same time each facility must develop an ongoing research to optimize sample collection/processing and storage conditions. Because biobanking has gained an emerging importance in diagnostics, research, and epidemiology, many organizations have now their own biobanking facilities, characterized by different preserving techniques, their own functional protocols, and, ideally, their own bioinformatic procedures. For these reasons, although it requires huge investments in personnel, automation and storing facilities, biobanking is becoming a part of biomedical and environmental national scientific programs.

Millions of human, animal and microbiological samples are stored each year for diagnostic and research purposes, including applications in microbiology and infectious diseases, genetics, oncology, etc. In the microbiological setting, the most important reasons for biobanking could be summarized as follows:

(a) To realize epidemiological studies intended to compare samples of human or animal origin within the same epidemic episode or from episodes occurring at different points in time or at distant locations. Stored samples offer unique opportunities to study the genetic characteristics of microorganisms, to establish transmission modalities in the local or worldwide settings, or to perform additional analysis on old samples when new questions arise or new pathogens are suspected to appear. Infection control plans, including the development of vaccines or of adequate containment procedures are often based on these information.
(b) To ensure progresses in diagnostic procedures by comparing samples from the same individual at different points in time or from different subjects with similar diseases, and by analyzing stored samples with new analytical methods that may increase sensitivity or specificity of infectious disease detection.
(c) To perform research studies requiring large number of samples collected in different geographical locations or requiring multiple parameters to be analyzed in specialized laboratories throughout the world.
(d) To constitute repositories of human or animal cell lines or microorganisms used for diagnostic and research procedures (i.e., isolation of viruses in well characterized cell lines), to set up programs checking the quality in diagnostic and research laboratories or to provide reference (state of the art) reagents for research.
(e) To establish collections of microorganisms aiming at characterizing microbial diversity and microbial evolution in the world. Microorganisms are essential parts of the biosphere; they can be also used in production of drugs, as biocontrol agents, and for many other beneficial purposes. Studying and safeguarding microbial diversity for future use and exploitation is therefore of fundamental importance [2]. Microbial culture collection faces an immense task: for instance, over 1.5 million fungal species are estimated worldwide, but less than 100,000 are described [3]. At the current rate of discovery, it will take 700 years to describe them all. Biological banks may thus be, in the near future, an invaluable tool for accelerated discovery and characterization of microorganisms and for promoting their beneficial uses to mankind.

2. Current situation

Presently, thousands of laboratories of microbiology (including medical, veterinary and environmental microbiology), clinical chemistry, pathology, epidemiology, and genetics have their own ongoing programs for sample collection and biobanking. There are, however, some

public (government) and private non-profit organizations pursuing nation-wide or international programs for biobanking. At national level, the Swedish National Biobank Program (http://www.biobank.se) is a joint national program on functional genomics. The main objectives of this program are to increase the knowledge and the quality of the Swedish biobanking system, to increase usability and availability of stored samples and to increase ethical awareness. Another important nation-wide program, the United Kingdom Biobank (http://www.uk.biobank.ac.uk) aims at building a major resource to support a diverse range of research, which will, in turn, improve the prevention, diagnosis, and treatment of illnesses. Private non-profit reference culture collections were established more than 40 years ago. The World Directory of Collections of Cultures of Microorganisms (http://wdcm.nig.ac.jp), an activity of the World Federation for Culture Collections, holds an excess of 1 million microbial strains, of which 44% are fungi, 43% bacteria, 2% viruses, 1% cells, and 10% others. Two additional important organizations devoted to the acquisition, preservation and distribution of microorganisms and cell lines are the German Collection of Microorganisms and Cell Cultures (DSMZ, http://www.dsmz.de) and the American Type Culture Collection in the United States (ATCC, http://www.atcc.org). Both these organizations constitute invaluable tools, providing state of the art reagents, reference microorganisms and cell lines for research and diagnostic purposes. For an exhaustive list of the major international culture collections the reader is referred to Smith and Ryan [4].

When faced with financial constraints, some academic centers recently decided to transfer their genomic banks to private organizations; this type of collaboration may pose serious problems in the protection of human subjects, in property rights, and in the possible commercial use of future benefits to the community. To avoid these threats, the "Charitable trust" was recently suggested as a potentially effective model for genomic biobanks, Because it complies with privacy rules and with benefits to the community, without losing its value in biological research and in epidemiology [5].

3. Purpose of the review

The purpose of this review is to summarize the resources necessary to set up a biobanking facility; the challenges and pitfalls of sample collection and the most important techniques used for separation and storage of samples will also be presented and discussed. The review will finally deal with principles of electronic data management and of accurate quality control procedures. The factors affecting the quality and the future use of biological samples will be discussed with particular attention to the nature of samples to be stored (i.e., blood, bacteria, fungi, etc.). This review considers some statements that may generally apply to biobanks, but are not for all biobanks. The purposes of the repository (research, diagnosis, epidemiology, industry, etc.), the type of specimen, the availability of personnel and equipment as well as other factors, deeply influence the characteristics of each biobank.

4. Staff and equipment

A functional biobanking facility requires adequate resources in terms of personnel, space, laboratory instrumentation, computers, and of quality system, including protocols and reference reagents. If human samples are stored, ethical issues must be solved. In literature, there are few indications on minimum personnel requirements for a biological bank [6]. The personnel may be a part of the laboratory performing all the routine or research work of the laboratory itself, while in turn holding the biological bank; in alternative, the personnel may be dedicated solely to biobanking, as it may happen in centralized facilities. Although a detailed analysis of the biobanking process and its throughputs is necessary before deciding the type of organization and its needs, two to three laboratory technicians may be considered as the minimum requirement to ensure a continuous biobanking service by processing, aliquoting, storing the samples, and holding the sample archive in all its aspects. Informatics greatly improves the management of a biological bank. Commercially available software packages may be satisfactory in small to medium biobanks, but ideally each facility should develop its own, dedicated software. In this case, a computer engineer or a computer programmer is required to develop and improve the software, in provision of the fact that systems should be amended continuously to meet the changing needs of the laboratory staff [6]. The coordinator of the biobank could be a component of the medical or PhD staff of the lab, who dedicates a part of his/her time to organize the biological bank, ensures the respect of the legal and ethical issues, keeps the contacts with the scientists who request the samples stored in the bank for their own diagnostic or research purposes, and defines with the administration space, personnel and equipment resources necessary to perform biobanking. Laboratory requirements include a processing room with a class II biological safety cabinet, a centrifuge and a microcentrifuge; this room may contain a personal computer with software dedicated to biobanking or a paper-based archive. An additional room is dedicated to the storing facilities. Samples are cryopreserved in freezers at −20 or

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Bacteria Collection Sheds Light On Urinary Tract Infections

ScienceDaily (Feb. 21, 2005)
— Food of animal origin, contaminated with E.coli, can lead to urinary tract infections in women, according to a team of bacteriologists.

"We found out that UTIs may be caused by ingesting food contaminated with E. coli," said Dr. Chobi DebRoy, director of Penn State's Gastroenteric Disease Center. Previously, this link was not established, she noted.

Senior author, Dr. Lee W. Riley, University of California-Berkeley, found that E.coli strains isolated from patients with UTIs were genetically related to E.coli strains from cows that were in the collection of strains at the Gastroenteric Disease Center. Riley and DebRoy reported their findings in a recent issue of Clinical Infectious Diseases.

About 8 to 10 million people are diagnosed with urinary tract infections each year. Women are more likely to get UTIs than men because it is easier for the bacteria to reach their bladder. Fifty percent of all women will experience at least one episode of UTIs during their lifetime. UTIs are typically treated with antibiotics.

The researchers found that the E.coli causing the UTIs matched genetically with a sample of E.coli obtained from an animal source. They used E.coli samples collected over 40 years from the center to match up the bacteria causing UTIs with bacteria found in animals. They tested E.coli samples from dogs, cows, sheep, water and turkeys. The researchers then compared the samples genetically to the UTI causing bacteria and found that a sample from a cow matched well with the E.coli found in humans.

The team also found that the E.coli causing the infections is resistant to antibiotics. The possibility that these multidrug-resistant bacteria could have an animal origin has major public health implications because of the practice of administering subtherapeutic doses of antibiotics as growth promoters in animals.

E.coli is common bacteria found in humans and animals. Thousands of E.coli live in the organs of humans and animals and provide multiple benefits such as aiding in digestion of certain nutrients. However, E.coli is also commonly associated with illnesses caused by eating undercooked beef or drinking contaminated water.

Without access to the large collection of bacteria strains from the Gastroenteric Disease Center, it would have been difficult for the researchers to carry out the research, according to DebRoy. The Gastroenteric Disease Center has been collecting E.coli samples since 1965 and is the largest repository of E.coli in North America. The center has 60,000 E.coli strains isolated from cows, birds, pigs, humans, dogs, water and the environment. The center is located in the Department of Veterinary Science, Penn State's College of Agricultural Sciences, with a web site at: http://ecoli.cas.psu.edu/

Other researchers involved in this project include: Amee Manges, assistant professor, McGill University;

###

The research was supported by NIH and USDA National Research Initiative Competitive Grants Programs.

Adapted from materials provided by Penn State.

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◉ APA

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1 Background and Overview by Dr. Stou

2 Destruction of the SPL Collection of Isolates and Specimens – the Petitio

3 Documents Related to the Request to Transfer the Collection

4 Procedure for Storing Bacterial in the Special Pathogens Laboratory

5 The Functions of the Special Pathogens Laboratory – Janet E. Stout, Ph.D. PD & Research Documents

6 Documentation of Legionella-related Isolates and Specimens

7 Examples of Use of the Collection and Requests by Scientists

8 Stout CV and Relevant Publications

Confidential Resume itmbklirsgcyv3gfdku2nacstwzuxn9d05ca1@users.fedjobs.gov

Country of citizenship:	United States of America
Veterans' Preference:	No
Highest Grade:	GS-403-11, 03/1983-Present
Contact Current Employer:	No

AVAILABILITY

Job Type:	Permanent
Work Schedule:	Full Time

DESIRED LOCATIONS

US-PA-Pittsburgh

WORK EXPERIENCE

CONFIDENTIAL
Pittsburgh, PA US

2/1983 - Present
Grade Level: GS-11
Salary: $60,000 USD Per Year
Hours per week: 80

Microbiologist , 403
Janet E. Stout, PH.D.

Dr Stout received her Master's (1981) and Ph.D. (1992) degrees from the University of Pittsburgh, Graduate School of Public Health. She has been a member of the University of Pittsburgh Dept. of Medicine/Infectious Disease faculty as a Research Assistant Professor since 1993.

I. Research Activities

Dr Stout's area of expertise is the area of infectious disease/infection control. She is knowledgeable in clinical and environmental microbiology of nosocomial pathogens, with special expertise in Legionnaires' disease. She has over 80 peer-reviewed publications and has achieved international prominence as an investigator in this field. Her primary research interests include the epidemiology of hospital-acquired Legionellosis, including the prevention of this disease through the use of active disinfection methods. Her contributions in these areas have had a direct impact on the current approach used to manage this nosocomial infection.

Ia. Specific research accomplishments and changes in clinical or research practices as a result of work

In 1982, Dr. Stout found that the hospital water supply was the epidemiologic reservoir for nosocomial Legionnaires' disease (N Engl J Med 82). This finding was so novel and contrary to the dogma at the time (that Legionnaires' disease was transmitted via the air) that the study ultimately became the sentinel study for appreciation of hospital-acquired waterborne pathogens. With the discovery of the water supply as the reservoir, the focus of subsequent outbreak investigations changed - cooling towers were no longer found to be the primary source of hospital-acquired Legionnaires' disease.

Dr. Stout expanded her hypothesis to community-acquired Legionnaires' disease and published a series of studies demonstrating that the water supply in homes was a primary source of community-acquired Legionnaires' disease - not air conditioners or cooling towers (JAMA 87, Arch Environ Health 88, Epid Infect 92, N Engl J Med 92).

Her work has included the development and validation of methods for Legionella environmental culturing (J Clin Microbiol 95). The utility of molecular typing techniques for epidemiologic investigations was also evaluated: first, in 1988 using monoclonal antibody subtyping, outer membrane protein profiles, and plasmid analysis (J Infect Dis 88), and later using pulsed field gel electrophoresis (J Clin Microbiol 96 & J Infect Dis 2001).

Dr. Stout then focused on methods to control the bacterium in water by evaluating a variety of Legionella disinfection methods in the laboratory and in field evaluations. The outcome of these disinfection studies is the basis for the widespread use of these methods by hospitals throughout the world.
(CV available upon request)

EDUCATION

University of Pittsburgh, Graduate School of Public Health
Pittsburgh, PA US
Doctorate - 12/1992
Major: Microbiology
Relevant Coursework, Licensures and Certifications:
Epidemiology, Microbiology, Biostatistics (Transcripts available upon request)

AFFILIATIONS

University of Pittsburgh Research Asst. Professor

PROFESSIONAL PUBLICATIONS

Chang FY, Singh N, Gayowski T, Wagener MM, Meitzner SM, JE Stout, Marino, IR. Thrombocytopenia in liver transplant recipients. Transplantation 69:70-75, 2000.

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646-7887A

2. Reason for Submission: [ ] Redescription [ ] Reestablishment [ ] New [ ] Dept [X] Field [X] Other

3. Service

4. Employing Office Location: VAMC-Pgh., PA 15240

5. Duty Station: Oakland

6. CSC Certification No

Explanation (Show any positions replaced): Reclassified

Microbiologist
GS-403-11
646-7887 dated 2/5/85

7. Fair Labor Standards Act: [X] Exempt [ ] Nonexempt

8. Employment/Financial Stmt Required: [ ] Yes [X] No

9. Subject to FA Action: [X] Yes [ ] No

10. Position Status: [X] Competitive [ ] Excepted (Specify)

11. Position is: [ ] Supervy [ ] Managerial [ ] Neither

12. Sensitivity: [ ] Critical [ ] Noncritical [X] ADP-III Nonsensitive

13. Competitive Area Code

14. Agency Use

15. Classified/Graded by	Official Title of Position	Pay Plan	Occupational Code	Grade	Initials	Date
a. Civil Service Commission						
b. Department, Agency, or Establishment						
c. Bureau						
d. Field Office	Microbiologist	GS	403	11	DJ	12/14/93
e. Recommended by Supervisor or Initiating Office	Microbiologist	GS	403	11	BJ	11/23/93

16. Organizational Title of Position (if different from official title)

17. Name of Employee (if vacancy, specify): Janet Stout/Richard Vickers

18. Department, Agency, or Establishment: Veterans Administration

a. First Subdivision: VHA

b. Second Subdivision: Medical Center

c. Third Subdivision: Pathology & Laboratory Medicine Service

d. Fourth Subdivision: •Microbiology Section

e. Fifth Subdivision: Special Pathogens Sub-Section

19. Employee Review: This is an accurate description of the major duties and responsibilities of my position

Signature of Employee (optional)

20. Supervisory Certification: I certify that this is an accurate statement of the major duties and responsibilities of this position and its organizational relationships, and that the position is necessary to carry out Government functions for which I am responsible. This certification is made with the knowledge that this information is to be used for statutory purposes relating to appointment and payment of public funds, and that false or misleading statements may constitute violations of such statutes or their implementing regulations.

a. Typed Name and Title of Immediate Supervisor: Victor L. Yu, M.D.
Chief, Microbiology/Infectious Disease
Signature: [signature] Date: 11/26/93

b. Typed Name and Title of Higher-Level Supervisor or Manager (optional): Gurmukh Singh, M.D., Ph.D.
Chief, Pathology & Laboratory Medicine Service
Signature: [signature] Date: 11/23/93

21. Classification/Job Grading Certification: I certify that this position has been classified/graded as required by Title 5, U.S. Code, in conformance with standards published by the Civil Service Commission or, if no published standards apply directly, consistently with the most applicable published standards.

Typed Name and Title of Official Taking Action: Donna M Lekstrand
Personnel Management Specialist
Signature: [signature] Date: 12/14/93

22. Standards Used in Classifying/Grading Position: CPM, OCS, FP. GS-403 Microbiology Series dated 12/62

Information for Employees: The standards and information on their application are available in the personnel office. The classification of the position may be reviewed and corrected by the agency or the Civil Service Commission. Information on classification/job grading appeals and complaints on exemption from FLSA is available from the personnel office or the Commission.

23. Position Review	Initials	Date	Initials	Date	Initials	Date	Initials	Date	Initials	Date
a. Employee (optional)										
b. Supervisor										
c. Classifier										

24. Remarks

KF Also the positions reviewed

25. Description of Major Duties and Responsibilities (see attached)

Position Description
Microbiologist GS-403-11

PRINCIPLE DUTIES & FUNCTIONS

Incumbent is one of the Microbiologists for the professional and technical management of the Special Pathogens Unit in the Microbiology Section of the Pathology Service. Special Pathogens is a diagnostic, training, and clinical research laboratory varied in scope of operations, and is a nationally recognized Legionella resource/reference center. Incumbent is responsible for the day by day details required for uninterrupted flow of patient care testing or research projects, and laboratory functions.

The incumbent looks after the special needs of this unit with regard to clinical testing, reference testing, maintenance of procedure manuals, acquisition and storing of supplies, meeting accreditation standards and safety standards. The assignments require a high degree of skill in applying, adapting or modifying methods of procedures to meet the needs of specific work situations. He/She independently performs technical duties required for immediate patient care and for monitoring of the Medical Center environment for Legionella. Under the guidance of the Chief of Microbiology Section the incumbent performs pilot studies and other projects that are needed for patient care, reference laboratory testing and for environmental monitoring. These techniques require meticulous attention to detail and often will necessitate the modification of existing techniques or the establishment of new procedures. Since this is a growing and rapidly developing area, the incumbent must interpret results without clear precedent. Due to the varied nature of the duties, the incumbent must display initiative and originality in planning and carrying out his/her duties. The incumbent must have the ability to make refined observations. The incumbent must skillfully apply, adapt, and modify methods, procedures, and techniques in solving a wide range of problems or in meeting the needs of many different situations. The incumbent develops or revises analytical concepts and scientific guidelines through independent and collaborative research. The incumbent will modify or develop new methods to improve or expand quantitativeness, accuracy, precision, specificity or proficiency of analysis. The incumbent must be able to perform experiments independently under general guidance. He/She assists the Chief of Microbiology Section in identification of newly identified microorganisms. These procedures may necessitate modification of existing techniques and development of new procedures.

In the performance of official duties, incumbent has regular access to printed and electronic files containing sensitive data which must be protected under the provisions of the Privacy Act of 1974 and other applicable laws, federal regulations, VA statutes and policy, and DM&S policy. The incumbent is responsible for (1) protecting that data from unauthorized release or from loss

alteration, or unauthorized deletion and (2) following applicable regulations and instructions regarding access to computerized files, release of access codes, etc., as set out in a computer access agreement which the incumbent signs.

FACTOR 1. KNOWLEDGE REQUIRED BY THE POSITION

Incumbent must have a knowledge with work experience in both diagnostic and investigative Microbiology and Serology. Knowledge and experience is necessary to assist the Chief of Microbiology in training graduate students.

Incumbent must keep abreast of the latest developments and techniques occurring in all disciplines of clinical Microbiology by constantly reviewing the literature in such specific areas as

Legionella disease, methicillin resistant Staphylococcus infections, anaerobic isolation and identification methods for head and neck infection, or for any new disease agents described.

A working knowledge of the VA guidelines is necessary to meet administrative functions of Special Pathogens such as workload recording and peer review inspections.

FACTOR 2. SUPERVISORY CONTROLS

Incumbent will be directly responsible to the Chief, Microbiology Section and assigned to the Special Pathogens Unit of the Pathology & Laboratory Medicine Service. He/She reports to the Chief Medical Technologist of Pathology & Laboratory Medicine Service for Quality Management functions. Assignments are mostly broad in scope and microbiologist usually determines deadlines, when interim reports are to be given, and how the final results will be turned in to the Section Chief. Microbiologist will be expected to operate independently and on own initiative at a high level of technical and professional expertise.

FACTOR 3. GUIDELINES

Special Pathogens provides a immediate patient care responsibility in the medical center for the diagnosis of Legionnaires Disease. A detailed procedure manual is located at the workbench for Legionella culture, immunofluorescence, and antigen determinations on clinical samples. Incumbent is responsible for content preparation, management, and periodic review of the manual.

Incumbent regularly makes judgements not readily applicable to rigid guidelines. Guidelines used are the professional literature resources such as peer review journals, text books, or news media releases.

FACTOR 4. COMPLEXITY

The Special Pathogens Unit is a multi-disciplinary patient care unit where incumbent performs a variety of tasks such as quality control checks of standard and non-standard media and reagents, identification and isolation procedures of unusual bacteria or fungi, teaching and training of students, clinical research and Legionella resource/reference laboratory testing for VA and non-VA facilities. The variety and diverse nature of the tasks require the application of a broad and comprehensive understanding of the sciences to the rapidly developing areas of clinical microbiology, especially to the Legionellaceae. The incumbent functions as an authority and provides leadership in the assigned areas.

Under the guidance of the Section Chief the incumbent is responsible for the introduction and implementation of newly developed procedures which are required to resolve clinical and diagnostic problems. To meet specific situations and unusual problems that embrace any aspect of clinical microbiology in the VA setting, the incumbent must also devise new and unique approaches and methods, and, on the basis of expertise and experience, evaluate and interpret their validity, significance, and applicability for increased patient care.

FACTOR 5. SCOPE AND EFFECT

The incumbent must be competent to handle biohazardous material safely. He/she must be experienced in sterile technique and must be competent in microbiological procedures, including isolation and identification techniques for aerobic and anaerobic pathogens, mycobacteria, and fungi. He/she must be able to develop new sensitivity testing procedures, and to adapt serologic identification techniques such as direct FA, chemical techniques such as GLC and HPLC, or molecular tools such as restriction endonuclease activity to the problems presented.

If suitable media is not commercially available, the incumbent will be responsible for the production and quality testing of special media as needed. He/she will be responsible for stock maintenance and incumbent will establish, maintain, and review a comprehensive quality control program for the section to insure that standards for quality are maintained and met in a time-and-cost-effective manner and reports the same to the Chief Medical Technologist.

Incumbent performs duties as a Microbiologist for Special Pathogens Unit which serves as a national Legionella resource/reference laboratory for VAMC and non-VAMC institutions in such areas as identification of Legionella bacteria submitted, determination of urinary antigen levels, culture and immunofluorescence of clinical samples.

Incumbent assists the Chief of Microbiology in implementation of policy for screening the medical center environment for Legionella colonization. Results will be used to determine if eradication procedures of the environment are necessary. Microbiologist collects, processes samples and identifies isolates obtained. Unusual or subtle changes are reported to the Infection Control Committee in writing.

FACTOR 6. PERSONAL CONTACTS

Diverse duties and responsibilities of the position require incumbent to interact either in person, or by telephone, or by formal writing personnel such as co-workers, physicians, professional trainees, other microbiologists, scientists, public health officials and sales representatives.

FACTOR 7. PURPOSE OF CONTACTS

He/She contacts the house staff, physicians and other personnel in the Medical Center for reporting clinical results from Special Pathogens Unit and for the reporting of results of environmental monitoring. The incumbent contacts other scientists in the Health Center and the University for continuing education, teaching and modification of procedures for patient care testing. The incumbent attends local and national meetings for continuing education.

FACTOR 8. PHYSICAL DEMANDS

Manual dexterity and agility of both hands is required to transfer infectious materials into tubes and bottles while wearing gloves and using mechanical devices. Hand, eye, and mental coordination is required for long uninterrupted periods of time while standing or sitting. Walking between laboratories, buildings, and up and down stairs, and lifting of bulk supplies for storage.

FACTOR 9. WORK ENVIRONMENT

Work environment of incumbent is a diagnostic and research laboratory where biological, chemical, and radioactive hazards are constant risks. Protective wear such as gloves, safety goggles, gowns, or a lab coat will be used when handling hazardous materials such as respiratory discharges, urine, blood, carcinogenic or flammable or corrosive chemicals, and radioactive I-125 components. The use of a biological or a chemical blood and a bulk steam sterilizer is essential for daily duties. Incubators, refrigerator/freezers, electronic equipment, and microscopes are in constant use.

FACTOR 10. OTHER SIGNIFICANT FACTORS

Broad experience is necessary to recognize either common or unusual pathogens from non-routine systems such as isolation of Nocardia or Mycobacterium species growing on Legionella media. The incumbent should have experience in general diagnostic microbiology. He/she will interact with members of the Infectious Disease Section and infection control personnel with whom he/she will function as part of the infection control team.

The incumbent is encouraged to belong to professional organizations, participate in scientific meetings, and maintain professional contacts with other microbiologists and health-care professionals outside the VA Medical Center.

Department of Veterans Affairs

Memorandum

Date June 3, 1996

From Chief, Infectious Disease Section and Microbiology Laboratory (111E)

Subj: Establishment of a VA Reference Laboratory

To: Ernest Urban, Chief of Staff (11)

The Pittsburgh VAMC Special Pathogens Laboratory personnel are acknowledged leaders in Legionella microbiology testing. We have evaluated all the commercially available diagnostic tests and have determined the specificity and sensitivity for these tests. Our recommendations have become the basis for how these tests are used. Furthermore, the formulation of the most widely used medium for environmental culturing was derived from the Special Pathogens Laboratory. The first outbreaks of Legionnaires' disease in the Peoples Republic of China and Turkey were uncovered by personnel who were trained in the Pittsburgh VAMC laboratory.

I acknowledge the receipt of materials concerning establishment of a national VA Reference Laboratory that you sent me last year. I have met briefly with Dr. Gurmukh Singh, who has informed me that this is straightforward. I've also discussed briefly with Mr. McLaughlin on how we would publicize this laboratory. An informal committee (McLaughlin, Michaels, Stout, Yu) itemized the costs or the tests, but this should be re-reviewed. We now need to meet for a step-by-step approach toward converting this dream into a reality.

I project that Legionella cultures will become widely applied in all VAMCs in the next decade (as it has become for Allegheny County hospitals). The Allegheny County Guidelines which mandated that all hospitals in Allegheny County (Pittsburgh) culture their water supply and search for Legionnaires' disease resulted in high volume testing submitted to this VAMC two years ago. The Allegheny County Health Guidelines are being reviewed this month, and we expect another surge in testing.

I request a meeting for a ste-by-step approach toward converting the Special Pathogens Laboratory into a National VA Laboratory for Legionella.

VICTOR L. YU, M.D

cc: Gurmukh Singh, Chief, Laboratory Service
Thomas Cappello, Medical Center Director

Dir: Yu/memos
File: specpath.2

Department of
Veterans Affairs

Memorandum

Date: July 5, 1995

From: Chief, Infectious Disease Section and Microbiology Laboratory (

Subj: Laboratory Testing and Billing

To: William Boyle, Raymond Laughlin, Ron Michaels

A meeting was held on June 30, 1995 with the following individuals in attendance: V.L. Yu, M.D., Ray Laughlin, Bill Boyle, Ron Michaels, Jack Rihs, and Janet Stout. The meeting was held to finalize the mechanism for billing of microbiological testing performed at the Special Pathogens Laboratory and Clinical Microbiology Laboratory of this VAMC.

Prior to this meeting cost estimates were provided to Fiscal Services for *Legionella* testing, checkerboard antibiotic synergy testing, and mycobacteria testing. Mr. Boyle revised the costs to include VA overhead and utility costs. Mr. Boyle and Mr. Michaels provided cost figures for the proposed laboratory tests (enclosed). It was agreed that future billing would be based on these figures provided by Mr. Boyle.

Mr. Michaels and Mr. Boyle recommended that compensation for all *Legionella* testing services should be deposited in the Veterans Research Foundation of Pittsburgh corporation Mr. Laughlin agreed. On a quarterly basis, payment will be made to the "Hospital Care Appropriation" for VA institutional costs. This amount will be calculated for each test from the Medical Center cost provided by Mr. Boyle times the number of tests performed that quarter. Dr. Yu will contact Nick Squeglia to discuss how best to set this up. The format for billing will be "fee basis" to be performed by the Infectious Disease Section. Services provided to other VA Medical Centers can be paid via "expenditure transfers" through Mr. Boyle's office or via check.

According to Mr. Laughlin, a sharing agreement is not only unnecessary, but unwieldy, given that requests for testing are usually sporadic and total funds received from "regular" users is well below $25,000 annually.

Marketing of services was also discussed. It was the understanding of the group that advertising was permissible if it was done via the VRFP Corporation and on their letterhead. However, Dr. Yu suggested that Mr. Laughlin review the advertising "flier" or letter prior to its distribution. Dr. Yu will draft the flier for *Legionella* testing and synergy testing Jack will draft the flier for mycobacteria testing.

The Clinical Microbiology Laboratory is already a certified VA reference laboratory and Dr. Gurmukh Singh can assist us in the designation of the Special Pathogens Laboratory as a national VA reference laboratory.

VICTOR YU, M.D.

cc: Thomas Capello, Medical Center Director
Ernest Urban, M.D., Chief of Staff
Martin Sax, Ph.D., Chief, Research and Development
Jack Rihs, Supervisor, Microbiology Laboratory

VA FORM

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

Date June 4, 1996

From Chief, Pathology and Laboratory Medicine Service (113)

Subj VA Reference Laboratory, As per memo from Dr Yu, dated June 3, 1996.

To Chief of Staff (11)

1. The UD VAMC already has an approved Special Clinical Resource Center designation for the Pathology and Laboratory Medicine Service and the Service has been providing Reference Laboratory Testing for other VAs. The Legionella Reference Testing can be accommodated through the existing structure of the Special Clinical Resource Center of the Pathology and Laboratory Medicine Service without the need for establishing a separate unit.

2. I will be glad to participate in any discussion on this matter that may be deemed appropriate.

Gurmukh Singh, M.D., Ph.D.

cc: Victor Yu
A COPY LEGIONEL YU

Department of
Veterans Affairs

Memorandum

Date July 3, 1995

From Janet Stout, Ph.D., Microbiologist

Subj Outside Testing Services and Billing

To Victor L. Yu, M.D, Chief, Infectious Disease Section and Microbiology

A meeting was held on June 30, 1995 with the following individuals in attendance: V.L. Yu, M.D., Ray Laughlin, Bill Boyle, Ron Michaels, Jack Rihs, and Janet Stout. The meeting was held to finalize the mechanism for billing of microbiological testing performed at this VAMC for outside hospitals.

Prior to this meeting cost estimates were provided to Fiscal Services for *Legionella* testing, checkerboard antibiotic synergy testing, and mycobacteria testing. Mr. Boyle revised the costs to include VA overhead and utility costs. It was agreed that future billing would be based on the figures provided by Mr. Boyle.

Compensation for all Legionella testing services will be deposited in the Veterans Research Foundation of Pittsburgh corporation. On a quarterly basis, payment will be made to the "Hospital Care Appropriation" for VA institutional costs. This amount will be calculated for each test from the Medical Center cost provided by Mr. Boyle times the number of tests performed that quarter. Dr. Yu will contact Nick Squiglia to discuss how best to set this up.

The format for billing will be "fee basis." According to Mr. Laughlin, a sharing agreement is not necessary given that requests for testing are usually sporadic and total funds received from "regular" users is well below $25,000 annually.

Services provided to other VA Medical Centers can be paid via "expenditure transfers" through Mr. Boyle's office or via check.

Marketing of services was also discussed. It is my understanding that there are no VAMC imposed restrictions on advertising as long as it is done via the VRFP Corporation and on their letterhead. Dr. Yu suggested that Mr. Laughlin review the advertising "flier" or letter prior to its distribution. Dr. Yu will draft the flier for *Legionella* testing and synergy testing. Jack will draft the flier for mycobacteria testing.

THE STORY OF THE CONFLICT BETWEEN THE PITTSBURGH VA ADMINISTRATION AND THE SPECIAL PATHOGENS LABORATORY

*** Highest importance
** Moderately Important
* Important

The Pittsburgh VA Closes the Special Pathogens Laboratory*

July 10, 2006- The Pittsburgh VA administration unexpectedly and abruptly closes the Special Pathogens Laboratory - an internationally-recognized infectious disease reference laboratory.

Dr. Victor L. Yu requests that the VA Administration justify the closure of the lab in writing.

Appeal Letter to Secretary of Veterans Affairs, R.J. Nicholson

Dr. Yu asks for right of appeal to VA Central Office to forestall this questionable decision. He notes that the Special Pathogens Laboratory was created by VA Central Office and given its accomplishments, should not have been terminated so abruptly (48 hours) without due consideration.

Appeal Letter to R. James Nicholson (July 14, 2006)

The Pittsburgh VA Special Pathogens Laboratory is Honored Following the American Legion Convention in Pittsburgh

Ironically, on July 16th 2006 (the anniversary of the first outbreak of Legionnaires' disease in Philadelphia), a Pittsburgh newspaper ran a story honoring the contributions of the Special Pathogens Laboratory to the study and prevention of Legionnaires' disease. The contributions of Janet E. Stout, Ph.D. and Victor L. Yu, M.D. were highlighted.

Dr. Janet E. Stout and Special Pathogens Lab: History of a Remarkable Discovery

Front Page News! Closure of the Special Pathogens Laboratory*

Three days later, the newspaper must regrettably announce the closure of this preeminent laboratory. The report noted that when the lab closes "…hospitals across the nation might be hard-pressed to find a laboratory to test for the deadly bacteria found in tap water."

VA Closes Special Pathogens Lab: front page news

Justification of Closure of the Special Pathogens Laboratory by the VA**

A rebuttal to claims laid forth by the Pittsburgh VA administration to justify the closing of the VA Special Pathogens Lab demonstrated that the reasons for the closure were unfounded. This point-by-point rebuttal demonstrates that all of the alleged points are incorrect and are countered with documentation (note that no documentation to support their allegations was provided by the VA administration.)

Letters from Secretary Nicholson and Under-Secretary Feeley with rebuttals from Victor L. Yu and Janet E. Stout

Should the Pittsburgh VA Allow the Special Pathogens Laboratory to Complete the Legionella Cultures and Inform the Hospitals of the Results? A Humanitarian Plea.

Dr. Victor Yu advises the VA administration that important information would be lost if incubating cultures were not completed. He offers to move the cultures to another lab to complete the work. The VA refuses.

*The Pittsburgh VA allows cultures to die and go unread***

*Harassment of Special Pathogens Laboratory Personnel in the Last 14 Days of Its Existence****

A thread of emails pleading for concluding the work

*The aftermath of the Pittsburgh VA's refusal: A grateful VA Medical Center**** *and a frustrated and disheartened wife of a patient****

The Destructive Ripple Effect Following Closure of the Special Pathogens Laboratory

The fate of the Special Pathogens Laboratory, taken in the context of other decisions by the Pittsburgh VA administration, appears to indicate declining support for excellence in microbiology at the Medical Center.

Destruction of the VA Clinical Microbiology Laboratory

*Concerns of VA Staff Physicians**

Destruction of the Entire Collection of Legionella and Other Pathogens: A Senseless Tragedy***

Incredibly, this same administration ordered the destruction of a priceless and irreplaceable collection of microorganisms and human specimens that had been collected by Drs. Yu and Stout over the previous 25 years. Dr. Stout had been working with the Director of the VA Research Department to transfer the collection to a qualified laboratory at the University of Pittsburgh when this action occurred.

Unanswered letters to the VA Administration: How could this have occurred?

Television Coverage of the Destruction

News Coverage of the Destruction

was provided to Secretary Nicholson, Undersecretary Feeley, Congressman Doyle, or Congressman Murphy to verify these claims.

Moreland Claim # 1

Research Projects: "It was brought to the attention of the Director that the Special Pathogens Laboratory received research funds, but that there was no research currently being conducted as detected by an absence of an approved IRB proposal."

Reply: This is untrue. Attached are the documents showing IRB approvals (Attachment: IRB Approvals). Note the Attachment shows that R&D approval for "Various Studies of Legionella" was in force until December, 2006. Moreland's contention that no research was being conducted is refuted by over 200 articles published in the peer review scientific literature including the most visible and prestigious journals in the world including New England Journal of Medicine, JAMA, and Lancet, plus chapters in over 20 medical and microbiology textbooks.

Stout, Janet E

From: Fuhrer, Dawn Marie
Sent: Wednesday, November 23, 2005 11:50 AM
To: 'vly+@pitt.edu'
Cc: Stout, Janet E
Subject: RE: VA Research form

Thank you Dr. Yu. I did forward the continuing review form to Dr. Stout. We'll need it completed and returned by 12/07/05.

Thanks,
Dawn

-----Original Message-----
From: Victor L Yu [mailto:vly+@pitt.edu]
Sent: Wednesday, November 23, 2005 10:52 AM
To: Fuhrer, Dawn Marie
Subject: VA Research form

Dear Dawn

Although we have not received funding for thses studies, Dr Janet Stout informs me that we are expecting a grant for this study. So the answer to your question is "Yes."

Victor L Yu MD (111E-U) Direct: 412-688-6643
Infectious Disease Section Secretary: 412-688-6179
VA Medical Center Direct Fax: 412-688-6507
University Drive C Cell ph: 412-901-7707
Pittsburgh, PA 15240 Home: 412-343-7429
> -----Original Message-----
> From: Victor L Yu [mailto:vly+@pitt.edu] On Mon, 21 Nov 2005, Fuhrer,
> Dawn Marie wrote:
>
> I have a question. Is your study
>> titled: " Various Studies Examining Treatment, Prevalence and
>> Eradication of Legionella" which was originally approved by the VAPHS
>> R&D Committee 10/1/98 still active?
>>
>> Thanks,
>> Dawn
>>
>>>> Program Support Assistant
>>>> VA Pittsburgh Healthcare System
>>>> Research & Development (151U-H)
>>>> Phone (412)365-4278
>>>> Fax (412)365-4249
>>>> E-mail: Dawn.Fuhrer@med.va.gov
>>>>
>>>>
>>>
>>
>

Research & Development Committee
VA Pittsburgh Healthcare System #646
7180 Highland Drive • Pittsburgh, PA 15206

CONTINUING REVIEW SUBMISSION FORM

Date: July 10, 2006
Investigator: **Victor L. Yu, M.D.**
Protocol: Various Studies Examining Treatment, Prevalence and Eradication of Legionella
ID: 00137 Prom#: 0010 Protocol#: N/A

Initial R&D Approval Date: 10/01/1998
Previous Continuing Reviews: 01/25/2006
Approval Expiration: 12/11/2006

Submission Form Due Date: 10/04/2006
Continuing Review Date: 10/25/2006

Regulations specify that Continuing Review is required for all approved research studies. Failure to comply will result in suspension or termination.

Please provide the following:
1) An Abstract (Guidelines Attached)
2) Research Staff Form
3) A NEW VA Conflict of Interest Form for the PI and each Investigator, Co-investigator, or Collaborator devoting 5% or more effort to the project.
4) Any manuscripts that have been submitted for publication or peer reviewed abstracts of work that have been presented during the past year.

Have there been any changes, since the last report, with respect to:
1. Your role at the VA? ☐Yes ☐No
2. The programmatic relationship to VAPHS R&D activity? ☐Yes ☐No

If you answered yes to any of the above questions, attach documentation explaining the change.

3. Has the study terminated? ☐Yes ☐No If yes, provide a final report.

If you have any questions, please contact the Research Office at 412-688-6104.

Signature: _____ Date: _____
(ONLY THE PRINCIPAL INVESTIGATOR IS AUTHORIZED TO SIGN)

APPROVED/DISAPPROVED

Signature: _____ Date: _____
Chairperson, Research & Development Committee

Research & Development Committee
VA Pittsburgh Healthcare System #646
7180 Highland Drive • Pittsburgh, PA 15206

CONTINUING REVIEW SUBMISSION FORM

Date: July 10, 2006
Investigator: **Victor L. Yu, M.D.**
Protocol: Various Studies Examining Treatment, Prevalence and Eradication of Legionella
ID: 00137 Prom#: 0010 Protocol#: N/A

Initial R&D Approval Date: 10/01/1998
Previous Continuing Reviews: 01/25/2006
Approval Expiration: 12/11/2006

Submission Form Due Date: 10/04/2006
Continuing Review Date: 10/25/2006

Regulations specify that Continuing Review is required for all approved research studies. Failure to comply will result in suspension or termination.

Please provide the following:
1) An Abstract (Guidelines Attached)
2) Research Staff Form
3) A NEW VA Conflict of Interest Form for the PI and each Investigator, Co-investigator, or Collaborator devoting 5% or more effort to the project.
4) Any manuscripts that have been submitted for publication or peer reviewed abstracts of work that have been presented during the past year.

Have there been any changes, since the last report, with respect to:
1. Your role at the VA? ☐Yes ☐No
2. The programmatic relationship to VAPHS R&D activity? ☐Yes ☐No

If you answered yes to any of the above questions, attach documentation explaining the change.

3. Has the study terminated? ☐Yes ☐No If yes, provide a final report.

If you have any questions, please contact the Research Office at 412-688-6104.

Signature: _____ Date: _____
(ONLY THE PRINCIPAL INVESTIGATOR IS AUTHORIZED TO SIGN)

APPROVED/DISAPPROVED

Signature: _____ Date: _____
Chairperson, Research & Development Committee

Research & Development Committee
VA Pittsburgh Healthcare System #646
7180 Highland Drive • Pittsburgh, PA 15206

CONTINUING REVIEW SUBMISSION FORM

Date: November 17, 2005
Investigator: **Victor L. Yu, M.D.**
Protocol: Various Studies Examining Treatment, Prevalence and Eradication of Legionella
ID: 00137 Prom#: 0010 Protocol#: N/A

Initial R&D Approval Date: 10/01/1998
Previous Continuing Reviews: N/A
Approval Expiration:

Submission Form Due Date: 12/07/2005
Continuing Review Date: 12/28/2005

Regulations specify that Continuing Review is required for all approved research studies. Failure to comply will result in suspension or termination.

Please provide the following:
1) An Abstract (Guidelines Attached)
2) Research Staff Form
3) A NEW VA Conflict of Interest Form for the PI and each Investigator, Co-investigator, or Collaborator devoting 5% or more effort to the project.
4) Any manuscripts that have been submitted for publication or peer reviewed abstracts of work that have been presented during the past year.

Have there been any changes, since the last report, with respect to:
1. Your role at the VA? ☐Yes ☒No
2. The programmatic relationship to VAPHS R&D activity? ☐Yes ☒No

If you answered yes to any of the above questions, attach documentation explaining the change.

3. Has the study terminated? ☐Yes ☒No If yes, provide a final report.

If you have any questions, please contact the Research Office at 412-688-6104.

Signature: _____ Date: 12/6/05
(ONLY THE PRINCIPAL INVESTIGATOR IS AUTHORIZED TO SIGN)

APPROVED/DISAPPROVED

Signature: _____ Date: _____
Chairperson, Research & Development Committee

Transmission Report

Date/Time	12-06-2005	03:26:17 p.m.	Transmit Header Text	
Local ID 1	688 6950		Local Name 1	Line 1
Local ID 2			Local Name 2	

This document : Confirmed
(reduced sample and details below)
Document size : 8.5"x11"

FAX COVER SHEET

DATE: 12-6-05 TIME ___:___ (Eastern Standard time)

TO: Dawn Fabrey
Research

PHONE NO: (412) 365-4278

FAX NO: (412) 365-4249

FROM: Janet Stanek, PhD / Victor L. Yu, MD
Infectious Disease Section
VA Medical Center
University Drive C
Pittsburgh, PA 15240, U.S.A.

PHONE NO: (412) 688-6179 (Direct)
(412) 688-6000, x 81-4699

FAX NO: (412) 688-6950 (office fax)
(412) 688-6507 (alternate fax number, if above number is busy)

Total pages faxed including this cover sheet: 15

MESSAGE:

Dawn-
Originals in the mail today -
Faxing:
1) Continuing Review Form
2) Abstract
3) Staff Form
4) COI forms

faxgeneric
v.doc

al Pages Scanned : 15 Total Pages Confirmed : 15

	Job	Remote Station	Start Time	Duration	Pages	Line	Mode	Job Type	Results
1	047	94123654249	03:21:42 p.m. 12-06-2005	00:03:06	15/15	1	EC	HS	CP24000

Research & Development Committee
VA Pittsburgh Healthcare System #646
7180 Highland Drive • Pittsburgh, PA 15206

APPROVAL - Study Closure

Date: August 23, 2005
From: Jeffrey L. Peters, M.D., Chairperson
Investigator: Janet E. Stout, Ph.D.
Protocol: Exposure Assessment For Community Acquired Legionnaires' Disease
ID: 00253 Prom#: 0002 Protocol#: N/A

The following items were reviewed and approved through Expedited Review:

- Study Closure (07/07/2005)

Expedited Approval was granted on 08/16/2005. This Expedited review will be reported to the fully convened Research & Development Committee on 09/28/2005.

Institutional Review Board (IRB)
VA Pittsburgh Healthcare System #646
University Drive • Pittsburgh, PA 15240

IRB APPROVAL - Continuing Review

Date: October 25, 2004
From: Ali F. Sonel, M.D.
Investigator: Janet E. Stout, Ph.D.
Protocol: Exposure Assessment For Community Acquired Legionnaires' Disease
ID: 00253 Prom#: 0002 Protocol#: N/A

The following items were reviewed and approved through Expedited Review:

- Research Protocol (10/17/2003)
- Abstract (08/02/2004)
- Conflict of Interest - Janet Stout, Ph.D. (08/02/2004)
- Conflict of Interest - Robert R. Muder, MD (08/02/2004)
- Conflict of Interest - Victor L. Yu, MD (08/02/2004)
- Consent Form (09/27/2004)
- Continuing Review (08/02/2004)
- Research Staff Form (08/03/2004)
- Listing of Authorized Rep's to Administer Informed (08/02/2004)
- Manuscript/Publication/Abstract (08/02/2004)

Expedited Approval was granted on 09/20/2004 for a period of 12 months and will expire on 09/19/2005. Your Continuing Review is scheduled for 07/25/2005. This Expedited review will be reported to the fully convened Institutional Review Board (IRB) on 11/22/2004.

This request for continuing review was reviewed and approved by the IRB Chairman/Designee under the following expedited continuing review category:

Research previously approved and meets an expedited review category. Based on category # 1200.5, Category E.

Risk Assessment: Minimal; IRB Level of Scrutiny: Low (The risk assessment was made considering Social; Physical; Psychological; and Economic Risk).

AE Reporting Level: AE2
AE2 - All serious AEs that are possibly related and all unanticipated but not serious AEs that are at least possibly related to the study procedures need to be reported to the IRB using the current adverse event reporting form. AEs that are not study related should not be reported.

The Pittsburgh VAMC IRB is not connected with, has no authority over, and is not responsible for human research conducted at any other institution, except where a Memorandum of Understanding specifies otherwise. Separate approval [illegible] continuing reviews, amendments, and [illegible]

Institutional Review Board (IRB)
VA Pittsburgh Healthcare System #646
University Drive • Pittsburgh, PA 15240

IRB APPROVAL - Continuing Review

Date: January 26, 2004
From: Linda Fried, M.D.
Investigator: Janet E. Stout, Ph.D.
Protocol: Exposure Assessment For Community Acquired Legionnaires' Disease
ID: 00253 Prom#: N/A Protocol#: N/A

The following items were reviewed and approved at the 09/22/2003 meeting, contingent upon minor stipulations in each item marked with an asterisk (*):

- * Research Protocol (10/24/2002)
- Abstract (05/06/2003)
- Amendment (09/08/2003)
- Budget Page (09/08/2003)
- Conflict of Interest - Janet E. Stout, PhD (09/08/2003)
- Conflict of Interest - Robert Muder, MD (09/08/2003)
- Conflict of Interest - Victor Yu, MD (09/08/2003)
- * Consent Form (09/08/2003)
- Continuing Review (09/08/2003)
- Education - Human Subjects Research Training (09/22/2003)
- Listing of Authorized Rep's to Administer Informed (09/08/2003)
  Adverse Event Reporting Level 2
- IRB Level of Scrutiny - Low

Research Protocol (10/24/2002) was returned to you with minor stipulations. Revised Research Protocol (10/17/2003) incorporates the stipulations and is now approved.

Consent Form (09/08/2003) was returned to you with minor stipulations. The following revised items incorporate the stipulations and are now approved:

- Consent Form (10/30/2003)

The following additional items were received to address stipulations and are now approved:

- IRB Approval Forms/Consent (NY, Beaumont, MD) (10/30/2003)

The following Institutional Review Board (IRB) members recused themselves (or were otherwise excused) from deliberations and did not vote: Mary Ann W. Hart, LCSW, ACSW (excused).

Approval is granted for a period of 12 months and will expire on 09/21/2004. Your Continuing Review is scheduled for 08/23/2004.

The Pittsburgh VAMC IRB is not connected with, has no authority over, and is not responsible for human research conducted at any other institution, except where a Memorandum of Understanding specifies otherwise. Separate consent forms, initial reviews,

Print this Page for Your Records!.

EPA-funded study

AMERICAN SOCIETY FOR MICROBIOLOGY

43rd ICAAC, September 14 - 17, 2003, McCormick Place, Chicago, Illinois, USA

Control/Tracking Number : ICAAC03-A-1886-ASM
Activity : Abstract
Current Date/Time : 5/8/2003 11:02:44 AM

Community-acquired Legionnaires' Disease: Residential Water Systems Are an Under-appreciated Source of Exposure

J. E. STOUT[1], R. R. MUDER [1], A. P. DUFOUR [2], J. MCMAHON [3], S. SILVESTRI [3], L. STARSKY [3], J. JEFFRIES [3], B. GROSCH [3], T. ALLAN [4], H. SCAIFE [4], R. HYSING [4], P. SHEFFER [1], S. M. MIETZNER [1], V. L. YU [1];
[1]VA Medical Center, Pittsburgh, PA, [2]U.S. Environmental Protection Agency, Cincinnati, OH, [3]Allegheny County Health Dept., Pittsburgh, PA, [4]Cuyahoga County Board of Health, Cleveland, OH.

Background: Public health authorities do not investigate cases of sporadic community-acquired Legionnaires' disease (LD). As a result, the environmental source of these infections remains unknown. We conducted a prospective study to investigate whether residential water systems may be a source for these infections.

Methods: In an ongoing study, cases of community-acquired LD that were reported to the Health Departments in Allegheny County, PA, and Cuyahoga County, OH, from January 2002 to March 2003 were included in the study. A case of LD was confirmed if the diagnosis was made by urinary antigen testing or culture isolation of the organism. *Legionella* culture was performed on water and swab samples obtained from the residential water system of the case. A previous admission to a hospital warranted environmental testing of the hospital water system.
Results: 35 cases of LD caused by *L. pneumophila* serogroup 1 were identified (15 from OH and 20 from PA); 24 by culture, 10 by urine antigen, 1 by DFA. Environmental testing was performed for 60% (21/35) of cases. A link to home exposure was made for 24% (5/21) of these patients; 2/5 were confirmed by molecular typing by PFGE. In the homes of these patients, 92% (22/24) of water outlets were positive for *L. pneumophila* serogroup 1 vs. 0% (0/81) in the homes of non-linked patients ($p<0.001$). One case of *L. micdadei* infection was linked to a hospital water system.
Conclusion: Community-acquired LD is acquired from home exposure more often than previously appreciated. Residential water systems should be considered as possible vectors for sporadic cases of LD before implicating cooling towers and aerosol producing devices.
Commercial Relationship: J.E. Stout, None.

AMERICAN SOCIETY FOR MICROBIOLOGY

Control/Tracking Number : ICAAC05-A-1346-ASM
Activity : Abstract
Current Date/Time : 5/6/2005 2:32:44 PM

Reduced Susceptibility of *Legionella pneumophila* to the Antimicrobial Effects of Copper and Silver Ions

S. M. MIETZNER[1], A. HANGARD [1], J. E. STOUT [1], U. ROHR [2], M. L. PEDRO-BOTET [3], M. H. SAMORE [4], V. L. YU [1];
[1]VA Pittsburgh Healthcare System and Univ. of Pittsburgh, Pittsburgh, PA, [2]Abteilung für Hygiene, Sozial- und Umweltmedizin, Ruhr-Univ. Bochum, Bochum, Germany, [3]Hosp. Germans Trias i Pujol, Badalona, Spain, [4]Salt Lake VA Healthcare System, Salt Lake City, UT.

Background: Copper-silver ionization is considered an effective disinfection method for controlling *Legionella pneumophila* in hospital hot water systems. One hospital reported failure with ionization and suggested that *Legionella* had developed resistance to the ions. However, microbiological evidence of resistance was not presented. We compared the susceptibility to copper (Cu) and silver (Ag) ions of *L. pneumophila* strains isolated from 6 hospitals either before (pre) or after (post) installation of the ionization system.
Methods: A total of 29 *L. pneumophila* isolates were evaluated by the time-kill method in flasks containing 100 ml sterile tap water with copper (0.4 - 0.8 mg/L) and silver (0.04 - 0.08 mg/L). Ion solutions were generated in an ionization flow cell (LiquiTech, Inc.) Viability counts were performed in duplicate at 0, 3, 6, 24, and 48 h. Susceptible was defined as >99% reduction in viable count between 0 to 24 h and resistant was defined as <99% at 48 h. Isolates were also tested in a microdilution method developed to screen isolates for viability at 24 and 48 h.
Results: Pre-ionization isolates from 4 hospitals (n=10) were susceptible. 58 % (11/19) of post-ionization isolates from 6 hospitals were resistant (p=<0.005). All hospitals had a mix of susceptible and resistant strains from the post-ionization period. Time-kill and microdilution susceptibility results were concordant for 28/29 isolates tested. MIC's for Cu/Ag (mg/L) for susceptible and resistant strains were 0.25 - 0.51/0.04 - 0.07 and ⩾ 4.05/0.55, respectively.
Conclusion: *Legionella* can develop resistance to copper and/or silver ions. The impact of this finding on the long-term efficacy of ionization for *Legionella* disinfection has yet to be determined.
Author Disclosure Block: S.M. Mietzner, None.

Category (Complete): E
Keyword (Complete): Legionella pneumophila ; susceptibility ; ionization
Additional Information (Complete):
I do NOT have any off-label use(s) to disclose. : True

688 6050 Line 1 12:43:54 p.m. 09-04-2008 2/2

99/MP/MDE-1

Project/Program Title Legionella Colonization if Health Facility Water Systems

Principal Investigator Robert Myder, MD and Janet Stout, PhD

VAMC Pittsburgh, (UD), PA Review Date: 11/19/99

COMMITTEE FINDINGS

1. The information given in the Informed Consent under the Description of Research by Investigator is complete, accurate, and understandable to a research subject or surrogate who possesses standard reading and comprehension skills. ☒ YES ☐ NO

2. The informed consent is obtained by the principal investigator or a trained and supervised designate under suitable circumstances. ☒ YES ☐ NO

3. Every effort has been made to decrease risk to subject(s)? ☒ YES ☐ NO

4. The potential research benefits justify the risk to subject(s)? ☒ YES ☐ NO

5. If subject is incompetent and surrogate consent is obtained, have all of the following conditions been met: a) the research can't be done on competent subjects: b) there is no risk to the subject, or if risk exists the direct benefit to subject is substantially greater; c) If an incompetent subject resist, he/she will not have to participate: d) If there exists any question about the subject's competency, the basis for decision on competency has been fully described. ☒ YES ☐ NO

6. If the subject is paid, the payment is reasonable and commensurate with the subject's contribution. ☐ YES ☐ NO ☒ NA

7. Members of minority groups and women have been included in the study population whenever possible and scientifically desirable. ☒ YES ☐ NO

8. Comments: (Indicate if Expedited Review) This study is approved for the period of _____ to 11/19/00 . Extension beyond 11/19/00 requires reapproval of the SHS. Any adverse effects must be reported to the SHS and the Research Office.

RECOMMENDATION: ☒ APPROVED ☐ DISAPPROVE/REVISE

SIGNATURE OF CHAIRMAN DATE

RESEARCH & DEVELOPMENT COMMITTEE EVALUATION

Project ID#: 98/MISC/STOU-1

Investigator: Janet Stout, PhD and Robert Muder, MD

Title: Health Risk from Legionella in Hospital Water Systems

Meeting Date: 9/1/98

The result of the R&D Committee review of your proposal is:

____ Approved

✓ Approved with required modifications
To be verified by: Chairman Reviewer

____ Deferred pending further information

____ Disapproved

Attachments for your assistance:

✓ Assigned Reviewer's comments and suggestions

✓ R&D Committee review synopsis

****

If you wish to resubmit your conditionally approved, deferred, or disapproved proposal, your resubmission package **must** include:

1. A copy of this communication with attachments
2. A copy of the proposal with highlighted changes
3. A copy of the proposal without highlighted changes

Note: The R&D Committee meets the first Tuesday of every month. Submissions should be received in the Research Office at least two weeks prior to meeting date in order to guarantee prompt review.

AJIC practice forum

A proactive approach to prevention of health care–acquired Legionnaires' disease: The Allegheny County (Pittsburgh) experience

Cheryl L. Squier, RN, CIC,[b,c] Janet E. Stout, PhD,[c,d] Sharon Krsytofiak, MS, MT(ASCP), CIC,[b] Joan McMahon, RN, MPH,[a] Marilyn M. Wagener, MS,[d] Bruce Dixon, MD,[a] and Victor L. Yu, MD[c,d]
Pittsburgh, Pennsylvania

Background: The Allegheny County Health Department (ACHD) in Pennsylvania distributed the first guidelines for prevention and control of health care–acquired Legionnaires' disease (LD) by 1995. The proactive approach advocated in the guidelines differed notably from that of the Centers for Disease Control and Prevention (CDC) by recommending routine environmental testing of the hospital water distribution system even when cases of health care–acquired Legionnaires' disease had never been identified.
Objectives: Our purpose was to (1) evaluate the impact of the ACHD guidelines on the *Legionella* diagnostic and preventive practices of health care facilities in Allegheny and surrounding counties and (2) compare the incidence of health care–acquired LD before and after issuance of the ACHD guidelines.
Methods: CDC case reports of LD from 1991 to 2001 were tabulated and compiled by the ACHD Infectious Disease Unit and the Association for Professionals in Infection Control and Epidemiology, Inc, Three Rivers Chapter. A survey was distributed to 110 hospitals and long-term care facilities in the region. The results were analyzed as occurring either in the preguideline period (1991-1994) or postguideline period (1995-2001).
Results: A significant decrease in the number of health care–acquired cases was demonstrated between the preguideline (33%) and postguideline (9%) periods ($P = .0001$). In contrast, community-acquired cases increased from 67% pre guideline to 91% post guideline. A total of 71% of the facilities were colonized with *Legionella*. Disinfection of the water distribution system was initiated by 44% of facilities. Use of urinary antigen testing significantly increased from 40% pre guideline to 79% post guideline ($P = .0001$).
Conclusions: Health care–acquired LD declined significantly after the issuance of guidelines for prevention and control of health care–acquired LD. The decline was associated with health care facilities performing routine environmental monitoring of their water distribution systems followed by the initiation of disinfection methods if indicated. Two unanticipated benefits were (1) cases of LD in the community and long-term care facilities were uncovered as a result of increased availability of *Legionella* tests and (2) litigation and unfavorable publicity involving ACHD hospitals ceased. (Am J Infect Control 2005;33:360-7.)

"If you don't look for it, you won't find it. If you don't find it, you don't think you have a problem. If you don't think you have a problem, you don't do anything about it."

Bruce Dixon MD, Director
Allegheny County Health Department
CNN & Time television program, November 1999

From the Allegheny County Health Department,[a] the Association for Professionals in Infection Control and Epidemiology, Three Rivers Chapter,[b] the Veterans Administration Pittsburgh Healthcare System,[c] and the University of Pittsburgh,[d] Pittsburgh, Pennsylvania.

Reprint requests: Victor L. Yu, MD, VA Medical Center, Infectious Disease Section, University Drive C, Pittsburgh, PA 15240. E-mail: vly@[illegible]

doi:10.1016/j.ajic.2005.01.012

Since the early 1980s, it has been known that health care–acquired Legionnaires' disease occurs from exposure to *Legionella* in hospital water distribution systems.[1-3] As early as 1983, Pittsburgh investigators began advocating a proactive approach to prevention of health care–acquired Legionnaires' disease through active case detection and disinfection of the hospital water system.[4,5] This approach differed notably from that of the Centers for Disease Control and Prevention (CDC) by recommending routine environmental testing of the hospital water distribution system even if cases of health care–acquired Legionnaires' disease had never been discovered. In time, others would adopt this approach. Seven prospective studies have been performed in 52 hospitals in which cases of health care–acquired Legionnaires' disease had never been diagnosed. Environmental cultures for *Legionella* were performed on the water distribution systems of each of

'11 · Merit Rev
Study

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY JULY 2007, VOL. 28, NO. 7

ORIGINAL ARTICLE

Role of Environmental Surveillance in Determining the Risk of Hospital-Acquired Legionellosis: A National Surveillance Study With Clinical Correlations

Janet E. Stout, PhD; Robert R. Muder, MD; Sue Mietzner, MS; Marilyn M. Wagener, MS; Mary Beth Perri, BS; Kathleen DeRoos, MSN; Dona Goodrich, BS; William Arnold, MS; Theresa Williamson, MS; Ola Ruark, MSN; Christine Treadway, MSN; Elizabeth C. Eckstein, MSN; Debra Marshall, RN; Mary Ellen Rafferty, MS; Kathleen Sarro, RN; Joann Page, MS; Robert Jenkins, BA; Gina Oda, MS; Kathleen J. Shimoda, RN, BS; Marcus J. Zervos, MD; Marvin Bittner, MD; Sharon L. Camhi, MD; Anand P. Panwalker, MD; Curtis J. Donskey, MD; Minh-Hong Nguyen, MD; Mark Holodniy, MD; Victor L. Yu, MD; and the Legionella Study Group

OBJECTIVE. Hospital-acquired *Legionella* pneumonia has a fatality rate of 28%, and the source is the water distribution system. Two prevention strategies have been advocated. One approach to prevention is clinical surveillance for disease without routine environmental monitoring. Another approach recommends environmental monitoring even in the absence of known cases of *Legionella* pneumonia. We determined the *Legionella* colonization status of water systems in hospitals to establish whether the results of environmental surveillance correlated with discovery of disease. None of these hospitals had previously experienced endemic hospital-acquired *Legionella* pneumonia.

DESIGN. Cohort study.

SETTING. Twenty US hospitals in 13 states.

INTERVENTIONS. Hospitals performed clinical and environmental surveillance for *Legionella* from 2000 through 2002. All specimens were shipped to the Special Pathogens Laboratory at the Veterans Affairs Pittsburgh Medical Center.

RESULTS. *Legionella pneumophila* and *Legionella anisa* were isolated from 14 (70%) of 20 hospital water systems. Of 676 environmental samples, 198 (29%) were positive for *Legionella* species. High-level colonization of the water system (30% or more of the distal outlets were positive for *L. pneumophila*) was demonstrated for 6 (43%) of the 14 hospitals with positive findings. *L. pneumophila* serogroup 1 was detected in 5 of these 6 hospitals, whereas 1 hospital was colonized with *L. pneumophila* serogroup 5. A total of 633 patients were evaluated for *Legionella* pneumonia from 12 (60%) of the 20 hospitals: 377 by urinary antigen testing and 577 by sputum culture. Hospital-acquired *Legionella* pneumonia was identified in 4 hospitals, all of which were hospitals with *L. pneumophila* serogroup 1 found in 30% or more of the distal outlets. No cases of disease due to other serogroups or species (*L. anisa*) were identified.

CONCLUSION. Environmental monitoring followed by clinical surveillance was successful in uncovering previously unrecognized cases of hospital-acquired *Legionella* pneumonia.

Infect Control Hosp Epidemiol 2007; 28:818-824

Among cases of *Legionella* pneumonia that were reported to the Centers for Disease Control and Prevention (CDC) from 1980 to 1998, the percentage of cases identified as hospital-acquired ranged from 25% to 45%.[1] The hospital water system was identified as the source of these cases of *Legionella* pneumonia, most of which were caused by *Legionella pneumophila*.[2,3] Mortality associated with hospital-acquired *Legionella* pneumonia (28%) is approximately double the mortality for community-acquired cases (14%).[1]

The diagnosis of *Legionella* pneumonia cannot be made by

From the VA Pittsburgh Healthcare System (J.E.S., R.R.M., S.M., M.M.W.) and the University of Pittsburgh (J.E.S., R.R.M., S.M., M.M.W., V.L.Y.), Pittsburgh, and the Veterans Affairs Medical Center, Butler (K.S.), Pennsylvania; the William Beaumont Hospital, Royal Oak, Michigan (M.B.P., M.J.Z.); the Veterans Affairs Medical Center, Omaha, Nebraska (K.D., D.G., W.A., M.B.); the Southern Arizona Healthcare System, Tucson (T.W., S.L.C.); the Veterans Affairs Medical Center, Wilmington, Delaware (O.R., A.P.P.); the Louis Stokes Veterans Affairs Medical Center, Cleveland (C.T., E.C.E., C.J.D.), and the Veterans Affairs Medical Center, Dayton (D.M.), Ohio; the Stratton Veterans Affairs Medical Center, Albany, New York (M.E.R.); the Veterans Affairs Medical Center, Iowa City, Iowa (J.P.); the Veterans Affairs Medical Center, Gainesville, Florida (R.J., M.-H.N.); and the Veterans Affairs Palo Alto Health Care System, Palo Alto (G.O., M.H.), and the Veterans Affairs Medical Center, Long Beach (K.J.S), California. Members of the Legionella Study Group are listed at the end of the text.

Received August 29, 2006; accepted December 21, 2006; electronically published June 5, 2007.

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Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

Legionella IRB approval

Victor Yu <victorlyu@gmail.com> **Tue, Jul 15, 2008 at 2:23 PM**
To: "Holleman, Edith" <Edith.Holleman@mail.house.gov>, James Paul <James.Paul@mail.house.gov>
Cc: "Hammond, Tom" <Tom.Hammond@mail.house.gov>, Janet Stout <jes20micro@gmail.com>

Legionella IRB approval forms can be found on the website:
http://www.legionella.org/vaspl.asp
Click onto
Letters from Secretary Nicholson and Under-Secretary Feeley with rebuttals from Victor L. Yu and Janet E. Stout

http://www.legionella.org/vaspl/IRB%20Attachment-SPL.pdf

Note that the Legionella from VA hospitals participating in the VA Merit Review grant funded study were also destroyed..

Victor L Yu MD
Professor of Medicine
University of Pittsburgh
Pittsburgh, PA

Telephone:
Cell: 412-901-7707
Fax: 412-281-7445
Home: 412-343-7429
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The claims in all the communications are similar and can be summarized as follows:

"The results of this review indicated that the research funds were being used by the Special Pathogens Laboratory to conduct neither a research project, clinical services required by the VAPHS, or authorized work under a Memorandum of Understanding or contract."

Reply: All of the above alleged points are incorrect and we will rebut them with documentation. In contrast, please note that although the claims presented by Mr. Moreland are serious

MailMan message for STOUT,JANET B
Printed at PITTSBURGH.VA.GOV 14 Sep 98 10:41
Subj: R&D Committee Evaluation of 98/NISC/Stou-1 [#9232068] 14 Sep 98 09:47 66 Lines
From: MUDER,ROBERT R in 'IN' basket. Page 1

I received the R&D Committee's Evaluation of our proposal "Health Risk from Legionella in Hospital Water Systems." The review raised a number of excellent points, and Dr. Stout and I would like to thank the committee for their thoughtful review.

However, I have serious concerns about one point raised by the reviewer, and by the final action taken by the committee. The reviewer stated that informed consent would be required to use existing clinical information [illegible] specimens, and the final committee decision was to wait until we [illegible] a consent form to send it to SRS. This is problematic for [illegible] reasons:

[illegible] have been doing this type of reasearch for a number of years, [illegible] never had a requirement to obtain informed consent for the [illegible] use of existing patient data or microbiologic specimens. [illegible], the effort required to obtain informed consent would make such [illegible] research nearly impossible. In reconition of this, the [illegible] (in which this proposal is being submitted), not only does not [illegible] informed consent for this type of study, but specifically states [illegible] the following studies are exempt from IRB review:

"Research involving the collection or study of existing data, documents, records, pathologic specimens, or diagnostic specimens, if these sources are publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects." (PHS 398, p28)

exempt studies

Although the VA is not specifically bound by USPHS requirements, I question the necessity of imposing a standed that is much more stringent than what is universally accepted elsewhere in the federal research [illegible].

[illegible] agree that obtaining a separate urine specimen will require [illegible] consent. However, none [illegible] will be patients in this medical center, since [illegible] effective Legionella control in this facility for a number of [illegible] participating medical center will need to develop its own [illegible] obtaining consent for this. We have, in the grant, outlined [illegible] for verbal consent, but each participating center will need [illegible] decision on this. If they feel that written consent is [illegible] is almost certain that a local form will be used. Thus, there [illegible] reason to develop a form for this center.

[illegible] Finally, I do not believe that it is appropriate to defer submission of the proposal to SRS until we submit a consent form, given the reasons I have detailed above. In any event, are not such considerations the precise reason that the SRS conducts a separate and detailed review of proposals? We respectfully request that our proposal be forwarded to SRS without a consent form. We would be happy to make our arguments to that body, and will, of course, abide by their decision.

[illegible] this further with me, or with any member of

SPL Support of VA Researchers

Research Activities

1. As part of the VA IRB approved (NIH funded research through University of Pittsburgh), approximately 200 serum samples and ~ 100 isolates from transplant recipients have been saved. Freezer and refrigerator space needed to store these.

2. As part of the VA IRB approved (Industry funded aspergillosis study through VA), approximately 500 serum samples on transplant patients are saved. Freezer space is needed to store them at -70°C.

Clinical activities and patient care

1. As standard care, a pretransplant serum sample is saved on our liver transplant recipients. The purpose of this practice is that clinical situations often arise, such as an exposure to varicella zoster, donors with positive serologies for infectious agents, e.g., *Toxoplasma gondii*, endemic fungi, tuberculosis, etc that warrant knowledge of patients' pre-transplant exposure to these organisms. It is neither feasible nor cost-effective to test pre-transplant sera on liver transplant candidates for prior exposure to all potential pathogens. Testing sera as case by case situations warrant is appropriate and critical in the management of the recipient. The Pittsburgh VA currently performs about 50 transplants per year. .

2. Serum bactericidal and inhibitory titers as clinically indicated for management of patients with endocarditis or vertebral osteomyelitis.

3. Pulse field gel electrophoresis for strain typing as clinically warranted for individual patient management or suspected nosocomial outbreak. This need also falls in the domain of infection control.

Line 1 09:49:59 a.m. 08-29-2007 2/2

Department of Veterans Affairs

REPORT OF SUBCOMMITTEE ON HUMAN STUDIES

00/DRG/SING-1

Project/Program Title Prospective Assessment of Platelia Aspergillus Galactomannan for the Diagnosis of Aspergiliosis

Principal Investigator Nina Singh, MD

VAMC Pittsburgh, (UD), PA Review Date: 4/28/00

COMMITTEE FINDINGS

1. The information given in the Informed Consent under the Description of Research by Investigator is complete, accurate, and understandable to a research subject or surrogate who possesses standard reading and comprehension skills. ☒ YES ☐ NO

2. The informed consent is obtained by the principal investigator or a trained and supervised designate under suitable circumstances. ☒ YES ☐ NO

3. Every effort has been made to decrease risk to subject(s)? ☒ YES ☐ NO

4. The potential research benefits justify the risk to subject(s)? ☒ YES ☐ NO

5. If subject is incompetent and surrogate consent is obtained, have all of the following conditions been met: a) the research can't be done on competent subjects; b) there is no risk to the subject, or if risk exists the direct benefit to subject is substantially greater; c) If an incompetent subject resist, he/she will not have to participate; d) If there exists any question about the subject's competency, the basis for decision on competency has been fully described. ☒ YES ☐ NO

6. If the subject is paid, the payment is reasonable and commensurate with the subject's contribution. ☐ YES ☐ NO ☒ NA

7. Members of minority groups and women have been included in the study population whenever possible and scientifically desirable. ☒ YES ☐ NO

8. Comments: (Indicate if Expedited Review) This study is approved for the period of 5/18/00 to 4/28/01. Extension beyond 4/28/01 requires reapproval of the SHS. Any adverse effects must be reported to the SHS and the Research Office.

RECOMMENDATION: ☒ APPROVED ☐ DISAPPROVE/REVISE

SIGNATURE OF CHAIRMAN

DATE

688 6950 Line 1 06:43:24 p.m. 09-03-2008 2/3

Department of Veterans Affairs REPORT OF SUBCOMMITTEE ON HUMAN STUDIES

00/MISC/SING-1

Project/Program Title Staphylococcus Aureus Rectal Carriage and Association with Infections in Patients in Surgical Intensive Care Unit and Liver Unit

Principal Investigator Nina Singh, MD

VAMC Pittsburgh, (UD), PA Review Date: 1/26/01

WAIVER OF INFORMED CONSENT

COMMITTEE FINDINGS

1. The information given in the Informed Consent under the Description of Research by Investigator is complete, accurate, and understandable to a research subject or surrogate who possesses standard reading and comprehension skills. [X] YES [ ] NO

2. The informed consent is obtained by the principal investigator or a trained and supervised designate under suitable circumstances. [X] YES [ ] NO

3. Every effort has been made to decrease risk to subject(s)? [X] YES [ ] NO

4. The potential research benefits justify the risk to subject(s)? [X] YES [ ] NO

5. If subject is incompetent and surrogate consent is obtained, have all of the following conditions been met: a) the research can't be done on competent subjects; b) there is no risk to the subject, or if risk exists the direct benefit to subject is substantially greater; c) If an incompetent subject resist, he/she will not have to participate; d) If there exists any question about the subject's competency, the basis for decision on competency has been fully described. [X] YES [ ] NO

6. If the subject is paid, the payment is reasonable and commensurate with the subject's contribution. [ ] YES [ ] NO [X] NA

7. Members of minority groups and women have been included in the study population whenever possible and scientifically desirable. [X] YES [ ] NO

8. Comments: (Indicate if Expedited Review) This study is approved for the period of 2/7/01 to 1/26/02. Extension beyond 1/26/02 requires reapproval of the SHS. Any adverse effects must be reported to the SHS and the Research Office.

RECOMMENDATION: [X] APPROVED [ ] DISAPPROVE/REVISE

SIGNATURE OF CHAIRMAN Ali F. Sonel, M.D. DATE 2/7/01

Institutional Review Board (IRB)
VA Pittsburgh Healthcare System #646
University Drive • Pittsburgh, PA 15240

IRB APPROVAL - Continuing Review

Date: September 16, 2003
From: Ali F. Sonel, M.D., Chairperson
Investigator: Nina Singh, M.D.
Protocol: Cryptococcus Neoformans in Organ Transplant Recipients
ID: 00182 Prom#: N/A Protocol#: N/A

The following items were reviewed:

- Research Protocol (08/07/2003)
- Budget Page (08/07/2003)
- Conflict of Interest - Dr. Nina Singh (07/22/2003)
- Consent Form (08/29/2003)
- Continuing Review (08/07/2003)
- Education Certificate - Human Subjects Research Tr (08/25/2003)
- Listing of Authorized Rep's to Administer Informed (07/26/2003)

Expedited approval was granted on 08/27/2003 for a period of 12 months and will expire on 08/26/2004. Your Continuing Review is scheduled for 07/26/2004. This Expedited review will be reported to the fully convened Institutional Review Board (IRB) on 10/27/2003.

This Continuing Review was approved through the Expedited Review process.

Risk Assessment: MINIMAL; IRB Scrutiny: LOW (The risk assessment was made considering Social; Physical; Psychological; and Economic risk.)

SAE Reporting Level:
AE2 - All serious AEs that are possibly related and all unanticipated but not serious AEs that are at least possibly related to the study procedures need to be reported to the IRB using the current adverse event reporting form. AEs that are not study related should not be reported.

EXPEDITED Continuing Review categories:

No subjects have been enrolled and no additional risks have been identified.

Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two through eight of the categories published in the November 9, 1998

The Pittsburgh VAMC IRB is not connected with, has no authority over, and is

Institutional Review Board (IRB)
VA Pittsburgh Healthcare System #646
University Drive • Pittsburgh, PA 15240

IRB APPROVAL - Continuing Review

Date: July 26, 2003
From: Ali F. Sonel, M.D., Chairperson
Investigator: Nina Singh, M.D.
Protocol: Impact of Human Herpes Virus-6 on the Severity of Recurrent HCV Hepatitis in Liver Transplant Recipients.
ID: 00317 Prom#: N/A Protocol#: N/A

The following items were reviewed:

- Research Protocol (04/24/2003)
- Abstract (04/21/2003)
- Conflict of Interest - Dr. Singh (04/22/2003)
- Consent Form (07/15/2003)
- Continuing Review (04/21/2003)
- Memo regarding minority status of subjects (05/22/2003)
- Listing of Authorized Rep's to Administer Informed (07/29/2003)

Expedited approval was granted on 06/25/2003 for a period of 12 months and will expire on 06/24/2004. Your Continuing Review is scheduled for 03/22/2004. This expedited review will be reported to the fully convened Institutional Review Board (IRB) on 08/25/2003.

The following other committee reviews are scheduled:
Research & Development Committee [08/20/2003]

Approval by each of the following is required prior to study continuation:
Institutional Review Board (IRB)
Research & Development Committee

Approval for study continuation is contingent upon your compliance with the requirements of the Research Service for the conduct of studies involving human subjects.

The Pittsburgh VAMC IRB is not connected with, has no authority over, and is not responsible for human research conducted at any other institution, except where a Memorandum of Understanding specifies otherwise. Separate consent forms, initial reviews continuing reviews, amendments, and reporting of serious adverse events

Department of Veterans Affairs

REPORT OF SUBCOMMITTEE ON HUMAN STUDIES

95/MR/SING-1

Project/Program Title Human Herpesvirus-6 Infection in Liver Transplant Recipients

Principal Investigator Nina Singh, M.D.

VAMC Pittsburgh, (UD), PA Review Date 9/22/95

COMMITTEE FINDINGS:

1. The information given in the Informed Consent under the Description of Research by Investigator is complete, accurate, and understandable to a research subject or a surrogate who possesses standard reading and comprehension skills. [X] YES [ ] NO

2. The informed consent is obtained by the principal investigator or a trained and supervised designate under suitable circumstances. [X] YES [ ] NO

3. Every effort has been made to decrease risk to subject(s)? [X] YES [ ] NO

4. The potential research benefits justify the risk to subject(s)? [X] YES [ ] NO

5. If subject is incompetent and surrogate consent is obtained, have all of the following conditions been met: a) the research can't be done on competent subjects; b) there is no risk to the subject, or if risk exists the direct benefit to subject is substantially greater; c) if an incompetent subject resists, he will not have to participate; d) if there exists any question about the subject's competency, the basis for decision on competency has been fully described. [X] YES [ ] NO

6. If the subject is paid the payment is reasonable and commensurate with the subject's contribution. [ ] YES [ ] NO [X] NA

7. Comments: (Indicate if Expedited Review) This study is approved for the period of 10/31/95 to 10/31/96. Extension beyond 10/31/96 requires reapproval of the SHS. Any adverse effects must be reported to the SHS and the Research Office.

RECOMMENDATION: [X] APPROVE [ ] DISAPPROVE/REVISE

*All clinical studies are monitored by the SHS (IRB) as required by Federal Regulations.

SIGNATURE OF CHAIRMAN: RAOUL R. SALIP, M.D. DATE 10/31/95

1 Background and Overview by Dr. Stou

2 Destruction of the SPL Collection of Isolates and Specimens – the Petitio

3 Documents Related to the Request to Transfer the Collection

4 Procedure for Storing Bacterial in the Special Pathogens Laboratory

5 The Functions of the Special Pathogens Laboratory – Janet E. Stout, Ph.D. PD & Research Documents

6 Documentation of Legionella-related Isolates and Specimens

7 Examples of Use of the Collection and Requests by Scientists

8 Stout CV and Relevant Publications

Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

Inventory of destroyed specimens and microorganism of the VA Splecial Pathogens Lab

Victor Yu <victorlyu@gmail.com> **Wed, May 7, 2008 at 11:15 PM**
To: Janet Stout <jes20micro@gmail.com>
Cc: Sue Mietzner <smmietzner@yahoo.com>

Microroganisms - 8000

5000 Legionella
3000 Other bacteria, fungi

Patient sera - 3000

Legionella serologies
HIV

Patient specimens (urine, respratory tract) - Legionella

200

Victor L Yu MD
Professor of Medicine
University of Pittsburgh
Pittsburgh, PA

Telephone:
Cell: 412-901-7707
Fax: 412-281-7445
Home: 412-343-7429

---------- Forwarded message ----------
From: **Arthur Allen** <arthurallenw@aol.com>
Date: Mar 14, 2008 1:09 PM
Subject: thanks! couple other minor questions...
To: victorlyu@gmail.com

Dr. Yu,

You certainly have a lot of fans in the ID world. Drs. Bonnez (Rochester) and Relman (Stanford) among them.

Things I forgot to ask you:

Discarded Legionella Stock Collection

Record #	culture type	Company Name	source/pt.name	description	species name	sg	Sub type	Misc/pcu	frozen
14		CDC		WIGA-A110	L bozemanii				3/14/1980
15		CDC		A110-MI-15	L bozemanii				3/14/1980
16		CDC		A110-Ny-23	L dumoffii				3/14/1980
19		CDC			L pneumophila	1		Pontiac strain	3/14/1980
20		CDC			L pneumophila	1	Bellingham		3/14/1980
74		Presby UPMC						Non-existent	
75								Non-existent	
76								Non-existent	
77								Non-existent	
78								Non-existent	
79								Non-existent	
134		Presby UPMC		18B 40r NTP1	E. coli				8/10/1981
135		Presby UPMC		PBB 322	E. coli				8/10/1981
136		Presby UPMC		PAO2018	P. aeruginosa				8/10/1981
238		Mercy Hospital		Mercy isolate					11/1/1982
1137		Sewickley Hospital		eng HWT					6/18/1992
1140				stock #18	Sten. maltophila			PPA SAT+ PPA DFA-	4/23/2003
1253		University Drive VAMC		Jack's lab	S. pyrogenes				6/10/1993
1285		Janesville			L pneumophila	1			3
1548		Akron City Hosp		Isolate #3	L pneumophila	6			3/8/1996
1549		Akron City Hosp		Isolate #6	L pneumophila	1			3/8/1996
1551		Akron City Hosp		Isolate #14	L pneumophila	1	Bellingham		3/8/1996
1555		Akron City Hosp		Isolate #43	L pneumophila	7			3/8/1996
1716		ESBL			E. coli				3/4/1998
2503		Australian CDC		drying # 28861,					8/18/2001
2504		Australian CDC		drying # 28861,					8/18/2001
2505		Australian CDC		drying # 28862,					8/18/2001
2506		Australian CDC		drying # 28862,					8/18/2001
2507		Australian CDC		drying # 28863,					8/18/2001
2508		Australian CDC		drying # 28864,					8/18/2001
2509		Australian CDC		drying # 28864,					8/18/2001

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2510		Australian CDC		drying # 28865					8/18/2001
2511		Australian CDC		drying # 28866					8/18/2001
2512		Australian CDC		771152M,					8/18/2001
2513		Australian CDC		drying # 28885					8/18/2001
2514		Australian CDC		drying # 28886					8/18/2001
2515		Australian CDC		drying # 28887					8/18/2001
2516		Australian CDC		drying # 28888					8/18/2001
2588		Hospital		W4308	L pneumophila	1			1/7/2002
2759		University Drive VAMC		#60	S.aureus			MRSA	3/4/2003
2760		University Drive VAMC		#3369	S.aureus			MRSA	3/4/2003
2761		University Drive VAMC		#598	S.aureus			MRSA	3/4/2003
2762		University Drive VAMC		1769	S.aureus			MRSA	3/4/2003
2763		University Drive VAMC		# 1566	S.aureus			MRSA	3/4/2003
2764		University Drive VAMC		#24123	S.aureus			MRSA	3/4/2003
2765		University Drive VAMC		#568	S.aureus			MRSA	3/4/2003
2766		University Drive VAMC		#283	S.aureus			MRSA	3/4/2003
2767		University Drive VAMC		#112	S.aureus			MRSA	3/4/2003
3238		EICC		Building, 2.9092	L pneumophila			not 1-6, iso.1	3/17/2006
2	ATCC	ATCC		ATCC 33152	L pneumophila	1	Philadelphia	refrozen 3/13/98	3/14/1980
3	ATCC	ATCC		ATCC 33153	L pneumophila	1	Knoxville		3/14/1980
4	ATCC	ATCC		ATCC 33154	L pneumophila	2		Togus strain	3/14/1980
5	ATCC	ATCC		ATCC 33155	L pneumophila	3	Bloomington	Refrozen 3-13-98	3/14/1980
6	ATCC	ATCC		ATCC 33156	L pneumophila	4		Los Angeles strain	3/14/1980
7	ATCC	ATCC		ATCC 33215	L pneumophila	6		Chicago-2 strain	3/14/1980
11	ATCC	ATCC	Tatlock	ATCC 33218	L micdadei				3/14/1980
21	ATCC	ATCC	LS-13	ATCC 33297	L gormanii				4/7/1980
25	ATCC	ATCC	Tex-KL	ATCC 33279	L dumoffii				12/7/1981
43	ATCC	ATCC		ATCC 33216	L pneumophila	5		Dallas strain	1/19/1981
127	ATCC	ATCC		Phil1 (edge)	L pneumophila	1		Refreeze of record #2	4/16/1981

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Record #	Source Type	Company Name	Source Organism	Description	Genus Species		Subtype	Remarks	Date
211	ATCC	ATCC		Bactrol Disks	Ps. Aeruginosa				3/30/1990
212	ATCC	ATCC		ATCC# 14053	Candida albicans				3/30/1990
250	ATCC	ATCC			L. jordanis				1/13/1983
251	ATCC	ATCC			L. longbeacheae			Group 1	1/13/1983
252	ATCC	ATCC			L. longbeacheae			Group 2	1/13/1983
283	ATCC	ATCC			L. oakridgensis				4/22/1983
284	ATCC	ATCC			L.wadsworthi				4/22/1983
285	ATCC	ATCC			L. pneumophila	4	Los Angeles	(New)	4/22/1983
286	ATCC	ATCC			L. pneumophila	7	Chicago-8		4/22/1983
371	ATCC	ATCC			L. pneumophila	8	Concord 3		5/7/1984
372	ATCC	ATCC			L.sainthelensi				1/3/1990
480	ATCC	ATCC		ATCC #35072	L. feeleii			Restocked 07-07-89	4/29/1985
481	ATCC	ATCC		Serogroup 2	L. bozemanii	2			4/29/1985
677	ATCC	ATCC		ATCC 35250	L. hackelic				6/8/1987
678	ATCC	ATCC		ATCC 35299	L. parisiensis				6/8/1987
679	ATCC	ATCC		ATCC 35300	L. maceachernii			see 905	6/8/1987
680	ATCC	ATCC		ATCC 35304	L. rubrilucens			Restocked 1-3-90	6/8/1987
764	ATCC	ATCC		ATCC 43702	birminghamensis			restocked 1-3-90	1/27/1988
765	ATCC	ATCC		ATCC 35252	L. cherrii			restocked 1-3-90	1/27/1988
766	ATCC	ATCC		ATCC 43119	L. israelensis				1/27/1988
767	ATCC	ATCC		ATCC 35303	L. erythra			restocked 1-4-93	1/27/1988
768	ATCC	ATCC		ATCC 35298	jamestownensis				1/27/1988
769	ATCC	ATCC		ATCC 35302	L. steigerwaltii			restocked 1-3-90	1/27/1988
770	ATCC	ATCC		ATCC 35249	L. spiritensis			restocked 7-7-89	1/27/1988
782	ATCC	ATCC		ATCC 35301	L. santicrucis			restocked 1-3-90	3/14/1988
783	ATCC	ATCC		ATCC 35292	L. anisa			restocked 1-3-90	3/17/1988
803	ATCC	ATCC		ATCC 43753	L. cincinnatiensis				5/2/1988
905	ATCC	ATCC		#2	L. maceachernii				2/27/1989
906	ATCC	ATCC		ATCC 43877	L. moravica				3/6/1989
907	ATCC	ATCC		ATCC 43878	L. brunensis				3/6/1989
920	ATCC	ATCC		ATCC 35289	L. pneumophila	9			7/14/1989

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921	ATCC	ATCC		ATCC 43130	L. pneumophila	11			7/14/1989
922	ATCC	ATCC		ATCC 43290	L. pneumophila	12			7/14/1989
923	ATCC	ATCC		ATCC 43746	L. pneumophila	13			7/14/1989
924	ATCC	ATCC		ATCC 43703	L. pneumophila	14			7/14/1989
925	ATCC	ATCC		ATCC 35850	L.dumoffii			Non Browning	7/14/1989
926	ATCC	ATCC		ATCC 35849	L. feelii			Gp2	7/14/1989
931	ATCC	ATCC		ATCC 49180	L. tucsonensis				9
932	ATCC	ATCC		ATCC 35999	L. hackeliae			Group 2 Type A	1/1/1990
933	ATCC	ATCC		ATCC 35999	L. hackeliae			Group 2 Type B	1/1/1990
942	ATCC	ATCC		ATCC 43830	L. quinlivanii				2/9/1990
951	ATCC	ATCC		ATCC 35301	L. santicrucis			(A) room to 37C	6/25/1990
952	ATCC	ATCC		ATCC 35301	L. santicrucis			(B) room to room	6/25/1990
953	ATCC	ATCC		ATCC 43283	L. pneumophila	10			6/22/1990
954	ATCC	ATCC		ATCC 49322	L. sainthelensi			Group 2	6/22/1990
959	ATCC	ATCC		ATCC 29213	aureus				1/23/1991
967	ATCC	ATCC		ATCC 29212	faecalis				1/23/1991
968	ATCC	ATCC		ATCC 35218	E. coli				1/25/1991
1188	ATCC	ATCC		ATCC 49413	L. gratiana				2
1189	ATCC	ATCC		ATCC 49588	L. fairfieldensis				2
1191	ATCC	ATCC		ATCC 29213	aureus				2
1518	ATCC	ATCC		ATCC 29212	faecalis				11/8/1995
1519	ATCC	ATCC		ATCC 29213	S. aureus				11/8/1995
1520	ATCC	ATCC		ATCC 25922	E. coli				11/8/1995
1521	ATCC	ATCC		ATCC 27853	P. aeruginosa				11/8/1995
1626	ATCC	ATCC		ATCC 90028	C. albicans				9/16/1996
1627	ATCC	ATCC		ATCC 90029	C. albicans				9/16/1996
1628	ATCC	ATCC		ATCC 90030	C. glabrata				9/16/1996
1629	ATCC	ATCC		ATCC 90018	C. parapsilosis				9/16/1996
		ATCC		ATCC 35218	E. coli				3/6/1998
									3/6/1998

Discarded Legionella Stock Collection

Record #	Culture type	Prod/Company Name	source/p/name	Description	Species name	sg	Subtype	Misc	$frozen
1752	ATCC	ATCC		ATCC 17671	as mahophila			Xanthomonas	3/28/1998
1754	ATCC	ATCC		ATCC 13883	K. pneumoniae				5/7/1998
1957	ATCC	ATCC		ATCC #29213	S. aureus				11/5/1998
1962	ATCC	ATCC		ATCC #35545	L. bozemanii	2		restock of #481	8
1963	ATCC	ATCC	LS-13	ATCC 33297	L. gormanii			restock of #21	8
2047	ATCC	ATCC		ATCC #25922	E. coli				5/7/1999
2048	ATCC	ATCC		ATCC #29213	S. aureus				5/7/1999
2213	ATCC	ATCC			Campy. Jejuni			for serology Ag	5/19/2000
2232	ATCC	ATCC		ATCC 22853	Ps. Aeruginosa			for PF agar QC	6/30/2000
2233	ATCC	ATCC		ATCC 49271	Ps. Fluorescens			Binax	6/30/2000
2243	ATCC	ATCC	ATCC 700698	hetero.susp.	Staph. Aureus			2 -70 degree vials	7/27/2000
2244	ATCC	ATCC	ATCC 700699	resist;vanco	Staph. Aureus			vials frozen	7/27/2000
2410	ATCC	ATCC	49619	MICs	S. pneumoniae				3/22/2001
2440	ATCC	ATCC	700904	resistant RF -	S. pneumoniae	19	A	Pen=4mcg/ml	5/23/2001
2441	ATCC	ATCC	49619	QC strain	S.pneumoniae	19	F	from ATCC	5/23/2001
2547	ATCC	ATCC		ATCC 27863	P. aeruginosa			for media QC	11/9/2001
2769	ATCC	Spec Path Lab		ATCC#	S.epidermis			VANESSA'S PROJECT	3/5/2003
2859	ATCC	ATCC		ATCC 43106	L pneumophila	1	Allentown 1		8/10/2003
2860	ATCC	ATCC		ATCC 46109	L pneumophila	1	Olda		8/10/2003
2861	ATCC	ATCC		subsp.pneumop	L pneumophila	1	Bellingham		8/10/2003
2902	ATCC	ATCC		ATCC 32656	other			multivorum	10/3/2003
2903	ATCC	ATCC		ATCC 35654	other			Aeromonas hydrophil	10/3/2003
2904	ATCC	ATCC		ATCC 35655	other			Alcaligenes faecalis	10/3/2003
3132	ATCC	University Drive VAMC		#700603;	K. pneumoniae			ESBL+	6/28/2005
3222	ATCC	Spec Path Lab		for CCVC QC	C. neoformans			From Jack	1/13/2006
3241	ATCC	BD/BBL		P2 from	L pneumophila	1		for Media QC	3/29/2006
3248	ATCC	Remel		P2 from Culti-	L pneumophila	1			4/11/2003
1	Clinical	University Drive VAMC	Co10		L pneumophila	1			3/14/1980
8	Clinical	Presby UPMC	EK		L. micdadei				3/14/1980
9	Clinical	Presby UPMC	LR		L. micdadei				3/14/1980
10	Clinical	CDC	PGH 12		L. micdadei				3/14/1980

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12	Clinical	CDC			L pneumophila	6		3/14/1980
13	Clinical	CDC			L pneumophila	6		3/14/1980
17	Clinical	University Drive VAMC	Wa5		L pneumophila	1	Allentown	3/14/1980
18	Clinical	University Drive VAMC	Pe3		L pneumophila	1		3/14/1980
22	Clinical	Presby UPMC	Cr		L. micdadei			4/7/1980
23	Clinical	Presby UPMC	La5		L. micdadei			4/7/1980
24	Clinical	Presby UPMC	La		L. micdadei			4/7/1980
28	Clinical	University Drive VAMC	Ev		L pneumophila			5/1/1980
32	Clinical	University Drive VAMC	Mc		L. micdadei			6/5/1980
33	Clinical	University Drive VAMC	Ma		L. micdadei			0
35	Clinical	University Drive VAMC	Ca11		L pneumophila	1		0
36	Clinical	University Drive VAMC	Ca11		L. micdadei			0
37	Clinical	University Drive VAMC	Gu3		L pneumophila	1		1/5/1981
38	Clinical	University Drive VAMC	Ru		L. micdadei			1/5/1981
39	Clinical	University Drive VAMC	Ro2		L pneumophila	1		1/5/1981
55	Clinical	University Drive VAMC	Ma5		L pneumophila	1		4/24/1981
56	Clinical	University Drive VAMC	Mi4		L pneumophila	1		4/24/1981
57	Clinical	University Drive VAMC	Co3		L pneumophila	1		4/24/1981
58	Clinical	University Drive VAMC	Fo		L pneumophila	1	Allentown	4/24/1981
59	Clinical	University Drive VAMC	Ca12		L pneumophila	1		4/24/1981
60	Clinical	University Drive VAMC	Rh2		L pneumophila	1		4/24/1981
61	Clinical	University Drive VAMC	Ca3		L pneumophila	1		4/24/1981
62	Clinical	University Drive VAMC	Ke2		L pneumophila	1		4/24/1981
63	Clinical	University Drive VAMC	Ke2		L pneumophila	1		4/24/1981
64	Clinical	University Drive VAMC	Wh		L pneumophila	1		4/27/1981
65	Clinical	University Drive VAMC	B		L pneumophila	1		4/27/1981
66	Clinical	University Drive VAMC	Sm2		L pneumophila	1		4/27/1981
68	Clinical	University Drive VAMC	My		L pneumophila	1		4/27/1981
69	Clinical	University Drive VAMC	Fe					

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Record #	Isolate Type	Company Name	Source/Pt. Name	Specimen	Species Name	Serogroup	Subtype	Modification	Date
72	Clinical	University Drive VAMC	Ha2		L pneumophila	1			5/1/1981
73	Clinical	Presby UPMC	Presby		L pneumophila	6			5/1/1981
125	Clinical	Presby UPMC	EK	1A non protub	L. micdadei			original #8	4/6/1981
128	Clinical	University Drive VAMC	Ho4	Lung	L pneumophila	6			7/27/1981
130	Clinical	University Drive VAMC	Va4	Lung	L pneumophila	1			7/15/1981
131	Clinical	Presby UPMC	EK	1B protub.	L. micdadei			@ original #8	4/6/1981
138	Clinical	University Drive VAMC	Ba10	Lung	L pneumophila	1			1
139	Clinical	University Drive VAMC	Ba10	Lung	L micdadei			protub	1
143	Clinical	University Drive VAMC	R	Sputum	L pneumophila	1			1/14/1982
144	Clinical	University Drive VAMC	Co6	Lung (Autopsy)	L pneumophila	1			1/14/1982
145	Clinical	University Drive VAMC	Fla	Sputum	L pneumophila	1			1/14/1982
146	Clinical	University Drive VAMC	Co6	Sputum	L pneumophila	1			1/14/1982
147	Clinical	University Drive VAMC	My	Fluid	L. micdadei				1/19/1982
195	Clinical	University Drive VAMC	Mi5	B2	L pneumophila	1			1/25/1982
203	Clinical	University Drive VAMC	Si	B2	L pneumophila	1			2/5/1982
208	Clinical	University Drive VAMC	Sh4	Sputum	L pneumophila	1			2/16/1982
214	Clinical	University Drive VAMC	Ya4	1640Ap82	L pneumophila	1			4/9/1982
223	Clinical	University Drive VAMC	Za	Lung - autopsy	L pneumophila	1			6/18/1982
245	Clinical	University Drive VAMC	Fi	Lung - autopsy	L pneumophila	1			2/21/1991
247	Clinical	University Drive VAMC	My	#1 small protub.	L. micdadei			originally #147	2
248	Clinical	University Drive VAMC	My	proturb.	L. micdadei			originally #147	2
249	Clinical	University Drive VAMC	My	#3 Non proturb	L. micdadei			originally #147	2
266	Clinical	University Drive VAMC	B	Sputum	L pneumophila	1			4/15/1983
288	Clinical	University Drive VAMC	E	Sputum	L pneumophila	1			4/29/1983
290	Clinical	University Drive VAMC	Ha3	Sputum	L pneumophila	1			4/29/1983
293	Clinical	Sewickley Valley	Hu	Rt. Branch	L pneumophila	1			5/27/1983
294	Clinical	Sewickley Valley	AH	Lt. Branch	L pneumophila	1			5/27/1983
295	Clinical	University Drive VAMC	Je	TTA	L pneumophila	1			9/16/1983
296	Clinical	University Drive VAMC	Tr1	Sputum (206)	L pneumophila	1			2/21/1991
297	Clinical	University Drive VAMC	Tr1	Lung (219)	L pneumophila	1			9/22/1983
298	Clinical	University Drive VAMC	Ch	Blood (854)	L pneumophila	1			9/20/1983

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302	Clinical	University Drive VAMC	Ya2	Nov 83)	L pneumophila	1			3
303	Clinical	University Drive VAMC	Ya2	83)	L pneumophila	1			3
304	Clinical	University Drive VAMC	Ya2	83)	L pneumophila	1			2/21/1991
314	Clinical	University Drive VAMC	Tu3	Sputum #309	L pneumophila	1			2/16/1984
315	Clinical	University Drive VAMC	JF	TTA #1623	L pneumophila	1			2/16/1984
316	Clinical	University Drive VAMC	BN	Sputum #1314	L pneumophila	1			2/16/1984
317	Clinical	Presby/E&E	Al	54111	L pneumophila	6			2/7/1984
318	Clinical	Presby/E&E	Al	53175	L pneumophila	6			2/7/1984
319	Clinical	Presby/E&E	Al	53180	L pneumophila	6			2/7/1984
320	Clinical	Presby/E&E	Al	53093	L pneumophila	6			2/7/1984
321	Clinical	Presby/E&E	Al	52878	L pneumophila	6			2/7/1984
322	Clinical	Central Medical	TG		L pneumophila	1			1/30/1984
323	Clinical	Central Medical	TG		L pneumophila	1	Benidorm	Type 1	2/7/1984
324	Clinical	Central Medical	TG		L pneumophila	1		Type 2	2/7/1984
325	Clinical	University Drive VAMC	Bo2	#397 Feb 84	L pneumophila	1			2/15/1984
326	Clinical	Hospital	Sk	Lung	L pneumophila	1			2/16/1984
327	Clinical	University Drive VAMC	Hi	Feb 84	L pneumophila	1			2/20/1984
328	Clinical	University Drive VAMC	Bu4	Feb 84	L pneumophila	1			2/22/1984
354	Clinical	University Drive VAMC	Tr4	Mar 84	L pneumophila	1			4/5/1984
387	Clinical	University Drive VAMC	St6	Sputum	L pneumophila	1			7/13/1984
388	Clinical	University Drive VAMC	Fa2	July 84	L pneumophila	1			7/25/1984
389	Clinical	University Drive VAMC	Fa2	July 84	L pneumophila	1			7/25/1984
390	Clinical	Sewickley Hospital	Ca5	Sputum	L pneumophila	1			7/25/1984
396	Clinical	University Drive VAMC	Ye	247 Aug 84	L pneumophila	1			8/10/1984
404	Clinical	University Drive VAMC	Ye	353 Aug 84	L pneumophila	1			8/17/1984
407	Clinical	University Drive VAMC	Bo1	Aug 84	L pneumophila	1			8/24/1984
408	Clinical	University Drive VAMC	Ki	Aug 84	L pneumophila	1			8/27/1984
414	Clinical	University Drive VAMC	Co4	Sept 84	L pneumophila	1			9/12/1984
[illegible]	[illegible]	[illegible]	Ke2	None given	L pneumophila	3			4

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Record #	Source Type	Facility Name	Source Pt Name	Description	Species	Serotype	Subtype	Lab Comments	Thawed
432	Clinical	Franklin Hospital	Fo2	C(130)	L pneumophila	4			1/25/1985
433	Clinical	Franklin Hospital	Fo2	(122)	L pneumophila	4			1/25/1985
440	Clinical	University Drive VAMC	Ed	Sputum 1756	L. micdadei				3/18/1985
447	Clinical	University Drive VAMC	Ba2	Sputum	? Legionella				3/22/1985
448	Clinical	University Drive VAMC	Ur	Sputum	L pneumophila	1			3/27/1985
449	Clinical	University Drive VAMC	Pr	Sputum	L pneumophila	2			4/1/1985
450	Clinical	Denver-1		patient isolate	L pneumophila	1			4/10/1985
451	Clinical	Denver-2		patient isolat	L pneumophila	1			4/10/1985
452	Clinical	Denver-3		patient isolate	L pneumophila	1			4/10/1985
461	Clinical	Univ of Iowa	Pr3	(Prince)	L pneumophila	1		04-19-83	4/19/1985
462	Clinical	Univ of Iowa	De5	(Denny)	L pneumophila	1		04-13-83	4/19/1985
463	Clinical	Univ of Iowa	Su3	(Sullivan)	L pneumophila	1		04-13-83	4/19/1985
464	Clinical	Univ of Iowa	Mi2	(Milefchik)	L pneumophila	1		04-13-83	4/19/1985
465	Clinical	Univ of Iowa	Da	(Darrah)	L pneumophila	1		04-13-83	4/22/1958
473	Clinical	Central Medical	PG	sputum	L pneumophila	3			4/25/1985
482	Clinical	Easton Hospital	RH-2		L pneumophila	1		mixed - 2 colony types	4/29/1985
483	Clinical	Easton Hospital	RH-4	patient	L pneumophila	1			4/29/1985
484	Clinical	Easton Hospital	RH-5	patient	L pneumophila	1			4/29/1985
485	Clinical	Easton Hospital	RH-6	patient	L pneumophila	1			4/29/1985
488	Clinical	Easton Hospital	RH-1	patient	L pneumophila	1			5/7/1985
489	Clinical	Easton Hospital	RH-2	type 1	L pneumophila	1			5/16/1985
490	Clinical	Easton Hospital	RH-2	type 2	L pneumophila	1			5/16/1985
491	Clinical	Buffalo VAMC	Patient #41		L pneumophila	1			5/20/1985
492	Clinical	Buffalo	Patient #114-1		L pneumophila	1			5/20/1985
493	Clinical	Buffalo	Patient No. 114-2		L pneumophila	1			5/20/1985
507	Clinical	Stanford	ET		L pneumophila	1	2		6/10/1985
510	Clinical	University Drive VAMC	CB	Sputum	L pneumophila	1		Restocked 12-11-90	6/17/1985
511	Clinical	Buffalo	Patient #7124		L pneumophila	1			6/17/1985
512	Clinical	Buffalo	Patient #7125		L pneumophila	1			6/17/1985
513	Clinical	Buffalo	Patient #255		L pneumophila	1			6/17/1985
514	Clinical	Buffalo	Patient #256		L pneumophila	1			6/17/1985

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520	Clinical	University Drive VAMC	CB		aureus				7/12/1985
523	Clinical	University Drive VAMC	Od	Sputum	? Legionella				8/2/1985
524	Clinical	University Drive VAMC	Pa	Sputum	L pneumophila	3			9/5/1985
525	Clinical	University Drive VAMC	Bu5	Sputum	L pneumophila	3			9/5/1985
526	Clinical	University Drive VAMC	An2	Sputum	L pneumophila	1			9/5/1985
527	Clinical	Franklin Medical Center	K4	Thoracent.	L pneumophila	4			9/11/1985
528	Clinical	Franklin Medical Center	K3	11164 Sputum	L pneumophila	4			9/11/1985
541	Clinical	Pago home		Kitchen sink	L pneumophila	3			5
544	Clinical	University Drive VAMC	Fi4	Sputum	? Legionella			Restocked 6-24-86	5
549	Clinical	University Drive VAMC	Sh5	Sputum	L pneumophila	1			12/6/1985
552	Clinical	Buffalo VAMC	Patient I	No. 804	L pneumophila	1			5
553	Clinical	Buffalo VAMC	Patient II	No. 880	L pneumophila	1			5
554	Clinical	Buffalo	Patient II	No. 887	L pneumophila	1			5
555	Clinical	Buffalo	Patient II	No. 888	L pneumophila	1			5
556	Clinical	Buffalo	Patient II	No. 5453	L pneumophila	1			5
557	Clinical	Buffalo	Patient II	No. 5452	L pneumophila	1			5
564	Clinical	Buffalo	Patient	No. 1061	L pneumophila	1			1/14/1986
565	Clinical	Buffalo	Patient	No. 1062	L pneumophila	1			1/14/1986
573	Clinical	University Drive VAMC	Hi2	86	Proteus			Pos DFA Lp 1	4/23/2003
578	Clinical	Albany VAMC	CP	1670	L pneumophila	4			3/14/1986
579	Clinical	Albany VAMC	CP	3181	L pneumophila	4			3/14/1986
580	Clinical	Albany VAMC	CP	4582	L pneumophila	4			3/14/1986
584	Clinical	University Drive VAMC	Ri	Sputum	L pneumophila	1			5/14/1986
592	Clinical	University Drive VAMC	Ra	Sputum	L pneumophila	1	Allentown		8/1/1986
593	Clinical	Presby UPMC	Ho3	Sputum	L pneumophila	1			8/11/1986
594	Clinical	Mercy Hospital	Mi3	280 Aug 86	L. micdadei			Restocked 12-3-92	8/14/1986
622	Clinical	Mercy Hospital	Ho		L pneumophila	1			9/15/1986
624	Clinical	Franklin Hospital	Es	Sputum	L. dumoffi				
630	Clinical	University Drive VAMC	[illegible]						

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655	Clinical	University Drive VAMC	Do2	Sputum	L pneumophila	1			1/26/1987
659	Clinical	University Drive VAMC	Do2	Bronch	L pneumophila	1	Allentown		2/17/1987
668	Clinical	Medical Center	Fe2		L pneumophila	1			5/4/1987
681	Clinical	University Drive VAMC	Ca10	306 June 87	L. dumoffi				6/11/1987
682	Clinical	Mercy Hospital	Be5	Sputum	L pneumophila	1			6/25/1987
683	Clinical	Mercy Hospital	YB	Sputum	L pneumophila	1		colony #1	6/29/1987
684	Clinical	Mercy Hospital	YB	sputum	L pneumophila	1		colony #2	6/29/1987
685	Clinical	Mercy Hospital	YB	sputum	L pneumophila	1		colony #4	6/29/1987
718	Clinical	Mercy Hospital	ID		L pneumophila	1			9/10/1987
720	Clinical	Franklin Medical Center	La3		L pneumophila	1			9/17/1987
740	Clinical	University Drive VAMC	Mu	7898 Sputum	L pneumophila	1	Allentown		7
741	Clinical	Franklin Medical Center	Cr2	Sputum	L pneumophila	1			7
742	Clinical	University Drive VAMC	Mo2	8081	L pneumophila	1	Allentown		7
747	Clinical	Iowa, Des Moines	K2	Bronch	L pneumophila	1		Comm. Acq. Pts	7
749	Clinical	University Drive VAMC	Le	10775 Sputum	L pneumophila	1	Philadelphia		12/8/1987
750	Clinical	University Drive VAMC	Co1	88-67 sputum	L pneumophila	1	Olda	A	1/18/1988
751	Clinical	University Drive VAMC	Co1	88-67 Sputum	L pneumophila	6		B	1/18/1988
775	Clinical	Franklin Medical Center	Ca7	Sputum	L pneumophila	1	Allentown		2/16/1988
784	Clinical	Mercy Hospital	Kkaa		L pneumophila	1	Olda		3/28/1988
785	Clinical	Mercy Hospital	Ka		L pneumophila	1			3/28/1988
792	Clinical	University Drive VAMC		Foster	L pneumophila	1	Allentown		4/13/1988
808	Clinical	University Drive VAMC	Wi	Sputum	L pneumophila	1			5/23/1988
809	Clinical	University Drive VAMC	Wi	Autopsy lung	L pneumophila	1			5/23/1988
810	Clinical	University Drive VAMC	Wi	Sputum	L pneumophila	1		?other type	5/23/1988
811	Clinical	University Drive VAMC	Wi	Autopsy Lung	L pneumophila	1		?other type	5/23/1988
834	Clinical	University Drive VAMC	Do3	Sputum	L pneumophila	1	Allentown		6/10/1988
838	Clinical	University Drive VAMC	Br3	Sputum	L pneumophila	1			6/23/1988
842	Clinical	University Drive VAMC	Me	Sputum	L pneumophila	1	Allentown		7/4/1988
843	Clinical	University Drive VAMC	Ku2	Bronch	L pneumophila	1	Allentown		7/4/1988
853	Clinical	University Drive VAMC	Rs	Sputum	L pneumophila	1	Philadelphia		7/22/1988
854	Clinical	University Drive VAMC	RS	colony #1	L pneumophila	1	Allentown		7/27/1988

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855	Clinical	University Drive VAMC	RS	colony #4	L pneumophila	1	Allentown		7/27/1988
858	Clinical	University Drive VAMC	Au	Sputum	L pneumophila	1	Philadelphia		8/5/1988
867	Clinical	Franklin Hospital	JP		L pneumophila	1			8/22/1988
882	Clinical	University Drive VAMC	G	Sputum	L pneumophila	6			8
887	Clinical	University Drive VAMC	Sp	sputum	L pneumophila	1	oxford		12/5/1988
888	Clinical	University Drive VAMC	Du2	sputum	L pneumophila	1	Philadelphia		12/5/1988
889	Clinical	University Drive VAMC	Du2	88-19935	L pneumophila	1	Philadelphia		12/5/1988
895	Clinical	Charleston WV	0		L pneumophila	6			1/23/1989
908	Clinical	Univ of Kansas	Wa7	#6645 = 2-2-89	L pneumophila	1			4/7/1989
909	Clinical	Univ of Kansas	Wa7	89	L pneumophila	1			4/7/1989
910	Clinical	University Drive VAMC	Ma10	sputum	L pneumophila	1	Bellingham		5/3/1989
917	Clinical	University Drive VAMC	Gr2	sputum	L pneumophila	1	Allentown		7/7/1989
918	Clinical	WVa Medical Center	K5	sputum	L pneumophila	1	Philadelphia		7/13/1989
919	Clinical	WVa Medical Center	K5	pleural fluid	L pneumophila	1			7/13/1989
928	Clinical	Base	Hp	biopsy (4-3-89)	L pneumophila	1			9
929	Clinical	Lackland AFB	RA	BAL (4-18-89)	L pneumophila	1			9
930	Clinical	Lackland AFB	Ba		L pneumophila	1			12/8/1989
934	Clinical	Lackland AFB		#25	L pneumophila	1			
935	Clinical	Lackland AFB		#46	L pneumophila	1			
936	Clinical	Lackland AFB		#47	L pneumophila	3			
937	Clinical	Lackland AFB		#53	L pneumophila	3			
938	Clinical	Lackland AFB		#64	L pneumophila	3			
939	Clinical	Lackland AFB		#80	L pneumophila	1			
940	Clinical	Lackland AFB		#81	L pneumophila	1			
941	Clinical	Lackland AFB		#82	L pneumophila	1			
944	Clinical	Presby UPMC	Gu4		L pneumophila	1			3/18/1990
950	Clinical	Presby UPMC	Da5		L pneumophila	1		1:1 glycerin	6/12/1990
952	Clinical	Montefiore Hospital	Sh5	CA-LD patient	L pneumophila	1			7/12/1990
				[illegible] Bronch	L pneumophila	1	Philadelphia	Brucella broth	9/13/1990
									9/18/1990

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specimen #	specimen type	collection/company Name	source/pt name	description	species name	serotype	place	city	miscellaneous info	frozen #
969	Clinical	University Drive VAMC	HR	fluid	L pneumophila	5				1/25/1991
970	Clinical	University Drive VAMC	De2	91-567 blood	L pneumophila	1	Philadelphia			1/25/1991
972	Clinical	University Drive VAMC	Rh	lung	L pneumophila	5				2/1/1991
973	Clinical	University Drive VAMC	Ka3	sputum	L pneumophila	3				3/15/1991
986	Clinical	University Drive VAMC	PC	sputum	L pneumophila	1	Allentown			5/9/1991
987	Clinical	West Penn Hospital	Sz2		L pneumophila	3				5/9/1991
1000	Clinical	University Drive VAMC	Ha5	91-7960	L pneumophila	1	Philadelphia			5/29/1991
1007	Clinical	University Drive VAMC	Sh		L pneumophila	1				7/10/1991
1010	Clinical	Hospital	Cu		L. longbeachae			Group 1		7/26/1991
1015	Clinical	University Drive VAMC	Bla	sputum	L pneumophila	1	Bellingham			8/15/1991
1016	Clinical	Presby UPMC	NN		L pneumophila	1	Benidorm			8/19/1991
1041	Clinical	Mercy Hospital	JJ		L pneumophila	1				9/12/1991
1052	Clinical	University Drive VAMC	Wa10	bronch	L pneumophila	1	Allentown			1
1053	Clinical	University Drive VAMC	Wa10	pleural	L. micdadei					1
1069	Clinical	Mercy Hospital	He2		L pneumophila	1				1
1073	Clinical	University Drive VAMC	De7	sputum	L. bozemanii					1
1075	Clinical	Mercy Hospital	Ya	LUL autopsy	L pneumophila	1	Philadelphia			3/18/1992
1089	Clinical	Mercy Hospital	Ve		L pneumophila	1				3/26/1992
1090	Clinical	University Drive VAMC	K	92-4054	L pneumophila	1	Olda			3/26/1992
1107	Clinical	Mercy Hospital	Ma4		L pneumophila	1				4/16/1992
1108	Clinical	University Drive VAMC	GT	sputum	L pneumophila	1	Allentown			4/22/1949
1124	Clinical	Mercy Hospital	Wa2		L pneumophila	1				5/24/1992
1125	Clinical	University Drive VAMC	WJ		L pneumophila	1	Allentown	colony A		6/1/1992
1126	Clinical	University Drive VAMC	WJ		L pneumophila	1		colony B		6/1/1992
1127	Clinical	University Drive VAMC	WJ		L pneumophila	1		colony C		6/1/1992
1128	Clinical	Mercy Hospital	SK		L pneumophila	1				6/18/1992
1151	Clinical	Mercy Hospital	EC		L pneumophila	1				9/14/1992
1152	Clinical	University Drive VAMC	Mc5	sputum	L pneumophila	1				10/9/1992
1182	Clinical	Albany VAMC	Va2	blood isolate	L pneumophila	1				2
1183	Clinical	Albany VAMC	Va1	sputum	L pneumophila	1				2
1208	Clinical	Mercy Hospital	Sz		L pneumophila	1	Olda			2/8/1993

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1221	Clinical	Mercy Hospital	Wo	sputum 6668	L pneumophila	1				3/16/1993
1235	Clinical	University Drive VAMC	Ro5	93-4961	L pneumophila	1	Philadelphia			4/12/1993
1240	Clinical	Mercy Hospital	Wl	42-12	L pneumophila	1				4/27/1993
1263	Clinical	University Drive VAMC	Po	Sputum	L pneumophila	1	Philadelphia			7/30/1993
1268	Clinical	University Drive VAMC	Va1	sputum	L pneumophila	1	Allentown			9/17/1993
1281	Clinical	Mercy Hospital	RD		L pneumophila	1	Olda			10/8/1993
1294	Clinical	University Drive VAMC	Sc	sputum	L pneumophila	1	Allentown			3
1297	Clinical	Forbes Regional	CP		L pneumophila	6?				11/2/1993
1302	Clinical	Northwest MC		increase	?Legionella					3
1303	Clinical	Mercy Hospital	Ma	sputum (530)	L pneumophila	1	Olda	A		12/8/1993
1304	Clinical	Mercy Hospital	Ma	sputum (555)	L pneumophila	1	Olda	B		12/8/1993
1306	Clinical	Mercy Hospital	AG		L pneumophila	1	Olda			12/9/1993
1320	Clinical	Hospital	Cla		L pneumophila	1	Philadelphia			3
1321	Clinical	Westmoreland Hospital	Do		L pneumophila	1	Philadelphia			3
1333	Clinical	University Drive VAMC	St5	sputum	L pneumophila	1	Philadelphia			3/7/1994
1349	Clinical	University Drive VAMC	Go	sputum	L pneumophila	1	Philadelphia			4/22/1994
1358	Clinical	St. Clair Hospital	Jo	sputum	L pneumophila	5				6/9/1994
1359	Clinical	St. Margaret's Hospital	Ko	sputum	L pneumophila	1	4032E			6/28/1994
1360	Clinical	Mercy Providence	We2	3548	L pneumophila	1	Knoxville			7/8/1994
1361	Clinical	Mercy Providence	We2	18936	L pneumophila	1	03OE			7/8/1994
1364	Clinical	University Drive VAMC	St4	sputum	L pneumophila	1	Allentown			7/8/1994
1365	Clinical	University Drive VAMC	Br	sputum	L pneumophila	1	Philadelphia			7/8/1994
1366	Clinical	St. Margaret's Hospital	Pr2	Pl. fluid	L pneumophila	1	Oxford			7/8/1994
1383	Clinical	St. Margaret's Hospital	H	Bal (94-112)	L pneumophila	1	Olda	A		8/12/1994
1384	Clinical	St. Margaret's Hospital	H	Bal (94-112)	L pneumophila	1	Olda	B		8/12/1994
1390	Clinical	University Drive VAMC	St2	sputum	L pneumophila	1				9/16/1994
1391	Clinical	Mercy Hospital	SJ		L pneumophila	1	Allentown			4
1392	Clinical	St. Clair Hospital	RK		L pneumophila	5				4
1393	Clinical	[illegible]	[illegible]							

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Record #	Clinical/Type	Company Name	Source Initials	Sample Code	Species Name	Serg #	Sub Type	Comments	Date Received
1416	Clinical	University Drive VAMC	HW	95-655 sputum	L pneumophila	5			1/20/1995
1421	Clinical	St. Margaret's Hospital	OS		L pneumophila	1		large colony type	3/20/1995
1422	Clinical	St. Margaret's Hospital	OS		L pneumophila	1		small colony type	3/20/1995
1423	Clinical	St. Margaret's Hospital	OS		L pneumophila	1		3rd colony type	3/20/1995
1427	Clinical	Mercy Providence	LZ		L pneumophila	1			4/26/1995
1488	Clinical	Sewickley Hospital	Pr5		L pneumophila	1	Philadelphia		9/1/1995
1489	Clinical	Summerspill	Ba8		L pneumophila			not 1-7	9/1/1995
1490	Clinical	Sewickley Hospital	Mc7		L pneumophila	1	Philadelphia		9/1/1995
1511	Clinical	University Drive VAMC	CB		L pneumophila	1	Allentown		11/3/1995
1512	Clinical	University Drive VAMC	CB		L pneumophila	1	Allentown		11/3/1995
1513	Clinical	University Drive VAMC	CB		L pneumophila	1	Allentown		11/3/1995
1514	Clinical	University Drive VAMC	CB		L pneumophila	1	Allentown		11/5/1995
1515	Clinical	University Drive VAMC	CB		L pneumophila	1	Allentown		11/5/1995
1522	Clinical	West Penn Hospital	Ya3		L pneumophila	5			5
1523	Clinical	Jefferson Hospital	DZ		L pneumophila	1	Olda		5
1524	Clinical	Hospital	Fi3		L pneumophila	4			5
1550	Clinical	Akron City Hosp		Isolate #9	L pneumophila	1	Bellingham		3/8/1996
1552	Clinical	Akron City Hosp		Isolate #54	L pneumophila	1	Benidorm		3/8/1996
1553	Clinical	Akron City Hosp		Isolate #55	L pneumophila	1	Philadelphia		3/8/1996
1557	Clinical	West Penn Hospital	Gu	sputum 5470	L pneumophila	1	Olda		3/21/1996
1558	Clinical	University Drive VAMC	Bu3		T. glabrata			not FLU	3/29/1996
1570	Clinical	Sewickley Hospital	Ba5		L. bozemanii				4/18/1996
1573	Clinical	University Drive VAMC			C. tropicalis			PAV/PAC+/Aniso-Flu -	4/18/1996
1574	Clinical	University Drive VAMC	St3		P. aeruginosa				5/2/1996
1575	Clinical	University Drive VAMC	St3		yeast				5/2/1996
1576	Clinical	McKeesport Hospital	Ca9		L pneumophila	1	Olda		5/8/1996
1577	Clinical	McKeesport Hospital	Ca9		L pneumophila	1	Olda		5/8/1996
1578	Clinical	McKeesport Hospital	Ca9		L pneumophila	1			5/8/1996
1584	Clinical	Hospital	MK	315818	L pneumophila	1		Lp4	6/14/1996
1585	Clinical	Jefferson Hospital	RM	Bactec bottle	L pneumophila	5			6/21/1996
1586	Clinical	St. Margaret's Hospital	BB	2066)	L pneumophila	1	Olda		6/24/1996

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1592	Clinical	Aspinwall VAMC	HF		L pneumophila	1	Olda		7/21/1996
1599	Clinical	University Drive VAMC	Ma8		L pneumophila	1	Philadelphia		7/23/1996
1600	Clinical	University Drive VAMC	Ma8		L pneumophila	1	Philadelphia		7/23/1996
1601	Clinical	Sewickley Hospital	Ko2	#763804	L pneumophila	1	Philadelphia		7/23/1996
1615	Clinical	West Penn Hospital	LR	30-96-83	L pneumophila	1	Allentown	Litchfield Towers	8/22/1996
1616	Clinical	West Penn Hospital	Da2	89-17-59	L pneumophila	1	Allentown	Litchfield Towers	8/22/1996
1617	Clinical	Sewickley Hospital	BD	785402	L pneumophila	1	Knoxville		8/22/1996
1619	Clinical	University Drive VAMC	Sh3	9424	C. tropicalis			Yeast PAV/PAC + Fluc -	8/30/1996
1630	Clinical	University Drive VAMC	RD	col #1	L pneumophila	1	Allentown		11/1/1996
1631	Clinical	University Drive VAMC	RD	col #2	L pneumophila	1	Allentown		11/1/1996
1632	Clinical	University Drive VAMC	RZ	direct	L pneumophila	1	Allentown		11/1/1996
1633	Clinical	University Drive VAMC	RZ		L pneumophila	1	Allentown	PAV-2 #1	11/1/1996
1634	Clinical	University Drive VAMC	RZ		L pneumophila	1	Allentown	PAV #2	11/1/1996
1639	Clinical	Akron City Hosp	So3		L pneumophila	1	Allentown		11/1/1996
1641	Clinical	Sewickley Hospital	Mc6		L pneumophila	1	Philadelphia		11/1/1996
1642	Clinical	Hospital	Mi3		L pneumophila	1	Benidorm		11/1/1996
1644	Clinical	Ortho-McNeil	CAPS-018 study	JTA 01053	L. feelei				6
1645	Clinical	St. Clair Hospital	JS	H4318	L pneumophila	4		DFA +	6
1646	Clinical	Ortho-McNeil	CAPS-018 study	B-P 28008	?sp				2/13/1997
1647	Clinical	University Drive VAMC	pt JHG 19019		L pneumophila	1		col #1	2/28/1997
1648	Clinical	RWJ CAP study	JHG 19019	investigator	L pneumophila	1	Philadelphia	col #2	2/28/1997
1649	Clinical	University Drive VAMC	Ro3	Cap	L pneumophila	3			3/14/1996
1650	Clinical	University Drive VAMC	09011		legionella like				3/14/1996
1651	Clinical	Jefferson Hospital	Co2		L pneumophila	1			3/29/1997
1652	Clinical	University Drive VAMC	Ro3	#4474 (3-28)	L pneumophila	3		post-cipro	4/23/1997
1653	Clinical	New Zealand		93-188	L. longbeachae	1		from A. Cherescki	5/27/1997
1658	Clinical	Jefferson Hospital	Ha6		L pneumophila	1			6/13/1997
1663	Clinical	Memorial Hospital	Ke4	S97-572	L pneumophila	1			7/31/1997
				S97-578	L pneumophila	1			7/31/1997

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Record #	Isolate type	Company Name	Source/Claim #	Description	Species Name	Sp	Isolate type	Misc. Info	Date
1687	Clinical	Joly	Quebec pt		L pneumophila	1	Olda		11/2/1997
1696	Clinical	Aspinwall VAMC	Ni	sputum 19761	L pneumophila	1		PAV-2	7
1697	Clinical	Aspinwall VAMC	Ni	sputum 19761	L pneumophila	1		PAV-2	7
1698	Clinical	Aspinwall VAMC	Ni	sputum 19761	L pneumophila	1		PAC	7
1700	Clinical	University Drive VAMC	Os	CXT	bacillus			M-Tech species DFA 24	
1708	Clinical	Cox Health System	CD	wash	L pneumophila	1	Allentown		2/5/1998
1709	Clinical	Cox Health System		wash	L pneumophila	1			2/5/1998
1713	Clinical	Geisinger	WW	65 AICU	L pneumophila	1			2/19/1998
1714	Clinical	RWJ CAP study	HV	1-22-98	L pneumophila	1			2/24/1998
1717	Clinical	University Drive VAMC	F	#4143 urine	K. pneumoniae				3/5/1998
1718	Clinical	University Drive VAMC	Wa8	#3630 hand	K. pneumoniae				3/5/1998
1719	Clinical	University Drive VAMC	Pi2	#3476 blood	E. coli				3/5/1998
1720	Clinical	University Drive VAMC	Sn	#2915 blood	E. coli				3/5/1998
1721	Clinical	University Drive VAMC	Me2	#3679 feces	E. coli				3/5/1998
1722	Clinical	University Drive VAMC	Me2	#3679 feces	K. pneumoniae				3/5/1998
1723	Clinical	University Drive VAMC	Va3	#3957 feces	K. pneumoniae				3/5/1998
1724	Clinical	University Drive VAMC	Mc6	#3684 feces	E. coli				3/5/1998
1725	Clinical	University Drive VAMC	Pi2	#3683 feces	E. coli				3/5/1998
1726	Clinical	University Drive VAMC	Ay	#3741 feces	E. coli				3/5/1998
1753	Clinical	University Drive VAMC		enterococcus	Enterococcus			Beta +ve on horse blood	4/27/1998
1755	Clinical	University Drive VAMC	DM	(59) blood	Klebsiella "A"				5/7/1998
1756	Clinical	University Drive VAMC	DM	(60) blood	Klebsiella "B"				5/7/1998
1757	Clinical	University Drive VAMC	De3	(439) 338219	Klebsiella				5/7/1998
1758	Clinical	University Drive VAMC	Ar2	(438) 285547	Klebsiella				5/7/1998
1759	Clinical	University Drive VAMC	As	(441) 335463	Klebsiella				5/7/1998
1760	Clinical	University Drive VAMC	DQ	(442) 302050	Klebsiella				5/7/1998
1761	Clinical	University Drive VAMC	AB-2	(444) 299509	Klebsiella				5/7/1998
1762	Clinical	University Drive VAMC	EA	(447) 307409	Klebsiella				5/7/1998
1763	Clinical	University Drive VAMC	MS	(449) 336513	Klebsiella				5/7/1998
1764	Clinical	University Drive VAMC	CS	(440) 360114	Klebsiella				5/7/1998
1765	Clinical	University Drive VAMC	WM	(111) 97-36	Klebsiella				5/7/1998

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1766	Clinical	University Drive VAMC	WM	(126) 157-22	Klebsiella				5/7/1998
1767	Clinical	University Drive VAMC	WM	(131) 157-23	Klebsiella				5/7/1998
1768	Clinical	University Drive VAMC	PC	(140) 133-63	Klebsiella				5/7/1998
1769	Clinical	University Drive VAMC	PC	(157) 133-45	Klebsiella				5/7/1998
1770	Clinical	University Drive VAMC	CH	(146) 133-56	Klebsiella				5/7/1998
1771	Clinical	University Drive VAMC	CH	(148) 133-53	Klebsiella				5/7/1998
1772	Clinical	University Drive VAMC	KA	96B13513,	Klebsiella				5/7/1998
1773	Clinical	University Drive VAMC	GC	M.J.U.	Klebsiella				5/7/1998
1774	Clinical	University Drive VAMC	JR	95B10601,	Klebsiella				5/7/1998
1775	Clinical	University Drive VAMC	BC	blood	Klebsiella				5/7/1998
1776	Clinical	University Drive VAMC	Wa4	blood	Klebsiella				5/7/1998
1777	Clinical	University Drive VAMC	Bc	blood	Klebsiella				5/7/1998
1778	Clinical	University Drive VAMC	BC	blood	Klebsiella				5/7/1998
1779	Clinical	University Drive VAMC	BC	blood	Klebsiella				5/7/1998
1780	Clinical	University Drive VAMC	BC	blood	Klebsiella				5/7/1998
1781	Clinical	University Drive VAMC	Wa4	blood	Klebsiella				5/7/1998
1782	Clinical	University Drive VAMC		(335) 1910538	Klebsiella				5/7/1998
1783	Clinical	University Drive VAMC		(303) 497166	Klebsiella				5/7/1998
1784	Clinical	University Drive VAMC		(309) 5396064	Klebsiella				5/7/1998
1786	Clinical	University Drive VAMC	Po2	sputum	L pneumophila	1			5/12/1998
1787	Clinical	University Drive VAMC	JJ	(collected	Xanthomonas				3/19/1998
1788	Clinical	University Drive VAMC	Sh2	(collected	Xanthomonas				3/19/1998
1789	Clinical	University Drive VAMC	Ca6	12/06/96	Xanthomonas				3/19/1998
1790	Clinical	University Drive VAMC	An	12/7/96	Xanthomonas				3/19/1998
1791	Clinical	University Drive VAMC	WM	collected 2/6/97	Xanthomonas				3/19/1998
1792	Clinical	University Drive VAMC	Be4	collected	Xanthomonas				3/19/1998
1793	Clinical	University Drive VAMC	La2	collected	Xanthomonas				3/19/1998
1794	Clinical	University Drive VAMC	RG	collected	Xanthomonas				3/19/1998
1795	Clinical	University Drive VAMC	GR	wash collected	Xanthomonas				

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Record #	Culture Type	Company Name	Source	Strain	Species	Serotype	Subtype	Comments	Date
1812	Clinical	University Drive VAMC	ID #1281	study, #9 IV	K. pneumoniae			from Dr. Casellas	5/27/1998
1813	Clinical	University Drive VAMC	ID #1337	study, #10	K. pneumoniae			from Dr. Casellas	5/27/1998
1814	Clinical	University Drive VAMC	ID #20648	study, #11,	K. pneumoniae			from Dr. Casellas	5/27/1998
1815	Clinical	University Drive VAMC	ID #1	study, #16,	K. pneumoniae			from Dr. Klugman	5/27/1998
1816	Clinical	University Drive VAMC		study, #24,	K. pneumoniae			from South Africa	5/27/1998
1817	Clinical	University Drive VAMC		study, #25,	K. pneumoniae			from South Africa	5/27/1998
1818	Clinical	University Drive VAMC		study, #28,	K. pneumoniae				5/27/1998
1819	Clinical	University Drive VAMC		study, #31,	K. pneumoniae			from South Africa	5/27/1998
1820	Clinical	University Drive VAMC		study, #62,	K. pneumoniae			from South Africa	5/27/1998
1821	Clinical	University Drive VAMC		study, #71,	K. pneumoniae			from South Africa	5/27/1998
1822	Clinical	University Drive VAMC		study, #99, pus	K. pneumoniae			from South Africa	5/27/1998
1823	Clinical	University Drive VAMC		study, #163	K. pneumoniae			from Belgium	5/27/1998
1824	Clinical	University Drive VAMC		study, #164,	K. pneumoniae			from Belgium	5/27/1998
1825	Clinical	University Drive VAMC		study, #165,	K. pneumoniae			from Belgium	5/27/1998
1826	Clinical	University Drive VAMC		study, #166,	K. pneumoniae			from Belgium	5/27/1998
1827	Clinical	University Drive VAMC		study, #168,	K. pneumoniae			from Belgium	5/27/1998
1828	Clinical	University Drive VAMC		study, #172,	K. pneumoniae			from Belgium	5/27/1998
1829	Clinical	University Drive VAMC		study, #180,	K. pneumoniae			from Belgium	5/27/1998
1830	Clinical	University Drive VAMC		study, #181,	K. pneumoniae			from San Lucas	5/27/1998
1831	Clinical	University Drive VAMC		study, #182,	K. pneumoniae			from San Lucas	5/27/1998
1832	Clinical	University Drive VAMC		study, #183,	K. pneumoniae			from San Lucas	5/27/1998
1833	Clinical	University Drive VAMC		study, #252,	K. pneumoniae			from Dr. Lasellas	5/27/1998
1834	Clinical	University Drive VAMC		study, #253,	K. pneumoniae			from Dr. Lasellas	5/27/1998
1835	Clinical	University Drive VAMC		study, #255,	K. pneumoniae			from Dr Lasellas	5/27/1998
1836	Clinical	University Drive VAMC		study, #257,	K. pneumoniae			from Dr. Lasellas	5/27/1998
1837	Clinical	University Drive VAMC		study, #261,	K. pneumoniae			from Dr. Lasellas	5/27/1998
1838	Clinical	University Drive VAMC		study, #288,	K. pneumoniae			from Taiwan	5/27/1998
1839	Clinical	University Drive VAMC		study, #312,	K. pneumoniae			from Taiwan	5/27/1998
1840	Clinical	University Drive VAMC		study, #427,	K. pneumoniae			from Taiwan	5/27/1998
1862	Clinical	West Penn Hospital	Ba9	0000938487	L pneumophila	6			8/14/1998
1866	Clinical	Summersgill	We3	98B1199	L pneumophila	4			8/21/1998

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1891	Clinical	University Drive VAMC	MP	sputum	L pneumophila	1			10/1/1998
1892	Clinical	University Drive VAMC	MP	blood	L pneumophila	1			10/1/1998
1910	Clinical	Ortho McNeil	ZCR		L pneumophila	1		#1, Chicago, Ill	8
1911	Clinical	Ortho McNeil	ZCR		L pneumophila	1		#2, Chicago Ill	8
1918	Clinical	Shadyside Hospital	DB	M15792	S. aureus			colony 1	11/4/1998
1919	Clinical	Shadyside Hospital	DB	M15932	S. aureus				11/4/1998
1920	Clinical	Shadyside Hospital	JD	nose, M15513	CNS				11/4/1998
1921	Clinical	Shadyside Hospital	JD	M19838	CNS				11/4/1998
1922	Clinical	Shadyside Hospital	JD	M30030	CNS				11/4/1998
1923	Clinical	Shadyside Hospital	JD	M29479	CNS				11/4/1998
1924	Clinical	Shadyside Hospital	JD	M30030	CNS I				11/4/1998
1925	Clinical	Shadyside Hospital	MG	M29883	CNS				11/4/1998
1926	Clinical	Shadyside Hospital	MG	M30064	CNS				11/4/1998
1927	Clinical	Shadyside Hospital	MG	M30064	CNS I				11/4/1998
1928	Clinical	Shadyside Hospital	W-H1	M30231	S. aureus				11/4/1998
1929	Clinical	Shadyside Hospital	W-H1	M30887	S. aureus				11/4/1998
1930	Clinical	Shadyside Hospital	AH	M12772	CNS				11/4/1998
1931	Clinical	Shadyside Hospital	AH	M13670	CNS				11/4/1998
1932	Clinical	Shadyside Hospital	JI	M14390	CNS				11/4/1998
1933	Clinical	Shadyside Hospital	JI	M14462	CNS				11/4/1998
1934	Clinical	Shadyside Hospital	JI	M14390	S. aureus				11/4/1998
1935	Clinical	Shadyside Hospital	JI	M14462	S. aureus				11/4/1998
1936	Clinical	Shadyside Hospital	LJ	M19935	CNS				11/4/1998
1937	Clinical	Shadyside Hospital	LJ	Nose, M20762	CNS				11/4/1998
1938	Clinical	Shadyside Hospital	LJ	M19935	CNS I				11/4/1998
1939	Clinical	Shadyside Hospital	RK	M31747	CNS				11/4/1998
1940	Clinical	Shadyside Hospital	RK	M32069	CNS				11/4/1998
1941	Clinical	Shadyside Hospital	AS	M11380	CNS				11/4/1998
			LJP	M30808	CNS				11/4/1998

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Record #	culture type	Company Name	source pt name	description	species name	sg	sub type	Miscellaneous	Tr Date
1945	Clinical	Shadyside Hospital	DC	M11925	CNS I				11/5/1998
1946	Clinical	Shadyside Hospital	DC	M11925	CNS				11/5/1998
1947	Clinical	Shadyside Hospital	DC	M12001	CNS				11/5/1998
1948	Clinical	Shadyside Hospital	JD	M14735	CNS				11/5/1998
1949	Clinical	Shadyside Hospital	JD	Rhose, M30030	CNS II				11/5/1998
1950	Clinical	Shadyside Hospital	LJ	nose, M20762	CNS I				11/5/1998
1951	Clinical	Shadyside Hospital	AS	nasal, M11687	CNS				11/5/1998
1952	Clinical	Shadyside Hospital	HW	M30279	CNS				11/5/1998
1953	Clinical	Ortho McNeil	TDE	98C1974	L pneumophila	1		Peoria, Ill	11/5/1998
1958	Clinical	Penn State Geisinger	He	98B2159	L pneumophila	1			8
1959	Clinical	Ortho McNeil	DLH	98C2463	L pneumophila	1		Nashville, TN	8
1961	Clinical	Geisinger Health Sup.	F34		L pneumophila	1			8
1964	Clinical	West Penn Hospital	Wa9	98B2836	L pneumophila	1			8
1965	Clinical	Center	Tu1	98B2954	L pneumophila	1			1/5/1999
1966	Clinical	West Penn Hospital	AM	98B2957	L pneumophila	2			1/5/1999
1979	Clinical	Ortho McNeil	M-CT	99C3180	L pneumophila	4		Brooklyn NY	1/29/1999
1981	Clinical	Sewickley Valley	Wl2		L pneumophila	1			2/4/1999
1984	Clinical	University Drive VAMC	Le2	#31	MRSA				2/11/1999
1985	Clinical	University Drive VAMC	Co5	#32	MRSA				2/11/1999
1986	Clinical	University Drive VAMC	St7	#33	MRSA				2/11/1999
1987	Clinical	University Drive VAMC	Be2	#34	MRSA				2/11/1999
1988	Clinical	University Drive VAMC	Fe3	#35	MRSA				2/11/1999
1989	Clinical	University Drive VAMC	Mc2	#36	MRSA				2/11/1999
1990	Clinical	University Drive VAMC	Fa	#37	MRSA				2/11/1999
1991	Clinical	University Drive VAMC	We	#38	MRSA				2/11/1999
1992	Clinical	University Drive VAMC	Pr4	#39	MRSA				2/11/1999
1993	Clinical	University Drive VAMC	Ma3		MRSA				2/11/1999
1994	Clinical	University Drive VAMC	Ma3	#41	MRSA				2/11/1999
1995	Clinical	University Drive VAMC	G2	#42	MRSA				2/11/1999
1996	Clinical	University Drive VAMC	Ro4	#43	MRSA				2/11/1999
1997	Clinical	University Drive VAMC	Ho2	#44	MRSA				2/11/1999

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Record #	culture type	Company Name	source pt name	description	species name	sg	sub type	Miscellaneous	Tr Date
1998	Clinical	University Drive VAMC	Co8	#45	MRSA				2/11/1999
1999	Clinical	University Drive VAMC	Du3	#46	MRSA				2/11/1999
2000	Clinical	University Drive VAMC	Co9	#47	MRSA				2/11/1999
2001	Clinical	University Drive VAMC	Ha9	#48	MRSA				2/11/1999
2002	Clinical	Sewickley Valley	Ha7	99B3566	L pneumophila	1			2/19/1999
2008	Clinical	University Drive VAMC	Tr2	99B2736	L pneumophila	1		type 1	2/25/1999
2009	Clinical	University Drive VAMC	Tr2	99B2736	L pneumophila	1		type 2	2/25/1999
2010	Clinical	Associated Clinical Labs	Gi	(ST2760015,	L pneumophila	5			2/25/1999
2019	Clinical	Associated Clinical Labs	Gi	ST2858811	L pneumophila	5			3/10/1999
2028	Clinical	Center	Le3	X48045	L pneumophila	1			3/12/1999
2029	Clinical	Center	Ro	H20252	L pneumophila	1			3/12/1999
2030	Clinical	PA Dept of Health	Le3	PA99B1920	L pneumophila	1		from Geisinger	3/12/1999
2039	Clinical	Center	DM	779022	L pneumophila	1			4/1/1999
2040	Clinical	Sewickley Hospital	DW	99B4955	L pneumophila	1			4/12/1999
2059	Clinical	University Drive VAMC	RM	99B129	M. Fortuitum				5/24/1999
2064	Clinical	Johnstown PA	BS	99B5545	L pneumophila	1			6/28/1999
2114	Clinical	Ortho McNeil	PMM	culture,	L pneumophila	1		Columbia, SC	8/19/1999
2120	Clinical	University Drive VAMC	Pe	13545	S. aureus				8/17/1999
2121	Clinical	University Drive VAMC	Pe	13530	S. aureus				8/17/1999
2122	Clinical	University Drive VAMC	Sa4	14019	S. aureus				8/17/1999
2123	Clinical	University Drive VAMC	Bu2	99A6645	L pneumophila	1			9/10/1999
2124	Clinical	University Drive VAMC	Ha	99A6642	L pneumophila	1			9/16/1999
2127	Clinical	West Penn Hospital	Ro2	99B6883	L pneumophila	1			9/27/1999
2144	Clinical	University Drive VAMC	Sc3	99A7275	L pneumophila	1			9
2158	Clinical	Ortho McNeil	PB	99C8164	L pneumophila	1			9
2171	Clinical	Hospital	Ya5	00B8468	L pneumophila	1			1/14/2000
2174	Clinical	Wheeling Hospital	Co1	LLL 0B8696	L pneumophila	1			1/27/2000
2189	Clinical	Sewickley Hospital	Ma6	0B10447	BW fluores				3/23/2000

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Record #	Culture type	Hospital/Company Name	Specimen Name	Specimen Description	Species name	Serotype	Genotype	Miscellaneous	Date
2218	Clinical	Turner		(008915)	L pneumophila	1			5/30/2000
2224	Clinical	Hospital	Da3	pt# 820413	L pneumophila	1			6/9/2000
2225	Clinical	VGH-Taiwan		patient in CICU	L pneumophila	6		Taiwan isolate	6/25/2000
2245	Clinical	West Penn Hospital	MS		L pneumophila	1			8/15/2000
2246	Clinical	Westmoreland Hospital	Hr		L pneumophila	1			8/22/2000
2256	Clinical	University Drive VAMC	Ob	sputum 9/17/00	L pneumophila	1			9/27/2000
2257	Clinical	West Penn Hospital	Wa1	0000987390	L pneumophila	1			9/27/2000
2289	Clinical	University Drive VAMC		Haynes -0020	L pneumophila	1			12/6/2000
2290	Clinical	University Drive VAMC	Le	00 21201	P.aeruginosa				12/8/2000
2291	Clinical	University Drive VAMC	Ble	0021594	E.aerogenes				0
2331	Clinical	West Penn Hospital	Ba7		L pneumophila	1			2/19/2001
2336	Clinical	Sewickly Valley	He4		L pneumophila	1			2/26/2001
2337	Clinical	Mercy Hospital	Ar		L pneumophila			Not 1-6	2/26/2001
2340	Clinical	University Drive VAMC	Pa2	Blood 2806	Staph aureus			For PFGE	3/2/2001
2341	Clinical	University Drive VAMC	Pa2	Blood 14603	Staph aureus			For PFGE	3/2/2001
2343	Clinical	University Drive VAMC	Br2	nares	S.aureus				3/13/2001
2344	Clinical	University Drive VAMC	Br2	rectal	S.aureus				3/13/2001
2345	Clinical	University Drive VAMC	Br2	blood	S.aureus				3/13/2001
2346	Clinical	University Drive VAMC	Tu2	nares	S.aureus				3/13/2001
2347	Clinical	University Drive VAMC	Tu	rectal	S.aureus				3/13/2001
2348	Clinical	University Drive VAMC	Tu2	blood	S.aureus				3/13/2001
2349	Clinical	University Drive VAMC	Ma2	nares	S.aureus				3/13/2001
2350	Clinical	University Drive VAMC	Ma2	rectal	S.aureus				3/13/2001
2351	Clinical	University Drive VAMC	Ma2	blood	S.aureus				3/13/2001
2352	Clinical	University Drive VAMC	Ke	nares	S.aureus				3/13/2001
2353	Clinical	University Drive VAMC	Ke	rectal	S.aureus				3/13/2001
2354	Clinical	University Drive VAMC	Ke	blood	S.aureus				3/13/2001
2355	Clinical	University Drive VAMC	Th	nares	S.aureus				3/13/2001
2356	Clinical	University Drive VAMC	Th	rectal	S.aureus				3/13/2001
2357	Clinical	University Drive VAMC	Th	blood	S.aureus				3/13/2001
2358	Clinical	University Drive VAMC	Ba4	nares	S.aureus				3/14/2001

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Record #	Culture type	Hospital/Company Name	Specimen Name	Specimen Description	Species name	Serotype	Genotype	Miscellaneous	Date
2359	Clinical	University Drive VAMC	Ba4	rectal	S.aureus				3/14/2001
2360	Clinical	University Drive VAMC	Ba4	blood	S.aureus				3/14/2001
2361	Clinical	University Drive VAMC	Li	nares	S.aureus				3/14/2001
2362	Clinical	University Drive VAMC	Li	rectal	S.aureus				3/14/2001
2363	Clinical	University Drive VAMC	Li	blood	S.aureus				3/14/2001
2364	Clinical	University Drive VAMC	Ka5	nares	S.aureus				3/14/2001
2365	Clinical	University Drive VAMC	Ka5	rectal	S.aureus				3/14/2001
2366	Clinical	University Drive VAMC	Ka5	blood	S.aureus				3/14/2001
2367	Clinical	University Drive VAMC	Ki2	nares	S.aureus				3/14/2001
2368	Clinical	University Drive VAMC	Ki2	blood	S.aureus				3/14/2001
2369	Clinical	University Drive VAMC	Pa3	nares	S.aureus				3/14/2001
2370	Clinical	University Drive VAMC	Pa3	blood	S.aureus				3/14/2001
2371	Clinical	University Drive VAMC	F	nares	S.aureus				3/14/2001
2372	Clinical	University Drive VAMC	F	nares	S.aureus				3/14/2001
2373	Clinical	University Drive VAMC	F	blood	S.aureus				3/14/2001
2374	Clinical	University Drive VAMC	Th	nares	S.aureus				3/14/2001
2375	Clinical	University Drive VAMC	Th	nares	S.aureus				3/14/2001
2376	Clinical	University Drive VAMC	On	nares	S.aureus				3/14/2001
2377	Clinical	University Drive VAMC	On	nares	S.aureus				3/14/2001
2378	Clinical	University Drive VAMC	Ba6	nares	S.aureus				3/14/2001
2379	Clinical	University Drive VAMC	Ba6	nares	S.aureus				3/14/2001
2380	Clinical	University Drive VAMC	An	abd. wd.	S.aureus				3/14/2001
2381	Clinical	University Drive VAMC	An	nares	S.aureus				3/14/2001
2382	Clinical	University Drive VAMC	He3	nares	S.aureus				3/14/2001
2383	Clinical	University Drive VAMC	He3	nares	S.aureus				3/14/2001
2384	Clinical	University Drive VAMC	R	sputum	S.aureus				3/14/2001
2385	Clinical	University Drive VAMC	R	nares	S.aureus				3/14/2001
2386	Clinical	University Drive VAMC	Mc6	blood	S.aureus				3/15/2001
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	S.aureus				3/15/2001

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Record #	Strain Type	Company Name	Strain name	Description	Species name	Sg	Sub type	Miscellaneous	Strain
2393	Clinical	University Drive VAMC	Ga	Nares	S.aureus				3/15/2001
2394	Clinical	University Drive VAMC	Ga	blood	S.aureus				3/15/2001
2395	Clinical	University Drive VAMC	Zd	nares	S.aureus				3/15/2001
2396	Clinical	University Drive VAMC	Zd	blood	S.aureus				3/11/1950
2397	Clinical	University Drive VAMC	P2	nares	S.aureus				3/15/2001
2398	Clinical	University Drive VAMC	P2	abdom. Wd	S.aureus				3/15/2001
2399	Clinical	University Drive VAMC	Is	blood	S.aureus				3/15/2001
2400	Clinical	University Drive VAMC	Is	nares	S.aureus				3/15/2001
2401	Clinical	University Drive VAMC	Re	nares	S.aureus				3/15/2001
2402	Clinical	University Drive VAMC	Re	nares	S.aureus				3/15/2001
2403	Clinical	University Drive VAMC	Th2	number)	S.aureus				3/16/2001
2404	Clinical	University Drive VAMC	Th2	nares	S.aureus				3/16/2001
2405	Clinical	University Drive VAMC	Th2	nares	S.aureus				3/16/2001
2406	Clinical	University Drive VAMC	Wa3	blood	S.aureus				3/16/2001
2407	Clinical	University Drive VAMC	Wa	nares	S.aureus				3/16/2001
2408	Clinical	University Drive VAMC	Wa3	blood	S.aureus				3/16/2001
2409	Clinical	University Drive VAMC	Wa3	blood	S.aureus				3/16/2001
2413	Clinical	University Drive VAMC	P34	blood	S.aureus				4/4/2001
2414	Clinical	University Drive VAMC	Tr3	blood	S.aureus				4/4/2001
2415	Clinical	Associated Clinical Labs	K	Erie, PA	L pneumophila	6			4/5/2001
2424	Clinical	Albany VAMC	study #001	From resp.	GNR				4/20/2001
2425	Clinical	Albany VAMC	Pt. 001	study	L pneumophila	1			4/24/2001
2426	Clinical	US EPA			L pneumophila	1			5/8/2001
2427	Clinical	Albany VAMC	Pt 001	study	GNR			yel #1	5/8/2001
2429	Clinical	University Drive VAMC	Wl3	#1, 18912	K.pneumoniae				5/16/2001
2430	Clinical	University Drive VAMC	Pe2	#2,	K. pneumoniae				5/16/2001
2431	Clinical	University Drive VAMC	Pe2	#3, 22538	K. pneumoniae				5/16/2001
2432	Clinical	University Drive VAMC	Pe2	#4, 653	K. pneumoniae				5/16/2001
2433	Clinical	University Drive VAMC	Pe2	#5, 2100	K. pneumoniae				5/16/2001
2434	Clinical	University Drive VAMC	Sm3	#6, 6437	K. pneumoniae				5/16/2001
2435	Clinical	University Drive VAMC	Sm3	#7, 5448	K. pneumoniae				5/16/2001

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2444	Clinical	University Drive VAMC	Wa6	#1, nares	S.aureus				5/24/2001
2445	Clinical	University Drive VAMC	Wa	#2, rectal	S.aureus				5/24/2001
2446	Clinical	University Drive VAMC	Wa	#3, urine	S.aureus				5/24/2001
2447	Clinical	University Drive VAMC	St	#4, nares	S.aureus				5/24/2001
2448	Clinical	University Drive VAMC	St	#5,rectal	S.aureus				5/24/2001
2449	Clinical	University Drive VAMC	St	#6, sputum	S.aureus				5/24/2001
2450	Clinical	University Drive VAMC	Kr3	#7, nares	S.aureus				5/24/2001
2451	Clinical	University Drive VAMC	Kr3	#8, feces	S.aureus				5/24/2001
2452	Clinical	University Drive VAMC	Kr3	#9, sputum	S.aureus				5/24/2001
2453	Clinical	University Drive VAMC	Cr1	#10, blood	S.aureus				5/24/2001
2454	Clinical	University Drive VAMC	Cr1	#11, nares	S.aureus				5/24/2001
2455	Clinical	University Drive VAMC	Cr1	#12rectal	S.aureus				5/24/2001
2456	Clinical	University Drive VAMC	Wh	#13,sputum	S.aureus				5/24/2001
2457	Clinical	University Drive VAMC	Wh	#14, nares	S.aureus				5/24/2001
2458	Clinical	University Drive VAMC	Wh	#15, rectal	S.aureus				5/24/2001
2459	Clinical	University Drive VAMC	Do4	#16, sputum	S.aureus				5/24/2001
2460	Clinical	University Drive VAMC	Do4	#17, nares	S.aureus				5/24/2001
2461	Clinical	University Drive VAMC	Do4	#18, rectal	S.aureus				5/24/2001
2462	Clinical	University Drive VAMC	Fe	#19, nares	S.aureus				5/24/2001
2463	Clinical	University Drive VAMC	Fe	#20, feces	S.aureus				5/24/2001
2464	Clinical	University Drive VAMC	Fe	#21,sputum	S.aureus				5/24/2001
2465	Clinical	University Drive VAMC	Sm	#22,nares	S.aureus				5/24/2001
2466	Clinical	University Drive VAMC	Sm	#23rectal	S.aureus				5/24/2001
2467	Clinical	University Drive VAMC	Sm	#24,blood	S.aureus				5/24/2001
2468	Clinical	University Drive VAMC	Ha8	#25,nares	S.aureus				5/24/2001
2469	Clinical	University Drive VAMC	Ha8	#26, rectal	S.aureus				5/24/2001
2470	Clinical	University Drive VAMC	Ha8	#27, sternal wd	S.aureus				5/24/2001
2487	Clinical	ACHD	P	sputum	L pneumophila	1			6/20/2001
2491	Clinical	Orlin McNeil	[illegible]	[illegible]	[illegible]				[illegible]

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Record #	Culture type	Lab Company Name	Lab Card name	Specimen	Species Name	Sg-1 Sub type	Sg-1 Mab	Comments	Date
2517	Clinical	University Drive VAMC		alike	B. vesicularis			grows on BAP	8/18/2001
2537	Clinical	Mercy Hospital	MS	BAL lower lung	L longbeachese			confirmed by CDC	10/8/2001
2543	Clinical	Hospital	JL		L pneumophila	5			1
2546	Clinical	Mercy Hospital	Mu2		L pneumophila	1			11/2/2001
2577	Clinical	VGH-Taiwan		Sputum	L pneumophila	6			1/7/2002
2584	Clinical	VGH-Taiwan		Sputum	L pneumophila	6			1/7/2002
2587	Clinical	VGH-Taiwan		Sputum	L longbeachese			longbeachese	1/7/2002
2591	Clinical	Butler VAMC	AB		L pneumophila	1			1/30/2002
2601	Clinical	Cuyahoga-EPA	AK	from lung tissue	L pneumophila	1		EPA study	3/14/2002
2602	Clinical	UC Davis	ED	Liver A8611	K.pneumo			For virulence studies	4/4/2002
2603	Clinical	UC Davis	ED	Liver A 10090	K.pneumo			For virulence studies	4/4/2002
2608	Clinical	Beaver Medical Center	AH	Sputum (EPA)	L pneumophila	1			5/1/2002
2609	Clinical	Ortho McNeil	EB	Investigator	L dumoffii				5/3/2002
2626	Clinical	ACHD - EPA Study	SJB	Patient	L pneumophila	1			6/6/2002
2628	Clinical	University Drive VAMC	De4	look alike	Lactobacillus?				6/14/2002
2629	Clinical	Cleveland Clinic - EPA	HR	sputum	L pneumophila	1			6/19/2002
2630	Clinical	Cuyahoga-EPA	S-G	Sputum	L pneumophila	1			6/19/2002
2631	Clinical	University Drive VAMC	LB	sputum	L pneumophila	5			6/19/2002
2639	Clinical	ACHD - EPA Study	MJ		L pneumophila	1			7/2/2002
2640	Clinical	ACHD - EPA Study	MJ		L pneumophila	1			7/2/2002
2646	Clinical	ACHD - EPA Study	DB	Mercy Patient	L pneumophila	1			7/24/2002
2649	Clinical	Cuyahoga-EPA	PM	Patricia Maran	L. micdadei				8/1/2002
2655	Clinical	Beaver Medical Center	DR		L pneumophila	1			8/14/2002
2659	Clinical	Cuyahoga-EPA	CB-2	Hosp., Dr.	L. micdadei				8/15/2002
2660	Clinical	Cuyahoga-EPA	CD	Hosp., Dr.	L pneumophila	1			8/15/2002
2685	Clinical	ACHD - EPA Study		Lary Carson	L pneumophila	1			9/12/2002
2700	Clinical	Presby UPMC	Mc3	?	Lanisa			sent to CDC	9/30/2005
2701	Clinical	Spec Path Lab		transplant-	K. pneumoniae				10/2/2002
2702	Clinical	Spec Path Lab		transplant-	K. pneumoniae				10/2/2002
2703	Clinical	Spec Path Lab		transplant-	K. pneumoniae				10/2/2002
2704	Clinical	Spec Path Lab		transplant-5448	K. pneumoniae				10/2/2002

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Record #	Culture type	Lab Company Name	Lab Card name	Specimen	Species Name	Sg-1 Sub type	Sg-1 Mab	Comments	Date
2705	Clinical	Spec Path Lab		transplant-	K. pneumoniae				10/2/2002
2706	Clinical	Spec Path Lab		transplant-	K. pneumoniae				10/2/2002
2707	Clinical	Cuyahoga-EPA	Pi	System	L pneumophila	1			10/9/2002
2710	Clinical	Cuyahoga-EPA	CB	Cleveland Clinic	L. micdadei				10/9/2002
2713	Clinical	Cuyahoga-EPA	WL	Hospital	L pneumophila	1			2
2714	Clinical	(Orange,CA)	IS		L pneumophila	6		blood culture	2
2715	Clinical	ACHD - EPA Study	Bo	from Mercy	L pneumophila	1	10-21-02		2
2716	Clinical	ACHD - EPA Study	Fl5	St.Clair patient	L pneumophila	1		Respiratory	2
2717	Clinical	ACHD - EPA Study	AL	Mercy Hosp.	L pneumophila	1		resp.	2
2722	Clinical	Tucson VAMC	Va	isolate	L pneumophila	1			11/4/2002
2724	Clinical	University Drive VAMC	Tu4	sputum	L pneumophila	1			11/6/2002
2725	Clinical	J.H. Bayview	GJ		S.aureus			for PFGE	11/8/2002
2726	Clinical	J.H. Bayview	Be6		S.aureus			for PFGE	11/8/2002
2727	Clinical	J.H. Bayview	HS		S.aureus			for PFGE	11/8/2002
2728	Clinical	J.H. Bayview	W-H		S.aureus			for PFGE	11/8/2002
2729	Clinical	J.H. Bayview	JJ		S.aureus			for PFGE	11/8/2002
2730	Clinical	J.H. Bayview	RG		S.aureus			for PFGE	11/8/2002
2731	Clinical	ACHD - EPA Study	SS	Hosp.	L pneumophila	1			2
2738	Clinical	Hospital		T44868	L pneumophila	1		Isolate	2
2739	Clinical	ACHD - EPA Study	AL	Patient	L pneumophila	1		Isolate	2
2740	Clinical	Cuyahoga-EPA	NS	Metro Health	L pneumophila			not 1-6, to CDC	2
2743	Clinical	Cuyahoga-EPA	Ja2		L.feelie			Confirmed by the CDC	2
2745	Clinical	Cuyahoga-EPA	GAG	Health Ctr.	L pneumophila	1			2
2747	Clinical	Cuyahoga-EPA	JR		L pneumophila	1			1/15/2003
2748	Clinical	ACHD - EPA Study	AO		L pneumophila	6			1/15/2003
2775	Clinical	Seton MC		Sputum	L pneumophila	1		for PFGE	3/7/2003
2781	Clinical	Shadyside UPMC	CM	Nasal	S.aureus			MRSA	4/11/2003
2782	Clinical	Shadyside UPMC	CM	L. Knee	S.aureus			MRSA	4/11/2003
[illegible]	[illegible]	[illegible]	[illegible]	Blood culture	S.maltophilia			strain 1?	4/23/2003

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Record #	Specimen type	Site	Company Name	Site	Short hospt name	Site Description	Species Genus	Sg	Sub type	Sub Type Description	Frozen
2787	Clinical		ACHD - EPA Study		Ha4	Shadyside PT	L pneumophila	1			4/25/2003
2790	Clinical		St. Paul Hospital		FB	ear M59 516-1	P. aeruginosa			str 1, Pan R	
2791	Clinical		St. Paul Hospital		FB	ear M59516-2	P. aeruginosa			str 2, pan R	
2792	Clinical		St. Paul Hospital		FB	ear M45607	P. aeruginosa			PAN R	
2808	Clinical		ACHD - EPA Study		AL	sputum	L pneumophila	1			5/14/2003
2809	Clinical		ACHD - EPA Study		AL	Bronch.	L pneumophila	1			5/14/2003
2811	Clinical		EPA Study		MD	Isolate	L pneumophila	1			5/21/2003
2825	Clinical		ACHD - EPA Study		AW		L pneumophila	1			5/30/2003
2833	Clinical		MD - EPA		MD #1	resp	L pneumophila	1			6/18/2003
2835	Clinical		MD - EPA		KN #2		L pneumophila	1			6/20/2003
2836	Clinical		ACHD - EPA Study		KR		L pneumophila	1			6/20/2003
2837	Clinical		ACHD - EPA Study		PB	Sewickly Valley	L pneumophila	1			6/27/2003
2838	Clinical		ACHD - EPA Study		DR	Sewickly Valley	L pneumophila	1			6/30/2003
2839	Clinical		ACHD - EPA Study		O't	Sputum - AGH	L pneumophila	1			7/2/2003
2845	Clinical		ACHD - EPA Study		HS	sputum - AGH	L pneumophila	1			7/18/2003
2846	Clinical		ACHD - EPA Study		JS	Sputum - Mercy	L pneumophila	1			7/18/2003
2857	Clinical		Health-EPA		JT	Isolate	L pneumophila	1			8/6/2003
2858	Clinical		MD - EPA		CF		L pneumophila	1			8/8/2003
2868	Clinical		West Penn Hospital		JS	Bronch washing	L pneumophila	1		for PFGE	8/14/2003
2869	Clinical		Ohio EPA		L1181	sputum	L pneumophila	1			8/20/2003
2873	Clinical		ACHD - EPA Study		CK	sputum	L pneumophila	1			8/22/2003
2887	Clinical		ACHD - EPA Study		GB	Respiratory	L pneumophila	1			9/3/2003
2890	Clinical		ACHD - EPA Study		DS	Respiratory	L pneumophila	1			9/5/2003
2898	Clinical		University Drive VAMC		JG	Sputum	L pneumophila	1			9/24/2003
2899	Clinical		ACHD - EPA Study		Gr	Sputum	L pneumophila	1			9/26/2003
2908	Clinical		MD - EPA Study		Be	sink	L anisa				10/9/2003
2932	Clinical		Cuyahoga-EPA		TM	Washing	L pneumophila	1			3
2933	Clinical		Health-EPA		BP	Sputum	L pneumophila	1			3
2934	Clinical		University Drive VAMC		JH	Blood Culture	Enteric GNR			Unable to ID	3
2935	Clinical		University Drive VAMC		DO	Blood Culture	S. marcescens				3
2936	Clinical		University Drive VAMC		EM	Blood Culture	S. marcescens				3

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Record #	Specimen type	Site	Company Name	Site	Short hospt name	Site Description	Species Genus	Sg	Sub type	Sub Type Description	Frozen
2937	Clinical		EPA Respiratory Study			Beaumont	L pneumophila	1			3
2942	Clinical		University Drive VAMC		De	Sputum					3
2943	Clinical		University Drive VAMC		CR	Sputum	L pneumophila	1			3
2944	Clinical		University Drive VAMC		CR	Sputum	L pneumophila	1			3
2947	Clinical		Cuyahoga-EPA		RK	Washing	L pneumophila	1			1/28/2004
2948	Clinical		University Drive VAMC		Ca14	Urine	S.aureus				2/3/2004
2949	Clinical		University Drive VAMC		Ca14	Blood	S.aureus				2/3/2004
2950	Clinical		University Drive VAMC		S	Urine	S.aureus				2/3/2004
2951	Clinical		University Drive VAMC		S	Blood	S.aureus				2/3/2004
2952	Clinical		University Drive VAMC		La6	Urine	S.aureus				2/3/2004
2953	Clinical		University Drive VAMC		La6	Blood	S.aureus				2/3/2004
2954	Clinical		University Drive VAMC		Wh	Urine	S.aureus				2/3/2004
2955	Clinical		University Drive VAMC		Wh	Blood	S.aureus				2/3/2004
2956	Clinical		University Drive VAMC		Ne	Urine	S.aureus				2/3/2004
2957	Clinical		University Drive VAMC		Ne	Blood	S.aureus				2/3/2004
2958	Clinical		University Drive VAMC		Ka3	Urine	S.aureus				2/3/2004
2959	Clinical		University Drive VAMC		Ka4	Blood	S.aureus				2/3/2004
2960	Clinical		University Drive VAMC		Br2	Blood, 1532	S. maltophilia				2/3/2004
2983	Clinical		Dr. Muder Staph		Ca14	Nares (231)	S.aureus				5/14/2004
2984	Clinical		Dr. Muder Staph		Ne	Nares (77)	S.aureus				5/14/2004
2985	Clinical		Dr. Muder Staph		S	Nares (25)	S.aureus				5/14/2004
2986	Clinical		Dr. Muder Staph		Wh	Nares (51)	S.aureus				5/14/2004
2987	Clinical		Dr. Muder Staph		Kr	Urine (135)	S.aureus				5/14/2004
2988	Clinical		Dr. Muder Staph		Kr2	Urine 224	S.aureus				5/14/2004
2989	Clinical		Dr. Muder Staph		Ku	Urine (32)	S.aureus				5/14/2004
2990	Clinical		Dr. Muder Staph		Ku	Urine (118)	S.aureus				5/14/2004
2991	Clinical		Dr. Muder Staph		No	Urine (134)	S.aureus				5/14/2004
2992	Clinical		Dr. Muder Staph		No	Nares (143)	S.aureus				5/14/2004
2993	Clinical		Dr. Muder Staph		To	[illegible]	[illegible]				

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Record #	Isolation Type	Company/Name	Source	Name	Genus/species name	SG	Sub type	Easy/Each/Recent	Date
2996	Clinical	Dr. Muder Staph	To?	Nares (43)	S.aureus				5/14/2004
2997	Clinical	Patterson/Rello	JGZ	Brain Abscess	pneumoniae				5/14/2004
3001	Clinical	Metro Health	Be3	wound, chest	P. aeruginosa				6/23/2004
3002	Clinical	Metro Health	JB	sputum trap	P.aeruginosa				6/23/2004
3003	Clinical	Metro Health	Fr	(left lung)	P.aeruginosa				6/23/2004
3004	Clinical	Metro Health	MR	burn, Left axilla	P.aeruginosa				6/23/2004
3017	Clinical	Hospital	Bo4	Bronch	L pneumophila	1			7/1/2004
3018	Clinical	University Drive VAMC	JS	Blood	L pneumophila	1			7/5/2004
3019	Clinical	University Drive VAMC	SC	culture	L pneumophila	1		Wilmington pt.	7/7/2004
3020	Clinical	Quest	HR	#H1473594	K. pneumoniae			for mouse studies	7/20/2004
3021	Clinical	U of Utah MC	JR	2/16/04	L pneumophila	1		post-ionization	7/21/2004
3022	Clinical	U of Utah MC	SS	2/6/04	L pneumophila	1		post-ionization	7/21/2004
3023	Clinical	U of Utah MC	RG	collected	L pneumophila	1		pre-ionization	7/21/2004
3028	Clinical	University Drive VAMC	Gr3	sputum	L pneumophila	5			8/4/2004
3039	Clinical	University Drive VAMC	Jefferson Hospital	sputum	L pneumophila	1			9/15/2004
3044	Clinical	Beaver Medical Center	DE		L pneumophila	1			9/30/2004
3053	Clinical	Medical Center		Specimen #122	L pneumophila	2			10/8/2004
3054	Clinical	Omaha VAMC		Respiratory	L pneumophila	1			4
3061	Clinical	CHP (Children's)	KK	11/6/04	L pneumophila	1			4
3071	Clinical	EPA Study	TA	patient;	L pneumophila	1			4
3073	Clinical	University Drive VAMC	DK	TX; ascites fluid	S.maltophilia				1/4/2005
3074	Clinical	University Drive VAMC	Sa2	blood	s.maltophilia			micro 04 27170	1/7/2004
3075	Clinical	University Drive VAMC	Sa2	blood	A.xylosoxidans			Micro 04 29403	1/7/2005
3076	Clinical	University Drive VAMC	Sa2	sputum	S.maltophilia			micro 04 29488	1/7/2005
3077	Clinical	University Drive VAMC	Mo4	blood	S.maltophilia			micro 04 23218	1/7/2005
3078	Clinical	(Orange,CA)	IP	F4832	L pneumophila	1			1/12/2005
3081	Clinical	University Drive VAMC	JO	1/17/05	P.aeruginosa			Micro 05 1330	1/21/2005
3082	Clinical	University Drive VAMC	JO	cath tip	P.aeruginosa			Micro 05 1235	1/21/2005
3087	Clinical	Tucson VAMC	GR	Plueral fluid	L pneumophila	1			2/4/2005
3088	Clinical	University Drive VAMC	Ca	12/18/04	marcesens			Micro 04 28626	2/15/2005
3089	Clinical	University Drive VAMC	Ku3	12/10/04	marcesens			Micro 04 28031	2/15/2005

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3090	Clinical	University Drive VAMC	Mo3	10/19/04	marcesens			Micro 04 22986	2/15/2005
3091	Clinical	University Drive VAMC	Ti	blood coll. ?	marcesens			Micro 04 27277	2/15/2005
3092	Clinical	University Drive VAMC	Ca	1/26/05	marcesens			Micro 05 2028	2/15/2005
3093	Clinical	University Drive VAMC	Ca2	1/31/05. Mixed	marcesens			Micro 05 2502	2/15/2005
3094	Clinical	University Drive VAMC	S	coll.1/31/05	marcesens			Micro 05 2501	2/15/2005
3098	Clinical	CHP (Children's)	EL	Bronch lavage	L pneumophila	1		1st infection	3/4/2005
3102	Clinical	University Drive VAMC		#167; Belgium	K. pneumoniae			invasive	3/17/2005
3103	Clinical	University Drive VAMC	Ca2	#3093; Jack	marcesens			col type #1	3/18/2005
3104	Clinical	University Drive VAMC	Ca2	#3093; Jack	marcesens			col type #2	3/18/2005
3119	Clinical	Cleveland VAMC	CAP 14	respiratory	dens			pneumo look alike	6/14/2005
3130	Clinical	MT State Health Lab	Deac.Billings PT1	#498634, DOC	L pneumophila				
3131	Clinical	MT State Health Lab	Deac. Billings PT2	lab#412222,	L pneumophila				
3138	Clinical	University Drive VAMC	MB	American	L pneumophila	1			8/15/2005
3152	Clinical	CHP (Children's)	EL	col.8/26/05	L pneumophila	1		2nd infection	9/1/2005
3189	Clinical	Mercy Hospital	RB	blood	L pneumophila	1			9/30/2005
3190	Clinical	Mercy Hospital	RB	sputum	L pneumophila	1			9/30/2005
3249	Clinical	University Drive VAMC		Lactobacillus				Dr. Nina Singh	4/13/2006
26	Environmental	University Drive VAMC		7W (Shower)	L pneumophila	5			5/1/1980
27	Environmental	University Drive VAMC		8W (Shower)	L pneumophila	5			5/1/1980
29	Environmental	University Drive VAMC		7W (Shower)	L pneumophila	1			5/1/1980
30	Environmental	University Drive VAMC		8W (Shower)	L pneumophila	1			5/1/1980
31	Environmental	University Drive VAMC		7W Shower	L. micdadei				6/5/1980
34	Environmental	Presby UPMC		Yee- Filter	L pneumophila	1			9/29/1980
40	Environmental	University Drive VAMC		9E Shower	L pneumophila	1			1/19/1981
41	Environmental	University Drive VAMC		9E Spigot	L pneumophila	1			1/9/1981
42	Environmental	University Drive VAMC		MICU-B Spigot	L pneumophila	1			1/9/1981
44	Environmental	University Drive VAMC		MICU-B Spigot	L pneumophila	5			1/21/1981
45	Environmental	University Drive VAMC		H2O	L pneumophila	1			1/30/1981
				SICU - H2O	L pneumophila	1			1/30/1981

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Record #	Culture Type	Location	Name	Source	Description	Species	Serotype	Sub type	Miscellaneous	Date
49	Environmental	CDC			Atlanta-2	L pneumophila	2			2/20/1981
50	Environmental	CDC			Atlanta					2/20/1981
51	Environmental	GSPH			Yee-684	L pneumophila	4		Cross reacted with Lp5	2/25/1981
52	Environmental	GSPH			Yee-687	L pneumophila	4		Cross reacted with Lp5	2/25/1981
53	Environmental	GSPH			Yee 429A	L pneumophila			smooth	3/23/1981
54	Environmental	GSPH			Yee 429B	L pneumophila			rough	3/23/1981
67	Environmental	University Drive VAMC			SICU-5	L micdadei				4/27/1981
80	Environmental	University Drive VAMC			line	L pneumophila	5			5/1/1981
81	Environmental	University Drive VAMC			CCU spigot 2	L pneumophila	1			5/1/1981
82	Environmental	University Drive VAMC			7W-43 H2O	L pneumophila	1			5/1/1981
83	Environmental	University Drive VAMC			6E Rt. Sh	L pneumophila	1			5/1/1981
84	Environmental	University Drive VAMC			7W-44 spigot	L pneumophila	1			7/15/1981
85	Environmental	University Drive VAMC			4E Rt.Sh	L pneumophila	1			5/1/1981
86	Environmental	University Drive VAMC			8W Rt Sh	L pneumophila	1			5/1/1981
87	Environmental	University Drive VAMC			SICU-5	L pneumophila	5			5/9/1981
88	Environmental	University Drive VAMC			11E Janitor	L pneumophila	1			5/1/1981
89	Environmental	University Drive VAMC			9E-39-16 spigot	L pneumophila	1			5/1/1981
90	Environmental	University Drive VAMC			valve H2O	L pneumophila	1			5/1/1981
91	Environmental	University Drive VAMC			valve	L pneumophila	1			5/1/1981
92	Environmental	University Drive VAMC			9E-32 spigot	L pneumophila	1			5/1/1981
93	Environmental	University Drive VAMC			1W-116 spigot	L pneumophila	5			5/1/1981
94	Environmental	University Drive VAMC			valve H2O	L pneumophila	1			5/1/1981
95	Environmental	University Drive VAMC			HWT #4 1st	L pneumophila	1			5/1/1981
96	Environmental	University Drive VAMC			HWT #4 2nd	L pneumophila	1			5/1/1981
97	Environmental	University Drive VAMC			9E-36	L pneumophila	5			5/1/1981
98	Environmental	University Drive VAMC			10E-20	L pneumophila	1			5/1/1981
99	Environmental	University Drive VAMC			9E-30	L pneumophila	1			5/1/1981
100	Environmental	University Drive VAMC			3W-133	L pneumophila	1			5/1/1981
101	Environmental	University Drive VAMC			2ER - shower	L pneumophila	1			5/1/1981
102	Environmental	University Drive VAMC			6W-133	L pneumophila	1			5/1/1981
103	Environmental	University Drive VAMC			10E-36	L pneumophila	1			5/1/1981

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104	Environmental	University Drive VAMC			11W-106	L pneumophila	1			5/1/1981
105	Environmental	University Drive VAMC			10E-115	L pneumophila	1			5/1/1981
106	Environmental	University Drive VAMC			Valve H2O	L pneumophila	1			5/1/1981
107	Environmental	University Drive VAMC			valve	L pneumophila	5			5/1/1981
108	Environmental	University Drive VAMC			supply line	L pneumophila	1			5/1/1981
109	Environmental	University Drive VAMC			9E-20 H2O	L pneumophila	1			5/4/1981
110	Environmental	University Drive VAMC			11E Rt Sh H2O	L pneumophila	1			5/1/1981
111	Environmental	University Drive VAMC			supply line	L pneumophila	1			5/1/1981
112	Environmental	University Drive VAMC			valve	L pneumophila	1			7/15/1981
113	Environmental	University Drive VAMC			cold supply line	L pneumophila	1			5/1/1981
114	Environmental	University Drive VAMC			4E-6 spigot	L pneumophila	1			5/4/1981
115	Environmental	University Drive VAMC			4E-6 Spigot	L pneumophila	5			5/1/1981
116	Environmental	University Drive VAMC			HWT 3 1st	L pneumophila	1			5/4/1981
117	Environmental	University Drive VAMC			SICU - 5 Spigot	L pneumophila	1			5/1/1981
118	Environmental	University Drive VAMC			SICU - 4 Spigot	L pneumophila	1			5/1/1981
119	Environmental	University Drive VAMC			9W-120 Spigot	L pneumophila	1			5/1/1981
120	Environmental	University Drive VAMC			MICU - 1 Spigot	L pneumophila	1			5/1/1981
121	Environmental	University Drive VAMC			Shower	L pneumophila	1			5/1/1981
122	Environmental	University Drive VAMC			Shower H2O	L pneumophila	5			5/4/1981
123	Environmental	University Drive VAMC			(umbonate)	L pneumophila	1		@ original #40	3/9/1981
124	Environmental	University Drive VAMC			(smooth)	L pneumophila	1		@ original #40	3/9/1981
129	Environmental	University Drive VAMC			HWT #1 & #2	L pneumophila	1			5/1/1981
132	Environmental	University Drive VAMC			HWT #4	L. micdadei			2nd sample	7/24/1981
133	Environmental	University Drive VAMC			HWT #3					7/24/1981
137	Environmental	University Drive VAMC			HWT #3	L pneumophila	5			8/14/1981
140	Environmental	University Drive VAMC			H2O	L pneumophila	1			1
141	Environmental	University Drive VAMC			11E Shower	L pneumophila	1			1
142	Environmental	University Drive VAMC			MICU #1 H2O	L pneumophila	1			1

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Record #	Sample type	Company Name	Source Room #	Description	Species name	Sg	Sub type	Reason discarded	Date
151	Environmental	University Drive VAMC		1W 116	L pneumophila	1		pre-Nov heat	1/20/1982
152	Environmental	University Drive VAMC		room	L pneumophila	1		pre-Nov heat	1/20/1982
153	Environmental	University Drive VAMC		1W 145	L pneumophila	1		pre-Nov heat	1/20/1982
154	Environmental	University Drive VAMC		3W 107	L pneumophila	1		pre-Nov heat	1/20/1982
155	Environmental	University Drive VAMC		3W 113	L pneumophila	1		pre-Nov heat	1/20/1982
156	Environmental	University Drive VAMC		3W 133	L pneumophila	1		tossed on 2-23-83	1/20/1980
157	Environmental	University Drive VAMC		construction	L pneumophila	1		pre-Nov heat	1/20/1982
158	Environmental	University Drive VAMC		4E RT Shower	L pneumophila	1		pre-Nov heat	1/20/1982
159	Environmental	University Drive VAMC		area	L pneumophila	1		pre-Nov heat	1/20/1982
160	Environmental	University Drive VAMC		area	L pneumophila	1		pre-Nov heat	1/20/1982
161	Environmental	University Drive VAMC		patient area	L pneumophila	1		pre-Nov heat	1/20/1982
162	Environmental	University Drive VAMC		patient area	L pneumophila	1		pre-Nov heat	1/20/1982
163	Environmental	University Drive VAMC		9W132	L pneumophila	1		pre-Nov heat	1/20/1982
164	Environmental	University Drive VAMC		room sink	L pneumophila	1		pre-Nov heat	1/20/1982
165	Environmental	University Drive VAMC		Clinic	L pneumophila	1		pre-Nov heat	1/20/1982
166	Environmental	University Drive VAMC		Clinic	L pneumophila	1		pre-Nov heat	1/20/1982
167	Environmental	University Drive VAMC		Clinic	L pneumophila	1		pre-Nov heat	1/20/1982
168	Environmental	University Drive VAMC		clinic lens room	L pneumophila	1		pre-Nov heat	1/20/1982
169	Environmental	University Drive VAMC		nonpatient	L pneumophila	1		pre-Nov heat	1/20/1982
170	Environmental	University Drive VAMC		MICU #1 H2O	L pneumophila	1		from 12/4	1/21/1982
171	Environmental	University Drive VAMC		9W120 swab	L pneumophila	1		from 12/4	1/21/1982
172	Environmental	University Drive VAMC		H2O	L pneumophila	1		from 12/4	1/21/1982
173	Environmental	University Drive VAMC		H2O	L pneumophila	1		from 12/4	1/21/1982
174	Environmental	University Drive VAMC		9E132 swab	L pneumophila	1		from 12/4	1/21/1982
175	Environmental	University Drive VAMC		H2O	L pneumophila	1		from 1/4	1/22/1982
176	Environmental	University Drive VAMC		9E 132 H2O	L pneumophila	1		from 1/4	1/22/1982
177	Environmental	University Drive VAMC		swab	L pneumophila	1		from 1/4	1/22/1982
178	Environmental	University Drive VAMC		MICU #1 swab	L pneumophila	1		from 1/4	1/22/1982
179	Environmental	University Drive VAMC		#3 H2O	L pneumophila	1		from 1/4	1/22/1982
180	Environmental	University Drive VAMC		swab	L pneumophila	5		from 1/4	1/22/1982
181	Environmental	University Drive VAMC		10E136 Swab	L pneumophila	5		H2O increase	1/22/1982

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182	Environmental	University Drive VAMC		7W126 swab	L pneumophila	5		H2O increase	1/22/1982
183	Environmental	University Drive VAMC		9W117 Swab	L pneumophila	1		H2O increase	1/22/1982
184	Environmental	University Drive VAMC		10E118 swab	L pneumophila	1		H2O increase	1/22/1982
185	Environmental	University Drive VAMC		10W115 swab	L pneumophila	1		H2O increase	1/22/1982
186	Environmental	University Drive VAMC		10E114 swab	L pneumophila	1		H2O increase	1/22/1982
187	Environmental	University Drive VAMC		9W132 swab	L pneumophila	1		H2O increase	1/22/1982
188	Environmental	University Drive VAMC		sink	L pneumophila	1		H2O increase	1/22/1982
189	Environmental	University Drive VAMC		9E132 swab	L pneumophila	1		H2O increase	1/22/1982
190	Environmental	University Drive VAMC		9E136 swab	L pneumophila	1		H2O increase	1/22/1982
191	Environmental	University Drive VAMC		1W116	L pneumophila	1		Nov heat	1/22/1982
192	Environmental	University Drive VAMC		1W133	L pneumophila	1		Nov heat	1/22/1982
193	Environmental	University Drive VAMC		4E Rt shower	L pneumophila	1		Nov heat	1/22/1982
194	Environmental	University Drive VAMC		4E127	L pneumophila	1		Nov heat	1/22/1982
196	Environmental	University Drive VAMC		H2O	L. micdadei				1/25/1982
197	Environmental	University Drive VAMC		H2O	L. micdadei				1/25/1982
198	Environmental	University Drive VAMC		H2O	L pneumophila	1			1/25/1982
199	Environmental	University Drive VAMC		H2O	L. micdadei				1/25/1982
200	Environmental	University Drive VAMC		H2O	L. micdadei				1/25/1982
201	Environmental	University Drive VAMC		6W-20 spigot	L.micdadei				1/25/1982
202	Environmental	University Drive VAMC		6W-20 spigot	L pneumophila	1			1/25/1982
204	Environmental	University Drive VAMC		3W114 swab	L. micdadei				2/5/1982
205	Environmental	University Drive VAMC		swab	L. micdadei				2/5/1982
206	Environmental	University Drive VAMC		swab	L. micdadei				2/5/1982
207	Environmental	University Drive VAMC		swab	L. micdadei				2/5/1982
213	Environmental	University Drive VAMC			parapsilosis				4/7/1982
215	Environmental	University Drive VAMC			glabrata				5/12/1982
216	Environmental	University Drive VAMC			humacola				5/12/1982
[illegible]	Environmental	Kenilworth VAMC		Right	L pneumophila	6			5/21/1982
[illegible]	[illegible]	[illegible]		[illegible]	[illegible]	[illegible]			5/21/1982

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Record #	culture type	Company Name	source/pt name	description	species name	sg	Sub type	Miscellaneous	frozen
221	Environmental	Highland Drive VAMC		#1	L pneumophila	4			6/9/1982
222	Environmental	Highland Drive VAMC		#3	L pneumophila	4			6/9/1982
224	Environmental	Aspinwall VAMC		Right	L pneumophila			4 wk post drain	6/21/1982
225	Environmental	Eye & Ear Hospital		5th Floor	L pneumophila	1			6/28/1982
226	Environmental	Eye & Ear Hospital		H2O	L pneumophila	1			6/28/1982
227	Environmental	Eye & Ear Hospital		swab	L pneumophila	1			6/28/1982
228	Environmental	Eye & Ear Hospital		swab	L pneumophila	6			6/28/1982
229	Environmental	University Drive VAMC		HWT #4	L pneumophila	5			7/22/1982
230	Environmental	University Drive VAMC		4	L pneumophila	1			8/20/1982
231	Environmental	Aspinwall VAMC		Left from 8-10	L pneumophila	1			9/17/1982
232	Environmental	Aspinwall VAMC		Right from 8-10	L pneumophila	1			9/17/1982
233	Environmental	Hospital Council #1		#41642 Hot #2	L pneumophila	1			2
234	Environmental	Hospital Council #1		#1	L pneumophila	5			2
235	Environmental	Hospital Council #1		#1	L pneumophila	4			2
236	Environmental	University Drive VAMC			Neoformaus			stock strain	2
237	Environmental	Hospital Council #1		#94914 Hot #2	L pneumophila	3			2
239	Environmental	Hospital Council #1		#41642A Cold	L pneumophila	1			2
240	Environmental	Hospital Council #1		#1	L pneumophila	1			2
241	Environmental	Hospital Council #1		#38234A Cold	L pneumophila	1			2
242	Environmental	Hospital Council #1		#38234B	L pneumophila	4			2
243	Environmental	Hospital Council #1		#90775 Hot #2	L pneumophila	2			2
244	Environmental	Hospital Council #1		#96328 Hot #1	L pneumophila	1			2
246	Environmental	University Drive VAMC		Filtrane	L pneumophila	1			2
253	Environmental	University Drive VAMC		HWT #1	L pneumophila	1			1/18/1983
254	Environmental	University Drive VAMC		HWT #2	L pneumophila	1			1/18/1983
255	Environmental	University Drive VAMC		Tank #3	L pneumophila	1			1/18/1983
256	Environmental	Hospital Council #2		#90775A(1) A	L pneumophila	2			1/19/1983
257	Environmental	Hospital Council #2		90775A(1) C	L pneumophila	3	Lansing		1/19/1983
258	Environmental	Hospital Council #2		90775B (1)	L pneumophila	1			1/19/1983
259	Environmental	Hospital Council #2		94914C (1)	L pneumophila	3	Lansing		1/19/1983
260	Environmental	Hospital Council #2		94914 F(1)	L pneumophila	3			1/19/1983

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261	Environmental	Hospital Council #2		33751 G	L pneumophila	1			1/19/1983
262	Environmental	Hospital Council #2		78837A (1)	L pneumophila	5			1/19/1983
263	Environmental	University Drive VAMC		swab	L pneumophila	1			3/14/1983
264	Environmental	Eye & Ear Hospital		HWT	L pneumophila	1			3/28/1983
265	Environmental	Eye & Ear Hospital		HWT	L pneumophila	6			3/28/1983
267	Environmental	Hospital Council #3		99695 DS-2	L pneumophila	4			4/15/1983
268	Environmental	Hospital Council #3		96328A T-1	L pneumophila	1			4/15/1983
269	Environmental	Hospital Council #3		96328E DS-5	L pneumophila	1			4/15/1983
270	Environmental	Hospital Council #3		78837A DS_2	L pneumophila	5			4/15/1983
271	Environmental	Hospital Council #3		90775A T-1	L pneumophila	2			4/15/1983
272	Environmental	Hospital Council #3		90775C T-2	L pneumophila	1			4/15/1983
273	Environmental	Hospital Council #3		90775E T-3	L pneumophila	1			4/15/1983
274	Environmental	Hospital Council #3		90775G DS5	L pneumophila	2			4/15/1983
275	Environmental	Hospital Council #3		33751A T1	L pneumophila	1			4/15/1983
276	Environmental	Hospital Council #3		33751C DS2	L pneumophila	1			4/15/1983
277	Environmental	Hospital Council #3		33751D DS2	L pneumophila	1			4/15/1983
278	Environmental	Hospital Council #3		56920A DS2	L pneumophila	3			4/15/1983
279	Environmental	Hospital Council #3		94914 T4	L pneumophila	3			4/15/1983
280	Environmental	Hospital Council #3		41642C DS10	L pneumophila	1			4/15/1983
281	Environmental	Hospital Council #3		41642E T2	L pneumophila	4			4/15/1983
282	Environmental	Hospital Council #3		41642F T2	L pneumophila	4			4/15/1983
287	Environmental	Hospital Council #3		56920	L pneumophila	3			4/29/1983
289	Environmental	Hospital Council #3		90775F T4	L pneumophila	2			4/29/1983
291	Environmental	Highland Drive VAMC		HWT Bldg. 9	L pneumophila	4			5/11/1983
292	Environmental	University Drive VAMC		H2O Fountain	L pneumophila	1			5/23/1983
299	Environmental	Hospital Council #4		41642B GNR	L rubrilucens				3
300	Environmental	Hospital Council #4		56920B	L pneumophila	1			3
301	Environmental	Hospital Council #4		90775F	L pneumophila	3	Lansing		3

Discarded Legionella Stock Collection

Record #	Culture Type	Company Name	Source/Pt. name	Site description	Species name	Ty	S/Sub type	Miscellaneous	Frozen
308	Environmental	Eye & Ear Hospital		.5E Ice Machine	L pneumophila	1			3
309	Environmental	Eye & Ear Hospital		HWT (Left)	L pneumophila	6			3
310	Environmental	University Drive VAMC		3W133 Swab	L pneumophila	1			1/13/1984
311	Environmental	University Drive VAMC		1W133 Swab	L pneumophila	1			1/13/1984
312	Environmental	University Drive VAMC		10E136 Swab	L pneumophila	1			1/13/1984
313	Environmental	University Drive VAMC		9W132 Swab	L pneumophila	1			1/13/1984
329	Environmental	University Drive VAMC		(Bowman's)	L pneumophila	1			2/27/1984
330	Environmental	University Drive VAMC		(Bowman's)	L pneumophila	1			2/27/1984
331	Environmental	Eye & Ear Hospital		(after C1 began	L pneumophila	1			3/1/1984
332	Environmental	University Drive VAMC		9E-29 (Hines')	L pneumophila	1			3/6/1984
333	Environmental	University Drive VAMC		(Burkett control)	L pneumophila	5			3/6/1984
334	Environmental	University Drive VAMC		(Hines')	L pneumophila	1			3/6/1984
335	Environmental	University Drive VAMC		(Burkett control)	L pneumophila	5			3/6/1984
336	Environmental	University Drive VAMC		(Yaremko's 11-	L pneumophila	1			3/6/1984
337	Environmental	University Drive VAMC		(Yaremko	L pneumophila	1			3/6/1984
338	Environmental	University Drive VAMC		(Yaremko	L pneumophila	1			3/6/1984
339	Environmental	University Drive VAMC		H2O	L pneumophila	1			3/12/1984
340	Environmental	University Drive VAMC		Fountain H2O	L pneumophila	1			3/12/1984
341	Environmental	University Drive VAMC		9W120 H2O	L pneumophila	1			3/12/1984
342	Environmental	University Drive VAMC		H2O	L pneumophila	1			3/12/1984
343	Environmental	University Drive VAMC		HWT #3	L pneumophila	1			3/12/1984
344	Environmental	University Drive VAMC		HWT #4	L pneumophila	1			3/12/1984
345	Environmental	University Drive VAMC		cold water	L. erythra				6/24/1986
346	Environmental	University Drive VAMC		cold water	L pneumophila	1			3/12/1984
347	Environmental	University Drive VAMC		cold water	L pneumophila	1			3/12/1984
348	Environmental	University Drive VAMC		(Burkett)	L pneumophila	1			3/12/1984
349	Environmental	University Drive VAMC		(Control for	L pneumophila	1			3/21/1984
350	Environmental	Allen Park VAMC		Fls. 7-10	L pneumophila	5			3/30/1984
351	Environmental	Eye & Ear Hospital		Rm 509	L pneumophila	1			3/30/1984
352	Environmental	Eye & Ear Hospital		Rm 509-2	L pneumophila	1			3/30/1984
353	Environmental	Eye & Ear Hospital		Rm 509-3	L pneumophila	1			3/30/1984

Discarded Legionella Stock Collection

Record #									
355	Environmental	University Drive VAMC		type 1				08-21-84 Dead	4/11/1984
356	Environmental	University Drive VAMC		type 2				08-21-84 Dead	4/11/1984
357	Environmental	University Drive VAMC		from #1 coil	unknown				6/13/1986
358	Environmental	Highland Drive VAMC		Rt. Shower-1	L pneumophila	1			4/13/1984
359	Environmental	Highland Drive VAMC		Rt Shower-2	L pneumophila	1			4/13/1984
360	Environmental	Highland Drive VAMC		sink-1	L pneumophila	1			4/13/1984
361	Environmental	Highland Drive VAMC		sink-2	L pneumophila	1			4/13/1984
362	Environmental	Buffalo VAMC		HWT 156(A)	L pneumophila	1			4/13/1984
363	Environmental	Buffalo VAMC		HWT 156(C)	L pneumophila	1			4/13/1984
364	Environmental	Buffalo VAMC		HWT 156(D)	L pneumophila	1			4/13/1984
365	Environmental	Buffalo VAMC		HWT 156(E)	L pneumophila	1			4/13/1984
366	Environmental	Buffalo VAMC		HWT 154(A)	L pneumophila	1			4/13/1984
367	Environmental	Buffalo VAMC		HWT 154(B)	L pneumophila	1			4/13/1984
368	Environmental	Buffalo VAMC		HWT 154(E)	L pneumophila	1			4/13/1984
369	Environmental	Highland Drive VAMC		sink	L pneumophila	1			4/16/1984
370	Environmental	Highland Drive VAMC		sink	L pneumophila	12			4/16/1984
373	Environmental	University Drive VAMC		Fountain H2O	L pneumophila	1			5/10/1984
374	Environmental	University Drive VAMC		H2O	L pneumophila	1			5/10/1984
375	Environmental	Highland Drive VAMC		Bldg. 9 201	L pneumophila	4			5/10/1984
376	Environmental	Highland Drive VAMC		117 #2 Shower	L pneumophila	4			5/17/1984
377	Environmental	Magee Hospital		2	L pneumophila	1		Restocked 6/13/90	7/9/1984
378	Environmental	Magee Hospital		1	L pneumophila	1			7/9/1984
379	Environmental	Magee Hospital		bathroom	L pneumophila	1			7/9/1984
380	Environmental	Magee Hospital		drinking	L pneumophila	1			7/9/1984
381	Environmental	Magee Hospital		room sink	L pneumophila	1			7/11/1984
382	Environmental	University Drive VAMC		type 1	L pneumophila	1			7/11/1984
383	Environmental	University Drive VAMC		type 2	L pneumophila	1			7/11/1984
[illegible]	Environmental	University Drive VAMC		H2O (Stevens	L pneumophila	1			7/13/1984

Discarded Legionella Stock Collection

Record #	culture type	Company Name	source pt name	Site Description	species name	%	culture type	Maintenance Stock	Collection
392	Environmental	Eye & Ear Hospital		Rm 616 Col #2	L pneumophila	1			7/27/1984
393	Environmental	Eye & Ear Hospital		Rm 618 Col #1	L pneumophila	1			7/27/1984
394	Environmental	Eye & Ear Hospital		Rm 518 Col #2	L pneumophila	1			7/27/1984
395	Environmental	Monongalia		Hot water	L pneumophila	6			8/3/1984
397	Environmental	University Drive VAMC		Fountain	L pneumophila	1			8/17/1984
398	Environmental	University Drive VAMC		Fountain	L pneumophila	1			8/17/1984
399	Environmental	University Drive VAMC		Fountain	L pneumophila	1			8/17/1984
400	Environmental	University Drive VAMC		Fountain	L pneumophila	1			8/17/1984
401	Environmental	University Drive VAMC		Fountain	L pneumophila	1			8/17/1984
402	Environmental	University Drive VAMC		Fountain	L pneumophila	1			8/17/1984
403	Environmental	Monongalia		HWT #1 H2O	L pneumophila	6			8/17/1984
405	Environmental	University Drive VAMC		84) #1 colony	L pneumophila	1			8/17/1984
406	Environmental	University Drive VAMC		#2 colony type	L pneumophila	1			8/17/1984
409	Environmental	Eye & Ear Hospital		Rm 514	L pneumophila	1			9/4/1984
410	Environmental	Eye & Ear Hospital		Rm 618	L pneumophila	1			9/4/1984
411	Environmental	Highland Drive VAMC		Rt Shower	L pneumophila	1			9/4/1984
412	Environmental	University Drive VAMC		(Pt Bowers env)	L pneumophila	1			9/4/1984
413	Environmental	University Drive VAMC		(Pt. Bowers	L pneumophila	1			9/4/1984
415	Environmental	Lee Apartment		H2O	L. erythra				8/24/1986
417	Environmental	Aspinwall VAMC		2A-2047	L pneumophila	1			4
419	Environmental	University Drive VAMC		Fountain	L pneumophila	1			12/6/1984
420	Environmental	University Drive VAMC		Fountain	L pneumophila	1			12/6/1984
421	Environmental	University Drive VAMC		Fountain	L pneumophila	1			12/6/1984
423	Environmental	University Drive VAMC		inhibitor of LDB	Non-Legionella				1/9/1985
424	Environmental	Chen home		Kitchen tap	L pneumophila	1			1/25/1985
425	Environmental	Chen home		Kitchen tap	L pneumophila	1			1/25/1985
426	Environmental	Chen home		Bathroom tap	L pneumophila	1			1/25/1985
427	Environmental	Highland Drive VAMC		Directors HWT	L pneumophila	1			1/25/1985
428	Environmental	Highland Drive VAMC		#122 HWT	L pneumophila	1			1/25/1985
429	Environmental	St. Clair Hospital		HWT #4 (144)	L pneumophila	5			1/25/1985
430	Environmental	St. Clair Hospital		ICU sink (146)	L pneumophila	5			1/25/1985

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Record #	culture type	Company Name	source pt name	Site Description	species name	%	culture type	Maintenance Stock	Collection
431	Environmental	St. Clair Hospital		5F Kitchen	L pneumophila	5			1/25/1985
434	Environmental	St. Clair Hospital		Room (141)	L pneumophila	5			1/25/1985
435	Environmental	St. Clair Hospital		Tank #5 (145)	L pneumophila	5			1/25/1985
436	Environmental	St. Clair Hospital		Tank 4	L. anisa				2/4/1985
437	Environmental	Franklin Hospital		(Patient Fox)	L pneumophila	4			2/12/1985
438	Environmental	Franklin Hospital		(Patient Fox)	L pneumophila	4			2/12/1985
439	Environmental	Franklin Hospital		Room 730	L pneumophila	4			2/12/1985
441	Environmental	Franklin Hospital		Room 1647	L anisa				3/18/1985
442	Environmental	Franklin Hospital		GRN	L pneumophila	6			3/18/1985
443	Environmental	Franklin Hospital		Room 1640 WT	L pneumophila	5			3/18/1985
444	Environmental	University Drive VAMC		Fountain	L pneumophila	1			3/22/1985
445	Environmental	University Drive VAMC		Fountain	L pneumophila	1		A, Restocked 12-13-90	3/22/1985
446	Environmental	University Drive VAMC		Fountain	L pneumophila	1		B	3/22/1985
453	Environmental	Denver-4		isolate	L pneumophila	1		Restocked 12-13-90	4/10/1985
454	Environmental	Denver-5		isolate	L pneumophila	1			4/10/1985
455	Environmental	Denver-6		isolate	L pneumophila	1			4/10/1985
456	Environmental	Highland Drive VAMC		1012	L pneumophila	6			4/16/1985
457	Environmental	Highland Drive VAMC		4038 Col #1	L pneumophila	1			4/16/1985
458	Environmental	Highland Drive VAMC		Hall Sink	L pneumophila	1			4/16/1985
459	Environmental	Highland Drive VAMC		3039	L pneumophila	6			4/16/1985
460	Environmental	Highland Drive VAMC		4038, Col #2	L pneumophila	1			4/16/1985
466	Environmental	Univ of Iowa		Room 7093	L pneumophila	1		04-13-83	4/19/1985
467	Environmental	Univ of Iowa		Room 7045	L pneumophila	1		04-13-83	4/19/1985
468	Environmental	Univ of Iowa		Room 7044	L pneumophila	1		04-13-83	4/19/1985
469	Environmental	Univ of Iowa		Room 3066	L pneumophila	1		04-13-83	4/19/1985
470	Environmental	Univ of Iowa		Room 3059	L pneumophila	1		04-13-83	4/19/1985
471	Environmental	Highland Drive VAMC		119 #2 Shower	L pneumophila				4/23/1985
472	Environmental	Highland Drive VAMC		sink	L pneumophila	[illegible]			
474	[illegible]	[illegible]							

Discarded Legionella Stock Collection

Record #	Culture type 1	Company Name 2	Source culture 3	description	species name	sg	sub type 2	[illegible]	frozen
477	Environmental	Magee Hospital		Men's Room	L pneumophila	1B			4/25/1985
478	Environmental	Eye & Ear Hospital		Rm 616	L pneumophila	1A			4/26/1985
479	Environmental	Eye & Ear Hospital		Rm 616	L pneumophila	1B			4/26/1985
486	Environmental	Easton Hospital		RH-10	L erythra			Restocked 06-07-85	4/29/1985
487	Environmental	Easton Hospital		HWT	L pneumophila	1			4/29/1985
494	Environmental	Buffalo		No. 148-1	L pneumophila	6			5/20/1985
495	Environmental	Buffalo		No. 148-2	L pneumophila	6			5/20/1985
496	Environmental	Buffalo		No. 148-3	L pneumophila	6			5/20/1985
497	Environmental	Buffalo		No. 171-1	L pneumophila	1			5/20/1985
498	Environmental	Buffalo		No. 171-2	L pneumophila	1		(glycerol)	5/20/1985
499	Environmental	Buffalo		No. 171-3	L pneumophila	1			5/20/1985
500	Environmental	Buffalo		No. 172-1	L pneumophila	1			5/20/1985
501	Environmental	Buffalo		No. 172-2	L pneumophila				5/20/1985
502	Environmental	Buffalo		No. 172-3	L pneumophila	1		(glycerol)	5/20/1985
503	Environmental	Buffalo		No. 178	L pneumophila	1		mixed colony types	5/20/1985
504	Environmental	Buffalo		type-1	L pneumophila	1			5/23/1985
505	Environmental	Buffalo		type-2	L pneumophila	1			5/23/1985
506	Environmental	Buffalo		type-3	L pneumophila	1			5/23/1985
508	Environmental	Stanford		core tank	L pneumophila	1	2		6/10/1985
509	Environmental	Stanford		CRC 326	L pneumophila	1	1		6/10/1985
515	Environmental	Buffalo		#267-1	L pneumophila	1		(Glycerol)	6/17/1985
516	Environmental	Buffalo		#267-2	L pneumophila	1			6/17/1985
517	Environmental	Buffalo		#270	L pneumophila	1		(Glycerol)	6/17/1985
518	Environmental	University Drive VAMC		(Borland's	L pneumophila	1			7/1/1985
519	Environmental	Highland Drive VAMC		quarters HWT	L pneumophila	1			7/1/1985
521	Environmental	Highland Drive VAMC		colony 2	L pneumophila	1			7/12/1985
522	Environmental	Highland Drive VAMC		HWT	L pneumophila	6			7/12/1985
529	Environmental	Angelo home		HWT	L pneumophila	1			10/8/1985
530	Environmental	Angelo home		HWT	L pneumophila	1			10/8/1985
531	Environmental	Angelo home		1st floor shower	L pneumophila	1			10/8/1985
532	Environmental	Angelo home		shower	L pneumophila	1			10/8/1985

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533	Environmental	Angelo home		Kitchen sink	L pneumophila	5			10/8/1985
534	Environmental	Angelo home		bathroom sink	L pneumophila	1			10/8/1985
535	Environmental	Angelo home		Basement sink	L pneumophila	1			10/8/1985
536	Environmental	West Penn Hospital		wing	L pneumophila	1			5
537	Environmental	West Penn Hospital		Tank #3 "C"	L pneumophila	3			5
538	Environmental	Pago home		HWT-1	L pneumophila	3			5
539	Environmental	Pago home		HWT	L pneumophila	3			5
540	Environmental	Pago home		Bathtub	L pneumophila	3			5
542	Environmental	Highland Drive VAMC		water	L pneumophila	1			5
543	Environmental	Highland Drive VAMC		outside cold	L pneumophila	1			5
545	Environmental	University Drive VAMC		water filter	L pneumophila	4			5
546	Environmental	Angelo home		(11-6)	L pneumophila	1			5
547	Environmental	Angelo home		Bath sink (11-6)	L pneumophila	1			5
548	Environmental	Angelo home		HWT	L pneumophila	1			5
550	Environmental	Angelo home		pump	L pneumophila	1			12/6/1985
551	Environmental	Angelo home		cold water	L pneumophila	1			12/6/1985
558	Environmental	Buffalo		No. 807	L pneumophila	1			5
559	Environmental	Buffalo		No. 816	L pneumophila	1			5
560	Environmental	Buffalo		No. 821	L pneumophila	1			5
561	Environmental	University Drive VAMC		8W Rt Shower	L pneumophila	1			1/8/1986
562	Environmental	Buffalo		No. 1065	L pneumophila	1			1/14/1986
563	Environmental	Buffalo		No. 1063	L pneumophila	1			1/14/1986
566	Environmental	Buffalo		No. 1068	L pneumophila	1			1/14/1986
568	Environmental	Angelo home		HWT	L pneumophila	1			2/7/1986
569	Environmental	Angelo home		HWT	L pneumophila	1			2/7/1986
570	Environmental	Remaly home		Bathroom sink	L pneumophila	1		Isolate 1	2/7/1986
571	Environmental	Remaly home		Bathroom sink	L pneumophila	1		Isolate 2	2/7/1986
[illegible]	[illegible]	Remaly home		Bathroom sink	L pneumophila	1			2/7/1986

Discarded Legionella Stock Collection

Record #	culture type	Company Name	source/p name	description	species name	pg	sub type	Miscellaneous	frozen
577	Environmental	Angelo home		HWT	L pneumophila	1			2/18/1986
581	Environmental	University Drive VAMC		Fe				No LDB growth	3/31/1986
582	Environmental	University Drive VAMC		Fe	L pneumophila				3/31/1986
583	Environmental	Angelo home		HWT	L pneumophila	6			4/25/1986
586	Environmental	University Drive VAMC		HWT #1	L pneumophila	5		May survey	6/10/1986
587	Environmental	St. Clair Hospital		Boiler A Wing	L pneumophila	5			6/11/1986
588	Environmental	St. Clair Hospital		Sink ICU	L pneumophila	5			6/11/1986
589	Environmental	St. Clair Hospital		Red Fluor. #4B	L erythro				6/24/1986
590	Environmental	St. Clair Hospital		Blue-White	L. anisa				6/24/1986
591	Environmental	American Legion	Cl	20)	L pneumophila	1			7/24/1986
595	Environmental	Briancliff		HWT #2 A-wing	L pneumophila	1			8/19/1986
596	Environmental	Briancliff		A-wing HWT #1	L pneumophila	1			8/24/1986
597	Environmental	Briancliff		wing S4	L pneumophila	1			8/19/1986
598	Environmental	Briancliff		HWT's B-wing	L pneumophila	1			8/19/1986
599	Environmental	Highland Drive VAMC		5 Bathtub	L pneumophila	1			8/19/1986
600	Environmental	Highland Drive VAMC		4 HWT	L pneumophila	1			8/19/1986
601	Environmental	American Legion	Ca8	Kitchen	L pneumophila	1			8/19/1986
602	Environmental	American Legion	Ca8	HWT	L pneumophila	1			8/19/1986
603	Environmental	American Legion	Ca8	HWT	L pneumophila	1			8/19/1986
604	Environmental	American Legion	Ki2	HWT	L pneumophila	1			8/19/1986
605	Environmental	American Legion	Ma9	Bathroom sink	L pneumophila	1			8/26/1986
606	Environmental	American Legion	Ma9	Bathroom sink	L pneumophila	1			8/26/1986
607	Environmental	American Legion	Sa	HWT	L pneumophila	1			8/26/1986
608	Environmental	American Legion	Sa	HWT	L pneumophila	1			8/26/1986
609	Environmental	American Legion	Sa	Bathroom	L pneumophila	1			8/26/1986
610	Environmental	American Legion		bathroom	L pneumophila	1			8/26/1986
611	Environmental	American Legion	O'H	Tub	L pneumophila	1			8/26/1986
612	Environmental	American Legion	O'H	HWT	L pneumophila	1			8/26/1986
613	Environmental	American Legion	Nu	Tub	L pneumophila	3			8/26/1986
614	Environmental	American Legion	Nu	Bathroom	L pneumophila	1			8/26/1986
615	Environmental	American Legion	Ra	machine	L pneumophila	5			8/26/1986

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Record #	culture type	Company Name	source/p name	description	species name	pg	sub type	Miscellaneous	frozen
616	Environmental	American Legion	Ra	8E Fountain	L pneumophila	1			8/26/1986
617	Environmental	American Legion	Co12	Bath tap	L pneumophila	1		colony 1	9/8/1986
618	Environmental	American Legion	Co12	Tub	L pneumophila	1		colony 1	9/8/1986
619	Environmental	American Legion	We1	Bath tap	L pneumophila			colony 3	9/8/1986
620	Environmental	American Legion	We1	Bath tap	L pneumophila			colony 1	9/8/1986
621	Environmental	University Drive VAMC		(West)	L pneumophila	1			9/10/1986
623	Environmental	Franklin Hospital			L pneumophila	4			6
625	Environmental	American Legion	Ar	Shower	L pneumophila	1		colony 1	6
626	Environmental	American Legion	Ar	Shower	L pneumophila	1		colony 2	6
627	Environmental	American Legion	O'H	HWT follow-up	L pneumophila	1			6
628	Environmental	American Legion	Sa	HWT follow-up	L pneumophila	1			6
629	Environmental	Ying home		Bathroom tap	L. oakridgensis				6
631	Environmental	St. Clair Hospital		Wing	L pneumophila	1			11/6/1986
632	Environmental	American Legion	JS	Kitchen tap	L pneumophila	1			5
635	Environmental	American Legion	Ba3	HWT, colony 1	L pneumophila	1			12/8/1986
636	Environmental	American Legion	Ba3	Bath tap Col#2	L pneumophila	1			12/8/1986
637	Environmental	American Legion	Da4	#3	L pneumophila	6			12/8/1986
638	Environmental	American Legion	Da4	#2	L pneumophila	1			12/8/1986
639	Environmental	American Legion	Mi	#1	L pneumophila	4			12/8/1986
640	Environmental	American Legion	Mi	Bath tap, Col #1	L pneumophila	4			12/8/1986
641	Environmental	Mercy Hospital	Ho	207 shower	L pneumophila	3			12/8/1986
642	Environmental	Mercy Hospital		Return Recirc.	L pneumophila	3			12/8/1986
643	Environmental	Presby UPMC		Radiation	L pneumophila	12			12/8/1986
644	Environmental	Presby UPMC		women's room.	L pneumophila	12			12/8/1986
645	Environmental	Falk Clinic		women's room	L pneumophila	1			12/8/1986
646	Environmental	Falk Clinic		women's room	L pneumophila	1			12/8/1986
647	Environmental	Falk Clinic		women's room	L pneumophila	6			12/8/1986
648	Environmental	Duquesne		6th floor bath	L pneumophila	1			

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Record #	Culture type	Company Name	Source pt name	Description	Species name	Sg	Sub type	Miscellaneous	Frozen
652	Environmental	Duquesne		Towers 302A	L pneumophila	1			6
653	Environmental	American Legion	Sa3	Bath sink	L pneumophila	1			1/26/1987
654	Environmental	American Legion	Sa3	Kitchen sink	L pneumophila	1			1/26/1987
656	Environmental	University Drive VAMC	Do2	colony #1	L pneumophila	1	Bellingham		2/2/1987
657	Environmental	University Drive VAMC	Do2	colony #2	L pneumophila	1			2/2/1987
658	Environmental	University Drive VAMC	Do2	colony #3	L pneumophila	1			2/2/1987
660	Environmental	Angelo/Farm		HWT	L pneumophila	6		Type-1	4/9/1987
661	Environmental	Angelo/Farm		HWT	L pneumophila	6		Type 2	4/9/1987
662	Environmental	Angelo home		HWT	L pneumophila	1			4/9/1987
663	Environmental	Angelo home		faucet	L pneumophila	1			4/9/1987
664	Environmental	Angelo/Farm		Bath sink	L pneumophila	1			4/13/1987
665	Environmental	Angelo home		HWT	L pneumophila	1			4/15/1987
666	Environmental	Angelo/Farm		HWT	L pneumophila	6		Type-1	4/15/1987
667	Environmental	Angelo/Farm		HWT	L pneumophila	6		Type 2	4/15/1987
669	Environmental	Highland Drive VAMC		Bldg. 6 1039W	L pneumophila	6			5/15/1987
670	Environmental	Highland Drive VAMC		Bldg. 6 1098E	L pneumophila	6			5/15/1987
671	Environmental	Godspeed House		2nd floor	L pneumophila	1			5/15/1987
672	Environmental	Highland Drive VAMC		(Sampling 5-26-	L pneumophila	6			6/8/1987
673	Environmental	Highland Drive VAMC		Midsh (5-26)	L pneumophila	6			6/8/1987
674	Environmental	Highland Drive VAMC		(5-26)	L pneumophila	6			6/8/1987
675	Environmental	Highland Drive VAMC		(wind) (5-26)	L pneumophila	1			6/8/1987
676	Environmental	Highland Drive VAMC		(5-26-87)	L pneumophila	1			6/8/1987
686	Environmental	Moore Farm		HWT	L pneumophila	6			6/29/1987
687	Environmental	St. Rosalia Convent		(Bravin's room)	L pneumophila	1		colony #1	7/17/1987
688	Environmental	St. Rosalia Convent		Room 11	L pneumophila	1		colony #2	7/17/1987
689	Environmental	St. Rosalia Convent		Room 11	L pneumophila	1		colony #3	7/17/1987
690	Environmental	St. Rosalia Convent		HWT	L pneumophila	1		colony #1	7/17/1987
691	Environmental	St. Rosalia Convent		Room	L pneumophila	1			7/20/1987
692	Environmental	St. Rosalia Convent		Health Room	L pneumophila	1			7/20/1987
693	Environmental	St. Rosalia Convent		HWT initial	L pneumophila	1		colony #2	7/20/1987
694	Environmental	Moore home		Bath sink	L. bozmanae	2		colony #1	7/24/1987

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Record #	Culture type	Company Name	Source pt name	Description	Species name	Sg	Sub type	Miscellaneous	Frozen
695	Environmental	Moore home		Bath sink	L bozemanae	2		colony #2	7/24/1987
696	Environmental	Moore home		Bath sink	L. bozmanae	2		colony #3	7/24/1987
697	Environmental	Moore home		Bath sink	l. bozmanae	2		colony #4	7/24/1987
698	Environmental	Angelo home		87)	L pneumophila	1			7/24/1987
699	Environmental	Angelo home		(7-9)	L pneumophila	1			7/24/1987
700	Environmental	Moore home		Bath sink (7-9)	L pneumophila	6			7/24/1987
701	Environmental	Highland Drive VAMC		(7-2)	L pneumophila	1			7/24/1987
702	Environmental	Hatfield Power Station		pipe surface	L pneumophila	4			8/5/1987
703	Environmental	Hatfield Power Station		fountain filter	L pneumophila	3			8/5/1987
704	Environmental	Hatfield Power Station		fountain filter	L pneumophila	3			8/5/1987
705	Environmental	Hatfield Power Station		basin	L pneumophila	6			8/5/1987
706	Environmental	Hatfield Power Station		basin scrape	L pneumophila	3			8/5/1987
707	Environmental	Hatfield Power Station		watering Bin	L pneumophila	1			8/5/1987
708	Environmental	Hatfield Power Station		watering Bin	L pneumophila	4			8/5/1987
709	Environmental	Hatfield Power Station		watering Bin	L pneumophila	1			8/5/1987
710	Environmental	Hatfield Power Station		watering Bin	L pneumophila	4			8/5/1987
711	Environmental	Hatfield Power Station		watering Bin	L pneumophila	1			8/5/1987
712	Environmental	Hatfield Power Station		sink faucet	L pneumophila	3			8/5/1987
713	Environmental	Hatfield Power Station		watering bin	L pneumophila	4			8/5/1987
714	Environmental	Aultman, Canton OH		#3	L. dumoffii				8/5/1987
715	Environmental	Aultman, Canton OH		#4	Legionella ?				8/20/1987
716	Environmental	St. Rosalia Convent		Room	L pneumophila	1			9/4/1987
717	Environmental	St. Rosalia Convent		Classroom sink	L pneumophila	1			9/4/1987
719	Environmental	University Drive VAMC		(1A)	L pneumophila	5			9/10/1987
721	Environmental	Hatfield Power Station		#1	L pneumophila		SAT 3+	CDC	9/18/1987
722	Environmental	Hatfield Power Station		#1	L pneumophila?			colony 2	9/18/1987
723	Environmental	Hatfield Power Station		#1	L pneumophila ?			colony 3	9/18/1987
[illegible]	Environmental	Hatfield Power Station		cooling system	L pneumophila ?			colony 1	9/18/1987
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	L pneumophila	1		colony 2	9/18/1987
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	9/18/1987

Discarded Legionella Stock Collection

Record #	Culture Type	Company Name	Source/pt name	Description	species name	sg	Sub type	Miscellaneous	Frozen
728	Environmental	Hatfield Power Station		Hydrant	L pneumophila	1		colony 2	9/18/1987
729	Environmental	Stylette		Chiller H2O	L pneumophila	1			11/3/1987
730	Environmental	Stylette		of H2O	L pneumophila	1			11/3/1987
731	Environmental	Stylette		Water Fountain	L pneumophila	1			11/3/1987
732	Environmental	Stylette		water	L pneumophila	1			11/3/1987
733	Environmental	Stylette		water	L pneumophila	6			11/3/1987
734	Environmental	Stylette		water	L pneumophila	1			11/3/1987
735	Environmental	Stylette		water	L pneumophila	5			11/3/1987
736	Environmental	Winslow (Perriopolis)			L pneumophila	6			11/6/1987
737	Environmental	Stylette		Fountain	L pneumophila	1			11/3/1987
738	Environmental	Stylette		Press 2	L pneumophila	6			11/3/1987
739	Environmental	Stylette		pool	L pneumophila	3			11/3/1987
743	Environmental	Stylette		water	L pneumophila	1			11/3/1987
744	Environmental	Stylette		Holding tank 1	L pneumophila	1			11/3/1987
745	Environmental	Stylette		Holding tank 2	L pneumophila	6			11/3/1987
746	Environmental	University Drive VAMC		sink	L pneumophila	5			11/3/1987
748	Environmental	Kline home		Kitchen	L pneumophila	1		Iowa patient	7
752	Environmental	University Drive VAMC		MICU)	L pneumophila	1		Dec "87" survey	1/22/1988
753	Environmental	Highland Drive VAMC		fountain	L pneumophila	1			1/27/1988
754	Environmental	Highland Drive VAMC		Shower	L pneumophila	1		colony #1	1/27/1988
755	Environmental	Highland Drive VAMC		Shower	L pneumophila	1		colony #2	1/27/1988
756	Environmental	Highland Drive VAMC		Shower	L pneumophila	1		colony #3	1/27/1988
757	Environmental	Highland Drive VAMC		Shower	L pneumophila	6		colony #1	1/27/1988
758	Environmental	Highland Drive VAMC		shower	L pneumophila	6		colony #2	1/27/1988
759	Environmental	Highland Drive VAMC		wind	L pneumophila	1			1/27/1988
760	Environmental	Highland Drive VAMC		fountain	L pneumophila	1			1/27/1988
761	Environmental	Highland Drive VAMC		Bldg. 6 1095E	L pneumophila	6		colony #2	1/27/1988
762	Environmental	Highland Drive VAMC		Bldg. 6 1098E	L pneumophila	1		colony #1	1/27/1988
763	Environmental	University Drive VAMC		wing	L pneumophila	1			1/27/1988
771	Environmental	University Drive VAMC		9E129 col A	L pneumophila	1	Bellingham		2/5/1988
772	Environmental	University Drive VAMC		9E129 col B	L pneumophila	1			2/5/1988

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Record #	Culture Type	Company Name	Source/pt name	Description	species name	sg	Sub type	Miscellaneous	Frozen
773	Environmental	University Drive VAMC		3W114 slopsink	L pneumophila	1			2/5/1988
774	Environmental	University Drive VAMC		3A126 (MICU)	L pneumophila	1			2/5/1988
776	Environmental	University Drive VAMC		3A142	L pneumophila	1	Bellingham		2/29/1988
777	Environmental	University Drive VAMC		station	L pneumophila	1	Bellingham	colony 1	2/29/1988
778	Environmental	University Drive VAMC		station	L pneumophila	1		colony 2	2/29/1988
779	Environmental	University Drive VAMC		9E126	L pneumophila	1	Allentown	colony 3	2/29/1988
780	Environmental	University Drive VAMC		9E133	L pneumophila	1	Allentown		3/2/1988
781	Environmental	University Drive VAMC		9E126	L pneumophila	1	Allentown		3/2/1988
786	Environmental	Mercy Hospital		11004	L pneumophila	1			3/28/1988
787	Environmental	Mercy Hospital		4223-S	L pneumophila	1			3/28/1988
788	Environmental	Mercy Hospital		8016	L pneumophila	4			3/28/1988
789	Environmental	Mercy Hospital		5015	L pneumophila	1			3/29/1988
790	Environmental	Mercy Hospital		7015	L pneumophila	1			3/29/1988
791	Environmental	Mercy Hospital		12025	L pneumophila	1			3/29/1988
793	Environmental	Highland Drive VAMC		Bldg. 6 1098E	L pneumophila	1			4/1/1988
794	Environmental	Highland Drive VAMC		Bldg. 6 1012W	L pneumophila	1			4/1/1988
795	Environmental	Highland Drive VAMC		Bldg. 6 1083E	L pneumophila	1			4/1/1988
796	Environmental	University Drive VAMC		3A125	L pneumophila	1			4/13/1988
797	Environmental	University Drive VAMC		3A126 A	L pneumophila	1			4/13/1988
798	Environmental	University Drive VAMC		3A126 B	L pneumophila	1			4/13/1988
799	Environmental	University Drive VAMC		3A145 A	L pneumophila	1			4/13/1988
800	Environmental	University Drive VAMC		3A145 B	L pneumophila	1			4/13/1988
801	Environmental	University Drive VAMC		3A146	L pneumophila	1			4/13/1988
802	Environmental	University Drive VAMC		#1	L pneumophila	1			4/14/1988
804	Environmental	wash station		cold water	L pneumophila	1		colony #1	5/19/1988
805	Environmental	wash station		cold water	L pneumophila	1		colony #2	5/19/1988
806	Environmental	wash station		cold water	L pneumophila	1		colony #3	[illegible]
807	Environmental	wash station							

Discarded Legionella Stock Collection

Record #	Culture type	Company Name	Source/routine	Description	Species name	Sg	Sub type	Serotype/group	Date
815	Environmental	Shadyside Manor		heater	L pneumophila	1			5/25/1988
816	Environmental	Shadyside Manor		shower room -	L pneumophila	1		colony #2	5/25/1988
817	Environmental	Shadyside Manor		Room 222	L pneumophila	1		colony #1	5/25/1988
818	Environmental	Shadyside Manor		shower	L pneumophila	1			5/25/1988
819	Environmental	Shadyside Manor		Room 203	L pneumophila	1		colony #1	5/25/1988
820	Environmental	Shadyside Manor		Room 203	L pneumophila	1		colony #5	5/25/1988
821	Environmental	Aspinwall VAMC		1U-1338 sink	L pneumophila	1			5/25/1988
822	Environmental	Highland Drive VAMC		Bldg. 6 1012W	L pneumophila	1			5/26/1988
823	Environmental	Highland Drive VAMC		door	L pneumophila	1			5/26/1988
824	Environmental	Shadyside Manor		shower room -	L pneumophila	1		colony #1 protub. Type	6/2/1988
825	Environmental	Shadyside Manor		(AT)	L pneumophila	1		colony #1	6/2/1988
826	Environmental	Shadyside Manor		(Dir)	L pneumophila	1		colony #3	6/2/1988
827	Environmental	Shadyside Manor		(Dir)	L pneumophila	1		colony #4	6/2/1988
828	Environmental	Schneider Eng.		water, W-4 (AT)	L pneumophila	1			6/3/1988
829	Environmental	Schneider Eng.		water, W-5 (AT)	L pneumophila	1			6/3/1988
830	Environmental	Schneider Eng.		water, W-6 (AT)	L pneumophila	1			6/3/1988
831	Environmental	Schneider Eng.		swab, S-2 (AT)	L pneumophila	1			6/3/1988
832	Environmental	Schneider Eng.		swab, S-3 (AT)	L pneumophila	1			6/3/1988
833	Environmental	Schneider Eng.		swab S-4 (AT)	L pneumophila	1			6/3/1988
835	Environmental	University Drive VAMC		9E120	L pneumophila	1		colony #1	6/16/1988
836	Environmental	University Drive VAMC		9E120	L pneumophila	1		colony #2	6/16/1988
837	Environmental	University Drive VAMC		9E fountain	L pneumophila	1	Bellingham		6/16/1988
839	Environmental	University Drive VAMC		9E ice	L pneumophila	1			6/24/1988
840	Environmental	University Drive VAMC		6E Rt Shower	L pneumophila	1	Allentown		6/24/1988
841	Environmental	University Drive VAMC		6E-143	L pneumophila	5			6/24/1988
844	Environmental	Center	Me	Rm 51A	L pneumophila	1			7/7/1988
845	Environmental	Center	Me	1	L pneumophila	1		colony #1	7/7/1988
846	Environmental	Center	Me	room #1	L pneumophila	1		colony #3	7/7/1988
847	Environmental	Center	Me	sample	L pneumophila	1		colony #1	7/7/1988
848	Environmental	Center	Me	HWT	L pneumophila	1		colony #1	7/7/1988
849	Environmental	Center	Me	HWT	L pneumophila	1		colony #2	7/7/1988

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Record #	Culture type	Company Name	Source/routine	Description	Species name	Sg	Sub type	Serotype/group	Date
850	Environmental	Center	Me	HWT	L pneumophila	1		colony #1	7/7/1988
851	Environmental	Center	Me	HWT	L pneumophila	1		colony #3	7/7/1988
852	Environmental	Center	Me	initial sample	L. erythra			restocked 8-22-88	7/11/1988
856	Environmental	University Drive VAMC	RS	9W fountain	L pneumophila	1	Bellingham	colony #1	8/1/1988
857	Environmental	University Drive VAMC	RS	9W fountain	L pneumophila	1	Bellingham	colony #4	8/1/1988
859	Environmental	University Drive VAMC		Utility room	L pneumophila	1			8/12/1988
860	Environmental	University Drive VAMC		utility room	L pneumophila	1			8/12/1988
861	Environmental	University Drive VAMC		utility room	L pneumophila	1			8/12/1988
862	Environmental	University Drive VAMC		SICU 3A141	L pneumophila	1			8/12/1988
863	Environmental	University Drive VAMC		HWT #3 col. A	L pneumophila	1	Bellingham		8/18/1988
864	Environmental	University Drive VAMC		HWT #3 col. B	L pneumophila	1	Philadelphia		8/18/1988
865	Environmental	University Drive VAMC		HWT #4	L pneumophila	5			8/18/1988
866	Environmental	University Drive VAMC		cooling tower	Legionella ?				8/25/1988
868	Environmental	University Drive VAMC		5E fountain	L pneumophila	1	Bellingham		8/25/1988
869	Environmental	University Drive VAMC		3W 107	L pneumophila	5		colony #1	8/25/1988
870	Environmental	University Drive VAMC		3W107	L pneumophila	5		colony #2	8/25/1988
871	Environmental	University Drive VAMC		9W fountain	L pneumophila	1	Bellingham	colony #1	8/25/1988
872	Environmental	University Drive VAMC		9W fountain	L pneumophila	1	Bellingham	colony #2	8/25/1988
873	Environmental	University Drive VAMC		4W-139	L pneumophila	1	Allentown	colony #2	8/25/1988
874	Environmental	University Drive VAMC		9E fountain	L pneumophila	1	Bellingham		8/25/1988
875	Environmental	University Drive VAMC		8W 106d	L pneumophila	5		colony #2	8/25/1988
876	Environmental	University Drive VAMC		8E right shower	L pneumophila	1	Allentown		8/31/1988
877	Environmental	Ol Corning - Clarion	JP	tower	L pneumophila	6			9/23/1988
878	Environmental	Ol Corning - Clarion	JP		L pneumophila	5?			9/23/1988
879	Environmental	Ol Corning - Clarion		mill use pond	L pneumophila	5			9/23/1988
880	Environmental	Ol Corning - Clarion		marley hot well	L pneumophila	6			9/23/1988
881	Environmental	Ol Corning - Clarion	JP	marley hot well	L pneumophila	7			9/23/1988
[illegible]	[illegible]	Highland Drive VAMC		sink	L pneumophila	1			8

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Record #	culture type	Company Name	source pt name	Description	species name	sg	Sub type	Miscellaneous	Frozen
890	Environmental	Aspinwall VAMC		322 fountain	L pneumophila	1		colony #1	5
891	Environmental	Aspinwall VAMC		322 fountain	L pneumophila	1		colony #2	5
892	Environmental	Aspinwall VAMC		316 kitchen	L pneumophila	1		colony #1 diff morph	5
893	Environmental	Aspinwall VAMC		316 kitchen	L pneumophila	1		colony #2	5
894	Environmental	Aspinwall VAMC		339 rt shower	L pneumophila	1			5
896	Environmental	Charleston WV		1	L pneumophila	6			1/23/1989
897	Environmental	Charleston WV		2	L pneumophila	6			1/24/1989
898	Environmental	Charleston WV		3	L pneumophila	6			1/24/1989
899	Environmental	Charleston WV		4	L pneumophila	6			1/24/1989
900	Environmental	Shadyside Manor		heater #2	L pneumophila	1		colony #1	2/8/1989
901	Environmental	Shadyside Manor		heater #2	L pneumophila	1		colony #4	2/8/1989
902	Environmental	Shadyside Manor		shower	L pneumophila	1			2/8/1989
903	Environmental	Togus VAMC		tank D	L pneumophila	1			2/24/1989
911	Environmental	University Drive VAMC		collection room	L pneumophila	1		colony #1	5/8/1989
912	Environmental	University Drive VAMC		2E sink	L pneumophila	1		colony #3	5/8/1989
913	Environmental	Magee Hospital		women's room	L pneumophila	1		colony #1	5/8/1989
914	Environmental	Magee Hospital		women's room	L pneumophila	1		colony #2	5/8/1989
915	Environmental	Magee Hospital		women's room	L pneumophila	1		colony #3	5/8/1989
916	Environmental	Magee Hospital		women's room	L pneumophila	1		colony #4	5/8/1989
927	Environmental	University Drive VAMC	Gr2	6E-143 sink	L pneumophila	1			7/21/1989
945	Environmental	Divine Providence		325	L pneumophila	1			4/12/1990
946	Environmental	Divine Providence		2North	L pneumophila	1			4/12/1990
947	Environmental	Divine Providence		spigot 3South	L pneumophila	1			4/12/1990
948	Environmental	University Drive VAMC		HWT #1	L pneumophila	?			4/12/1990
949	Environmental	University Drive VAMC		HWT #2	L pneumophila	?			4/12/1990
960	Environmental	University Drive VAMC		of cefamandole	L pneumophila	1			8/27/1990
961	Environmental	University Drive VAMC		sink (window)	L pneumophila	1		Brucella broth	9/13/1990
962	Environmental	University Drive VAMC		sink (window)	L pneumophila	1		Brucella broth	9/13/1990
963	Environmental	University Drive VAMC		sink (window)	L pneumophila	1		Brucella broth	9/13/1990
971	Environmental	University Drive VAMC	Rh	7W-114	L pneumophila	5			1/31/1991
974	Environmental	Kelly home		kitchen sink	L pneumophila	3			3/21/1991

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975	Environmental	Kelly home		shower	L pneumophila	3			3/21/1991
976	Environmental	Kelly home		HWT	L pneumophila	3			3/21/1991
977	Environmental	Kelly home		HWT	L pneumophila	1			3/21/1991
978	Environmental	Kelly home		HWT	L pneumophila	1			3/21/1991
979	Environmental	Mercy Hospital		type 1	L pneumophila	1		creamy	4/11/1991
980	Environmental	Mercy Hospital		type 2	L pneumophila	1		DFA+ filaments-sticky	4/11/1991
981	Environmental	Mercy Hospital		HWT #2	L pneumophila	1		creamy	4/11/1991
982	Environmental	Highland Drive VAMC		shower #3	L pneumophila	1			5/3/1991
983	Environmental	Highland Drive VAMC		shower #2	L pneumophila	6			5/3/1991
984	Environmental	Highland Drive VAMC		shower #1	L pneumophila	1			5/3/1991
985	Environmental	Highland Drive VAMC		shower #2	L pneumophila	6			5/3/1991
988	Environmental	University Drive VAMC		9W-132 #1	L pneumophila	1			5/13/1991
989	Environmental	University Drive VAMC		9W-132 #2	L pneumophila	1			5/13/1991
990	Environmental	University Drive VAMC	PC	6W rt shower	L pneumophila	1			5/21/1991
991	Environmental	University Drive VAMC		AT (BCYE)	species ?	?		colony #1	5/21/1991
992	Environmental	University Drive VAMC		AT(BCYE)	species ?	?		colony #2	5/21/1991
993	Environmental	Highland Drive VAMC		sample	L pneumophila	6			5/21/1991
994	Environmental	University Drive VAMC	PC	6W114	L pneumophila	1			5/28/1991
995	Environmental	University Drive VAMC	PC	6W133	L pneumophila	1			5/28/1991
996	Environmental	University Drive VAMC	Ha5	9W rt shower	L pneumophila	1			5/28/1991
997	Environmental	University Drive VAMC	Ha5	9W rt shower	L pneumophila	1			5/28/1991
998	Environmental	University Drive VAMC		#1	species ?	?		mixed morph	5/28/1991
999	Environmental	University Drive VAMC		#2	species ?	?			5/28/1991
1001	Environmental	West Penn Hospital		HWT	L pneumophila	1			6/18/1991
1002	Environmental	West Penn Hospital		HWT	L pneumophila	6			6/18/1991
1003	Environmental	West Penn Hospital		room 4319	L pneumophila	1			6/18/1991
1004	Environmental	West Penn Hospital		room 4319				species	6/18/1991
1005	Environmental	West Penn Hospital		room 3307	[illegible]	[illegible]			

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Record #	Culture Type	Company Name	Source Name	Specimen Source	Species Name	Sp	Sub type	Colony Count	Date
1011	Environmental	University Drive VAMC	Bu	4E rt shower	L pneumophila	1			8/5/1991
1012	Environmental	University Drive VAMC	Bu	4E fountain	L pneumophila	1		colony 2	8/5/1991
1013	Environmental	University Drive VAMC	Bu	4E fountain	L pneumophila	1		colony 3	8/5/1991
1014	Environmental	University Drive VAMC	Bu	4E fountain	L pneumophila	1		colony 4	8/5/1991
1017	Environmental	Mercy Hospital		HWT #1	L pneumophila	1		colony #1	8/19/1991
1018	Environmental	Mercy Hospital		HWT #1	L pneumophila	1		colony #2	8/19/1991
1019	Environmental	University Drive VAMC	Bla	sink near ice	L pneumophila	1			8/27/1991
1020	Environmental	University Drive VAMC	Bla	sink near ice	L pneumophila	1			8/27/1991
1021	Environmental	University Drive VAMC	Bla	sink near ice	L pneumophila	1			8/27/1991
1022	Environmental	University Drive VAMC	Bla	sink near ice	L pneumophila	5			8/27/1991
1023	Environmental	University Drive VAMC	Bla	sink near ice	L pneumophila	5			8/27/1991
1024	Environmental	University Drive VAMC	Bla	7W fountain	L pneumophila	1	Bellingham		8/27/1991
1025	Environmental	University Drive VAMC	Bla	7W fountain	L pneumophila	1	Bellingham		8/27/1991
1026	Environmental	Presby UPMC	NN	sink	L pneumophila	5			8/27/1991
1027	Environmental	Mercy Hospital		top (8-14-91)	L pneumophila	1			8/27/1991
1028	Environmental	Mercy Hospital		91)	L pneumophila	1			8/27/1991
1029	Environmental	Mercy Hospital		91)	L pneumophila	1			8/27/1991
1030	Environmental	Mercy Hospital		return	L pneumophila	?			8/27/1991
1031	Environmental	Mercy Hospital		18)	L pneumophila	1			8/28/1991
1032	Environmental	Mercy Hospital		bottom (8-19)	L pneumophila	1			8/28/1991
1033	Environmental	Mercy Hospital		19)	L pneumophila	?			8/28/1991
1034	Environmental	Mercy Hospital		19)	L pneumophila	?		colony 2	8/28/1991
1035	Environmental	Mercy Hospital		(8-19)	L pneumophila	1		colony 1	8/28/1991
1036	Environmental	Mercy Hospital		(8-19)	L pneumophila	?		colony 2; pink	8/28/1991
1037	Environmental	Mercy Hospital		left tower return	L pneumophila	1		colony 3	8/28/1991
1038	Environmental	Aspinwall VAMC	Bla	2A2063 sink	L pneumophila	1		colony 1	8/29/1991
1039	Environmental	Aspinwall VAMC	Bla	2A2063 sink	L pneumophila	1		colony 2	8/29/1991
1040	Environmental	Aspinwall VAMC	Bla	2A2063 sink	L pneumophila	1		colony 3	8/29/1991
1042	Environmental	Highland Drive VAMC		cold filter	pneumophila			colony 2	9/24/1991
1043	Environmental	Highland Drive VAMC		cold filter	pneumophila			colony 3	9/24/1991
1044	Environmental	Neubauer home		kitchen	Ps. aeruginosa				4/23/2003

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1045	Environmental	Mercy Hospital		return (9-20-91)	L pneumophila	1			9/27/1991
1046	Environmental	Mercy Hospital		91	L pneumophila	?		colony 1	9/27/1991
1047	Environmental	Neubauer home			yeast				10/1/1991
1048	Environmental	University Drive VAMC			aeruginosa			MIC Aztreonam = 2	10/2/1991
1049	Environmental	Mercy Hospital		return (9-20)	L pneumophila	1		pratub	10/4/1991
1050	Environmental	Mercy Hospital		return (9-20)	L pneumophila	?		colony #2	10/4/1991
1051	Environmental	Mercy Hospital		return (9-20)	L pneumophila	1		colony #3	10/4/1991
1054	Environmental	Neubauer home		shower				pink (dark type) GNR	1
1055	Environmental	Neubauer home		shower				pink (light type) GNR	1
1056	Environmental	University Drive VAMC	Wa10	4E fountain	L pneumophila	1	Bellingham	colony 1	1
1057	Environmental	University Drive VAMC	Wa10	4E fountain	L pneumophila	1	Bellingham	colony 2	1
1058	Environmental	University Drive VAMC	Wa10	4E fountain	L pneumophila	1	Bellingham	colony 3	1
1059	Environmental	Mercy Hospital		shock)	L pneumophila	1			1
1060	Environmental	Mercy Hospital		shock)	L pneumophila	1		colony 1	1
1061	Environmental	Mercy Hospital		shock)	L pneumophila	1		colony 2, sticky	1
1062	Environmental	Mercy Hospital		room 12025	L pneumophila	1			1
1063	Environmental	Mercy Hospital		return conc (10-	L pneumophila	1			1
1064	Environmental	Mercy Hospital		return	L pneumophila	1		colony 2	1
1065	Environmental	Highland Drive VAMC		hot water filter	?			colony 1	1
1066	Environmental	Highland Drive VAMC		hot water filter	?			colony 2	1
1067	Environmental	Highland Drive VAMC		BCYE	pneumophila				1
1068	Environmental	Highland Drive VAMC		cold water filter	?				1
1070	Environmental	Mercy Hospital		HWT #1	L pneumophila	1			1
1071	Environmental	Mercy Hospital		HWT #2	? LDB			colony #1 (pink)	1
1072	Environmental	Mercy Hospital		HWT #1	L pneumophila	1			1
1074	Environmental	Mercy Hospital	Ya	sputum	L pneumophila	1	Philadelphia	Sewickley to Mercy	3/16/1992
1076	Environmental	Highland Drive VAMC		cold filter	L pneumophila	1			3/20/1992
				hold filter	L pneumophila	1			3/20/1992

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Record #	Culture type	Company/Name	source pt name	description	species name	I-sg	Sub type	Miscellaneous	frozen
1081	Environmental	Mercy Hospital		92) 1st sample	L pneumophila	1			3/20/1992
1082	Environmental	Sewickley Hospital		ER-12 cold	L pneumophila	1			3/23/1992
1083	Environmental	Sewickley Hospital		CCU #16 hot	L pneumophila	?		not 1-6	3/23/1992
1084	Environmental	Sewickley Hospital		455 cold	L pneumophila	?		not 1-6	3/23/1992
1085	Environmental	Sewickley Hospital		571C hot	L pneumophila	1			3/23/1992
1086	Environmental	Sewickley Hospital		665C hot	L pneumophila	1			3/23/1992
1087	Environmental	Sewickley Hospital		665C cold	L pneumophila	1			3/23/1992
1088	Environmental	Sewickley Hospital		hot/eng. Rom	Legionella ?			not pneumophila	3/23/1992
1091	Environmental	Highland Drive VAMC		hot pre-filter	L pneumophila	6			3/30/1992
1092	Environmental	University Drive VAMC		fountain	L pneumophila	1	Bellingham		4/2/1992
1093	Environmental	University Drive VAMC		fountain near	L pneumophila	1	Bellingham		4/2/1992
1094	Environmental	University Drive VAMC		fountain near	L pneumophila	1	Bellingham		4/2/1992
1095	Environmental	Mercy Hospital		room 12025	L pneumophila	1		colony 1	4/7/1992
1096	Environmental	Mercy Hospital		room 12025	L pneumophila	1		colony 2	4/7/1992
1097	Environmental	Mercy Hospital		HWT #2	L pneumophila	1		colony 1	4/7/1992
1098	Environmental	Mercy Hospital		HWT #2	L pneumophila	1		colony 2	4/7/1992
1099	Environmental	Highland Drive VAMC		11/91)	L pneumophila	1			4/13/1992
1100	Environmental	Highland Drive VAMC		11/91)	L pneumophila	1			4/13/1992
1101	Environmental	Aspinwall VAMC	De7	fountain across	L pneumophila	1			4/13/1992
1102	Environmental	Aspinwall VAMC		Fish's office)	L pneumophila	1			4/13/1992
1103	Environmental	Aspinwall VAMC		1U fountain	L pneumophila	1			4/13/1992
1104	Environmental	University Drive VAMC	Co7	5E fountain	L pneumophila	1	Bellingham		4/13/1992
1105	Environmental	University Drive VAMC	Fi2	9W rt shower	L pneumophila	5			4/13/1992
1106	Environmental	University Drive VAMC		9W rt shower	L pneumophila	1		colony 2	4/13/1992
1109	Environmental	Highland Drive VAMC		hot filter #1	L pneumophila	1			5/24/1992
1110	Environmental	Highland Drive VAMC		hot filter #1	L pneumophila	6			5/24/1992
1111	Environmental	Highland Drive VAMC		hot filter #2	L pneumophila	6			5/24/1992
1112	Environmental	Highland Drive VAMC		hot filter #2	L pneumophila	6			5/24/1992
1113	Environmental	Highland Drive VAMC		cold filter	L pneumophila	1			5/24/1992
1114	Environmental	Highland Drive VAMC		cold filter	sp				5/24/1992
1115	Environmental	Highland Drive VAMC		bldg 6 1017 #3	L pneumophila	6			5/24/1992

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Record #	Culture type	Company/Name	source pt name	description	species name	I-sg	Sub type	Miscellaneous	frozen
1116	Environmental	Highland Drive VAMC		bldg 6 1100E	L pneumophila	1			5/24/1992
1117	Environmental	Highland Drive VAMC		bldg 6 1038W	L pneumophila	6			5/24/1992
1118	Environmental	University Drive VAMC	GT ?	9W rt shower	L pneumophila	1			5/24/1992
1119	Environmental	University Drive VAMC		9W rt shower	L pneumophila	1			5/24/1992
1120	Environmental	Mains home		bathtub	fluoribact. Sp				5/24/1992
1121	Environmental	Mercy Hospital		room 12025	L pneumophila	1			5/24/1992
1122	Environmental	Mercy Hospital		HWT 2	Leg. Sp?				5/24/1992
1123	Environmental	Mercy Hospital		HWT 2	L pneumophila	1			5/24/1992
1129	Environmental	University Drive VAMC		6W114	L pneumophila	5			6/18/1992
1130	Environmental	Sewickley Hospital		665C				colony 2	6/18/1992
1131	Environmental	Sewickley Hospital		665C	L pneumophila	1		colony 3	6/18/1992
1132	Environmental	Sewickley Hospital		BR					6/18/1992
1133	Environmental	Sewickley Hospital		engine room	L pneumophila	1			6/18/1992
1134	Environmental	Sewickley Hospital		717W BR	L pneumophila	1			6/18/1992
1135	Environmental	Sewickley Hospital		717W BR	L pneumophila	1			6/18/1992
1136	Environmental	Sewickley Hospital		eng. HWT	L pneumophila	1			6/18/1992
1138	Environmental	Sewickley Hospital		717W					6/18/1992
1139	Environmental	Sewickley Hospital		717W					6/18/1992
1141	Environmental	Sewickley Hospital		BCYE (from 6-				fluorescence sp	7/14/1992
1142	Environmental	Sewickley Hospital		BCYE				fluorescence sp	7/14/1992
1143	Environmental	Sewickley Hospital		S-701	L pneumophila	1			7/14/1992
1144	Environmental	Sewickley Hospital		(from 6-30-92				fluorescence sp	7/14/1992
1145	Environmental	Sewickley Hospital		old garage	L pneumophila	1			7/14/1992
1146	Environmental	Highland Drive VAMC		1017W (from 6-	L pneumophila	1			7/14/1992
1147	Environmental	Highland Drive VAMC		1017W	L pneumophila	6			7/14/1992
1148	Environmental	Highland Drive VAMC		filter hot 1095E	L pneumophila	1			7/14/1992
1149	Environmental	Highland Drive VAMC		filter hot 1017W	L pneumophila	1			7/14/1992
1150	Environmental	Highland Drive VAMC		filter hot 1017W	L pneumophila	1			

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Record #	Culture Type	Site Complex Name	Site Description	Description 2	Species name	Dg	Sub type 2	Miscellaneous	Internal #
1156	Environmental	Sewickley Hospital		water	L pneumophila	1		more purple	2
1157	Environmental	Sewickley Hospital		water	L pneumophila	1		more blue	2
1158	Environmental	Sewickley Hospital		swab	L pneumophila	1			2
1159	Environmental	Sewickley Hospital		water	L pneumophila	?			2
1160	Environmental	University Drive VAMC		9E114 sink	L pneumophila	1	Bellingham		2
1161	Environmental	University Drive VAMC		9E114 sink	L pneumophila	1	Bellingham		2
1162	Environmental	University Drive VAMC		9E fountain	L pneumophila	1	Bellingham		2
1163	Environmental	University Drive VAMC		7W-43	L pneumophila	1	Allentown		2
1164	Environmental	University Drive VAMC		CWT	L pneumophila	1		colony #1	2
1165	Environmental	University Drive VAMC		CWT	L pneumophila	1		colony 2	2
1166	Environmental	Mercy Hospital		return	L pneumophila	1			2
1167	Environmental	Mercy Hospital		tank #1 (top)	L pneumophila	1			2
1168	Environmental	Mercy Hospital		return	L pneumophila	1			2
1169	Environmental	Mercy Hospital		(post)	L pneumophila	1			2
1170	Environmental	Highland Drive VAMC		hot UV (pre)	L pneumophila	1			2
1171	Environmental	Highland Drive VAMC		cold UV (post)	L pneumophila	6			2
1172	Environmental	Highland Drive VAMC		bldg 6 1100E	L pneumophila	1			2
1173	Environmental	Highland Drive VAMC		bldg 6 1027W	L pneumophila	1			2
1174	Environmental	Highland Drive VAMC		bldg 6 1095E	L pneumophila	6			2
1175	Environmental	Highland Drive VAMC		1E	Blue white fl.				2
1176	Environmental	Highland Drive VAMC		bldg 6 cold filter	?				2
1177	Environmental	Highland Drive VAMC		1W	Blue white fl.				2
1178	Environmental	Albany VAMC		427A sink	L pneumophila	1			2
1179	Environmental	Albany VAMC		SICU sink	L pneumophila	1			2
1180	Environmental	Albany VAMC		510A sink	L pneumophila	1			2
1181	Environmental	Albany VAMC		918B shower	L pneumophila	1			2
1184	Environmental	Sewickley Hospital		C308	L pneumophila	1			2
1185	Environmental	Sewickley Hospital		C647	L pneumophila	1		colony #1	2
1186	Environmental	Sewickley Hospital		C647	L pneumophila	1		colony #2	2
1187	Environmental	Sewickley Hospital		W710	L pneumophila	1			2
1190	Environmental	University Drive VAMC		HWT #2 12/92	? Species			immediate	2

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Record #	Culture Type	Site Complex Name	Site Description	Description 2	Species name	Dg	Sub type 2	Miscellaneous	Internal #
1192	Environmental	Sewickley Hospital		W710 (A)	L pneumophila	1			1/14/1993
1193	Environmental	Sewickley Hospital		W710 (B)	pneumophila				1/14/1993
1194	Environmental	Sewickley Hospital		W710 (C)	L pneumophila	1			1/14/1993
1195	Environmental	Sewickley Hospital		W710 (D)	L pneumophila	1			1/14/1993
1196	Environmental	University Drive VAMC		8E rt shower	L pneumophila	1			1/14/1993
1197	Environmental	Highland Drive VAMC		bldg 5 1063E	L pneumophila	1			1/27/1993
1198	Environmental	Highland Drive VAMC		bldg 5 2087E	?	?			1/27/1993
1199	Environmental	Aspinwall VAMC		sink	L pneumophila	1			1/27/1993
1200	Environmental	Highland Drive VAMC		bldg 6 1095E	L pneumophila	6			2/3/1993
1201	Environmental	Highland Drive VAMC		Bldg 6 1095E	L pneumophila	6			2/3/1993
1202	Environmental	Aspinwall VAMC		1B153F	L pneumophila	1	oxford		2/5/1993
1203	Environmental	Aspinwall VAMC		1B153F	L pneumophila	1	oxford		2/5/1993
1204	Environmental	Aspinwall VAMC		Bldg. 50 GC106	L pneumophila	1			2/5/1993
1205	Environmental	Aspinwall VAMC		Bldg. 50 GC106	L pneumophila	1			2/5/1993
1206	Environmental	Sewickley Hospital		710W	L pneumophila	1			2/5/1993
1207	Environmental	Highland Drive VAMC		Bldg. 5 2087E	L pneumophila	1			2/5/1993
1209	Environmental	Szeszak home		HWT	L pneumophila	1			3/10/1993
1210	Environmental	Szeszak home		HWT	L pneumophila	1			3/10/1993
1211	Environmental	Szeszak home		HWT	L pneumophila	1			3/10/1993
1212	Environmental	Szeszak home		bathroom sink	L pneumophila	1			3/10/1993
1213	Environmental	Szeszak home		bathroom sink	L pneumophila	1			3/10/1993
1214	Environmental	Highland Drive VAMC		Bldg. 5 2087	L pneumophila	6			3/10/1993
1215	Environmental	Janesville		21-06	L pneumophila	1			3/10/1993
1216	Environmental	Janesville		21-07	L pneumophila	1			3/10/1993
1217	Environmental	Janesville		31-09	L pneumophila	1			3/10/1993
1218	Environmental	Janesville		4211	L pneumophila	1			3/10/1993
1219	Environmental	Janesville		21-27	L. bozmanii				3/10/1993
[illegible]	[illegible]	Janesville		21-27	L. bozmanii				3/10/1993
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	4/5/1993

Discarded Legionella Stock Collection

Record #	Culture type	Company Name	Source/Plant Name	Description	Species name	Sg	Sub type	Media/Source	Frozen
1225	Environmental	University Drive VAMC		HWT 3	L pneumophila	1			4/5/1993
1226	Environmental	University Drive VAMC		HWT 3	L pneumophila	1			4/5/1993
1227	Environmental	University Drive VAMC		HWT 3	blue-white fl				4/5/1993
1228	Environmental	McKeesport Hospital		4B	L pneumophila	1	Bellingham		4/8/1993
1229	Environmental	McKeesport Hospital		- 4B	L pneumophila	1			4/8/1993
1230	Environmental	McKeesport Hospital		Bldg. - 4B	L pneumophila	1			4/8/1993
1231	Environmental	McKeesport Hospital		boiler room 5A	L pneumophila	1			4/8/1993
1232	Environmental	McKeesport Hospital		boiler room 5A	L pneumophila	1			4/8/1993
1233	Environmental	McKeesport Hospital		boiler room 6A	L pneumophila	1			4/8/1993
1234	Environmental	McKeesport Hospital		boiler room 6A	L pneumophila	1			4/8/1993
1236	Environmental	Highland Drive VAMC		#1	L pneumophila	6			4/13/1993
1237	Environmental	Highland Drive VAMC		Bldg. 6 1089E	L pneumophila	6			4/13/1993
1238	Environmental	Highland Drive VAMC		#1	L pneumophila	6			4/13/1993
1239	Environmental	McKeesport Hospital		Shawdock - 4B				1-6	4/13/1993
1241	Environmental	Highland Drive VAMC		Bldg. 6 1081E	blue-white fl				4/27/1993
1242	Environmental	Highland Drive VAMC		Bldg. 6 1047W	L pneumophila	6			5/6/1993
1243	Environmental	Highland Drive VAMC		Bldg 6 1012W	L pneumophila	1			5/6/1993
1244	Environmental	Highland Drive VAMC		Bldg. 6 1063E	blue-white fl				4/27/1993
1245	Environmental	Highland Drive VAMC		Bldg. 6 1100E	L pneumophila	1			5/5/1993
1246	Environmental	Highland Drive VAMC		Bldg 5 1081	blue-white fl				5/27/1993
1247	Environmental	Highland Drive VAMC		Bldg 5 1085	L pneumophila	6			6/21/1993
1248	Environmental	Highland Drive VAMC		Bld 6 1047W	L pneumophila	6			6/21/1993
1249	Environmental	Highland Drive VAMC		#1	L pneumophila	6			6/21/1993
1250	Environmental	Highland Drive VAMC		Bldg 5 1019W	L pneumophila	6			6/21/1993
1251	Environmental	Highland Drive VAMC		Bldg 6 1027W	L pneumophila	1	Olda		6/21/1993
1252	Environmental	Highland Drive VAMC		#2	L pneumophila	1			6/21/1993
1254	Environmental	University Drive VAMC		fountain	blue-white fl.				6/14/1993
1255	Environmental	University Drive VAMC		HWT #2	blue-white fl.				6/14/1993
1256	Environmental	Aspinwall VAMC		Bldg 50 6D105	L pneumophila	1			6/21/1993
1257	Environmental	Aspinwall VAMC		GA110A	L pneumophila	1			6/21/1993
1258	Environmental	Aspinwall VAMC		Bldg 51 2B166	red fl.				6/21/1993

Discarded Legionella Stock Collection

Record #	Culture type	Company Name	Source/Plant Name	Description	Species name	Sg	Sub type	Media/Source	Frozen
1259	Environmental	Aspinwall VAMC		Bldg. 51 2A134	L pneumophila	1			6/21/1993
1260	Environmental	Mercy Hospital		12025	L pneumophila	1			6/21/1993
1261	Environmental	Jim Annette/Franklin			L pneumophila	1		San Francisco-like	6/21/1993
1262	Environmental	Jim Annette/Franklin			L pneumophila	15			6/21/1993
1264	Environmental	Highland Drive VAMC		#2	L. erythra			800 BCYE	9/10/1993
1265	Environmental	Highland Drive VAMC		#2	L. anisa			BP3 GVPC (B/W)	9/10/1993
1266	Environmental	Highland Drive VAMC		#2	L pneumophila	1		ACO DGVP (B/W)	9/10/1993
1267	Environmental	Highland Drive VAMC		Bldg 6 1100E	L pneumophila	1		BC3 GPAV	9/10/1993
1269	Environmental	Gateway View Plaza		polica)	L pneumophila	1			9/21/1993
1270	Environmental	Gateway View Plaza		polica)	L pneumophila	5			9/21/1993
1271	Environmental	Gateway View Plaza		(heinz)	L pneumophila	1			9/21/1993
1272	Environmental	Gateway View Plaza		(heinz)	L pneumophila	5			9/21/1993
1273	Environmental	Gateway View Plaza		(heinz)	L. bozemani				9/21/1993
1274	Environmental	Gateway View Plaza		(heinz)	L. bozemani				9/21/1993
1275	Environmental	Gateway View Plaza		(1st) (heinz)	L pneumophila	5			9/21/1993
1276	Environmental	Gateway View Plaza		(1st) (heinz)	L. bozemani				9/21/1993
1277	Environmental	Glen-Hazell (Kane)		room #216	L pneumophila	1		#1	9/30/1993
1278	Environmental	Glen-Hazell (Kane)		room 216	L pneumophila	1		#2	9/30/1993
1279	Environmental	Glen-Hazell (Kane)		room 216	L. bozemani				9/30/1993
1280	Environmental	Glen-Hazell (Kane)		room 216	Legionella sp.			species unknown	9/30/1993
1282	Environmental	University Drive VAMC	Ve1	9E ward sink	L pneumophila	1	Allentown		3
1283	Environmental	University Drive VAMC	Ve1	9E-33 sink	L pneumophila	1	Allentown		3
1284	Environmental	University Drive VAMC	Ve1	9E-33 sink	L pneumophila	1			3
1286	Environmental	McKeesport Hospital	Ka	HWT 3	L pneumophila			serotype unknown	3
1287	Environmental	University Drive VAMC		CWT	Legionella sp			species unknown	3
1288	Environmental	University Drive VAMC		HWT 3	L pneumophila	1			3
1289	Environmental	Mercy Hospital		HWT #1	L pneumophila	4			3
1290	Environmental	Mercy Hospital		12001	L pneumophila	1			3

Discarded Legionella Stock Collection

Record #	culture type	Job Company Name	Job City/Claim #	Job Description	Species name	Sg	Sub type	Misc.	Date
1295	Environmental	Ross	Ka	286 faucet	L. bozemanii				3
1296	Environmental	Ross	Ka	HWT #2	L pneumophila	6			3
1298	Environmental	Aspinwall VAMC		(6C106)	L pneumophila	1			11/2/1993
1299	Environmental	Aspinwall VAMC		(2A134)	L pneumophila	1			11/2/1993
1300	Environmental	University Drive VAMC		Cu/Ag study	Pasteruella sp.?				4/23/2003
1301	Environmental	University Drive VAMC		Cu/Ag study	s			rust color	4/23/2003
1305	Environmental	Louisville, Kentucky		IDLV-8	L pneumophila			serogroup unknown	12/6/1993
1307	Environmental	OSHA		swab	L pneumophila			serogroup unknown	3
1308	Environmental	OSHA		swab	L pneumophila			serogroup unknown	3
1309	Environmental	OSHA		water	L pneumophila			serogroup unknown	3
1310	Environmental	University Drive VAMC		glycine					3
1311	Environmental	University Drive VAMC		from Leg	s?) sp.				4/23/2003
1312	Environmental	University Drive VAMC		from Leg.	s				4/23/2003
1313	Environmental	University Drive VAMC		Positive H2O	s				4/24/2003
1314	Environmental	Aspinwall VAMC		water	L pneumophila	1	Olda		3
1315	Environmental	Aspinwall VAMC		water	L pneumophila	1	Olda		3
1316	Environmental	Aspinwall VAMC		water	L pneumophila			serogroup unknown	3
1317	Environmental	Highland Drive VAMC		bldg 6 1012W	L pneumophila			serogroup unknown	3
1318	Environmental	Highland Drive VAMC		bldg 6 1012W	L pneumophila	1	Olda		3
1319	Environmental	Highland Drive VAMC		bldg 6 1081E	blue-white fl.				3
1322	Environmental	OSHA		V9131				Genetics +	2/3/1994
1323	Environmental	OSHA		V9131				Genetics +	2/3/1994
1324	Environmental	OSHA		V9131				Genetics +	2/3/1994
1325	Environmental	OSHA		V9131				Genetics +	2/3/1994
1326	Environmental	OSHA		V9131				Genetics +	2/3/1994
1327	Environmental	Aspinwall VAMC		GC105 bldg 50	L pneumophila	1		A	2/3/1994
1328	Environmental	Aspinwall VAMC		BC105 bldg 50	L pneumophila	1		B	2/3/1994
1329	Environmental	Aspinwall VAMC		GC105 bldg 50	L pneumophila	1		C	2/3/1994
1330	Environmental	Aspinwall VAMC		bldg 51 1B1536	L pneumophila	1			2/3/1994
1331	Environmental	Shadyside Hospital		shower room	L. erythra			BCYE AC15	2/18/1994
1332	Environmental	Shadyside Hospital		shower room	L. erythra			BCYE AC15	2/18/1994

Discarded Legionella Stock Collection

Record #	culture type	Job Company Name	Job City/Claim #	Job Description	Species name	Sg	Sub type	Misc.	Date
1334	Environmental	(Oakmont)		4132 shower	Legionella sp			species unknown	3/10/1994
1335	Environmental	OSHA		R50701 water	L pneumophila			serogroup unknown	3/16/1994
1336	Environmental	OSHA		R50695 water	L pneumophila			serogroup unknown	3/16/1994
1337	Environmental	OSHA		R50695 water	L pneumophila			serogroup unknown	3/16/1994
1338	Environmental	OSHA		R50698 water	L pneumophila			serogroup unknown	3/16/1994
1339	Environmental	OSHA		R50701 water	L pneumophila			serogroup unknown	3/16/1994
1340	Environmental	OSHA		R50701 water	L pneumophila			serogroup unknown	3/16/1994
1341	Environmental	OSHA		R50701 water	L pneumophila			serogroup unknown	3/16/1994
1342	Environmental	OSHA		R50701 swab	Leg. sp ?			species unknown	3/16/1994
1343	Environmental	OSHA		R50701 swab	L pneumophila			serogroup unknown	3/16/1994
1344	Environmental	Braddock Hospital		CCU 5	L pneumophila	1			3/16/1994
1345	Environmental	Braddock Hospital		IMU #21	L pneumophila	1			3/16/1994
1346	Environmental	Braddock Hospital		CCU #5	blue-white fl. #1			glycine	3/30/1994
1347	Environmental	Braddock Hospital		CCU #5	L. erythra			-ve Poly II, BCYE/BC3	8/31/1994
1348	Environmental	Braddock Hospital		CCU #5	blue-white fl. #2			glycine	4/7/1994
1350	Environmental	Shadyside Hospital		room 308	L. erythra			-ve Poly II BCYE AF3	4/22/1994
1351	Environmental	Shadyside Hospital		room 308	L. rubrilucens			-ve Poly II GVPC swab 3	5/19/1994
1352	Environmental	Highland Drive VAMC		2100e	L. rubrilucens			BCYE AF3 #1	5/19/1994
1353	Environmental	Highland Drive VAMC		2100e	L. rubrilucens			BCYE AF3 #2	5/19/1994
1354	Environmental	St. Clair Hospital		HWT C2	L pneumophila	1			5/20/1994
1355	Environmental	St. Clair Hospital		HWT C-2	L pneumophila	5			5/20/1994
1356	Environmental	St. Clair Hospital		HWT A-2	?Legionella			-ve Poly II	5/20/1994
1357	Environmental	Highland Drive VAMC		bldg 2, 3036A	L. londinensis	2		Poly II	6/7/1994
1362	Environmental	Mercy Providence		room 516	L pneumophila	1	Benidorm		7/8/1994
1363	Environmental	Mercy Providence		room 503	L pneumophila	1	Benidorm		7/8/1994
1367	Environmental	University Drive VAMC		Heater #1	L pneumophila	1	Bellingham		7/11/1994
1368	Environmental	University Drive VAMC	Wi4	9W-43	L pneumophila	1	Philadelphia		7/12/1994
[illegible]	Environmental	University Drive VAMC		9W-43 sink	L pneumophila	1	Allentown		7/12/1994
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	1	Philadelphia		7/12/1994

Discarded Legionella Stock Collection

Record #	Routine type	Company Name	Source/pt. name	Description	species name	sg	Sub type 3	Material recovered	Date
1373	Environmental	St. Margaret's Hospital		heat	L pneumophila	1	Oxford		7/13/1994
1374	Environmental	St. Margaret's Hospital		heat	L pneumophila	1	Oxford		7/13/1994
1375	Environmental	St. Margaret's Hospital		heat	L pneumophila	1	Oxford		7/13/1994
1376	Environmental	Washington Hospital		faucet	L pneumophila	1			8/4/1994
1377	Environmental	Riverview		Barn HWT	L pneumophila	1			8/4/1994
1378	Environmental	Riverview		Barn HWT	L pneumophila	3			8/4/1994
1379	Environmental	Riverview		PCU shower	(red fl)				8/4/1994
1380	Environmental	Riverview		tub	L. bozemanii				8/4/1994
1381	Environmental	Riverview		PCU shower	L. bozemanii			probable species id	8/4/1994
1382	Environmental	Riverview		station	?Legionella sp				8/4/1994
1385	Environmental	Citizens General		HWT #2	L pneumophila	1		B	9/6/1994
1386	Environmental	Citizens General		faucet 220	L pneumophila	1		D	9/6/1994
1387	Environmental	Citizens General		faucet 220	(red fl)			E	9/6/1994
1388	Environmental	Citizens General		faucet 322	L pneumophila	1		F	9/6/1994
1389	Environmental	Citizens General		faucet 322	?Legionella sp			G	9/6/1994
1396	Environmental	University Drive VAMC		7E-133 faucet	L pneumophila	1	Allentown		4
1397	Environmental	University Drive VAMC		7W-129	L pneumophila	1	Allentown		4
1398	Environmental	University Drive VAMC		7W-129	L pneumophila	1	Allentown		4
1399	Environmental	University Drive VAMC		7W-129	L pneumophila	1			4
1400	Environmental	University Drive VAMC		7E-114	L pneumophila	1	Bellingham		4
1401	Environmental	University Drive VAMC		7E-114	L pneumophila	1	Allentown		4
1402	Environmental	University Drive VAMC		7E-114	L pneumophila	1			4
1403	Environmental	University Drive VAMC		Stainless	L pneumophila	1	Bellingham		4
1404	Environmental	University Drive VAMC		porcelain	L pneumophila	1	Bellingham		4
1405	Environmental	University Drive VAMC		drinking	L pneumophila	1	Bellingham		4
1406	Environmental	University Drive VAMC		drinking	L pneumophila	1	Bellingham		4
1407	Environmental	University Drive VAMC		drinking	L pneumophila	1	Bellingham		4
1408	Environmental	University Drive VAMC		drinking	L pneumophila	1	Bellingham		4
1409	Environmental	University Drive VAMC		drinking	L pneumophila	1	Bellingham		4
1410	Environmental	University Drive VAMC		drinking	L pneumophila	1	Bellingham		4
1411	Environmental	University Drive VAMC		fountain	L pneumophila	1	Bellingham		4

Discarded Legionella Stock Collection

Record #	Routine type	Company Name	Source/pt. name	Description	species name	sg	Sub type 3	Material recovered	Date
1412	Environmental	University Drive VAMC		fountain	L pneumophila	1	Bellingham		4
1413	Environmental	University Drive VAMC		fountain	L pneumophila	1	Bellingham		4
1414	Environmental	University Drive VAMC		fountain	L pneumophila	1	Bellingham		4
1415	Environmental	University Drive VAMC		fountain near	L pneumophila	1	Bellingham		4
1417	Environmental	St. Clair Hospital		D	L pneumophila	5			2/2/1995
1418	Environmental	St. Clair Hospital		D	L pneumophila	5			2/2/1995
1419	Environmental	St. Clair Hospital		E	L pneumophila	5			2/2/1995
1420	Environmental	St. Clair Hospital		E	L pneumophila			DFA (-) 1-6	2/2/1995
1424	Environmental	Clarksburg VAMC			?L pneumophila	5			4/21/1995
1425	Environmental	Clarksburg VAMC			L pneumophila	6			4/21/1995
1426	Environmental	Butler VAMC		HWT	L pneumophila	5			4/21/1995
1428	Environmental	Mercy Providence		room 209	L pneumophila	1			4/26/1995
1429	Environmental	Mercy Providence		room 203	L pneumophila	1			4/26/1995
1430	Environmental	Mercy Providence		room 213	L pneumophila	1			4/26/1995
1431	Environmental	Mercy Providence		kitchen	L pneumophila	1			4/26/1995
1432	Environmental	Butler VAMC		hand sink ICU	L pneumophila	5		sample 2	4/27/1995
1433	Environmental	Butler VAMC		hand sink ICU	L pneumophila	1		sample 2	4/27/1995
1434	Environmental	Butler VAMC		hand sink ICU	species - red			sample 2	4/27/1995
1435	Environmental	Butler VAMC		bath sink ICU	red			sample 4	4/27/1995
1436	Environmental	Butler VAMC		bath sink ICU	Legionella sp			sample 4	4/27/1995
1437	Environmental	Butler VAMC		room 438	Legionella sp			sample 5	4/27/1995
1438	Environmental	OSHA		R54618 #1	unknown				5/1/1995
1439	Environmental	OSHA		R54618 #2	unknown				5/1/1995
1440	Environmental	Toronto		roof H2O 1B	Legionella like				5/1/1995
1441	Environmental	Toronto		roof H2O 1C	Legionella like				5/1/1995
1442	Environmental	University Drive VAMC		fountain (post-	L pneumophila	1	Bellingham		6/23/1995
1443	Environmental	University Drive VAMC		(post heat)	L pneumophila	1	Bellingham		6/23/1995
1444	Environmental	University Drive VAMC							

Discarded Legionella Stock Collection

Record #	Culture type	Company Name	Source name	Site Option 3	species name	sg	sub type	Made source	Expires
1448	Environmental	Aspinwall VAMC		bldg 50 1A103	L pneumophila	1	Olda		6/23/1995
1449	Environmental	Aspinwall VAMC		bldg 50 1A132	L pneumophila	1	Olda		6/23/1995
1450	Environmental	University Drive VAMC		SE right shower	L pneumophila			serogroup unknown	6/23/1995
1451	Environmental	Mercy Wt		TP	L pneumophila	1			6/23/1995
1452	Environmental	Mercy Wt		2109 #2	L pneumophila	1			6/23/1995
1453	Environmental	Mercy Wt		2127	L pneumophila	1			6/23/1995
1454	Environmental	Mercy Wt		3109 #1	L pneumophila	1			6/23/1995
1455	Environmental	Mercy Wt		3109 #2	L pneumophila	1			6/23/1995
1456	Environmental	Mercy Wt		4211	L pneumophila	1			6/23/1995
1457	Environmental	P&K		#1 (5-15-95)	unknown			colony 2	7/7/1995
1458	Environmental	P&K		#6A (5-15-95)	unknown			GVPC	7/7/1995
1459	Environmental	P&K		#2A (5-15)	unknown			GVPC, colony 2	7/7/1995
1460	Environmental	P&K		#2A (5-15)	unknown			GVPC, colony 1	7/7/1995
1461	Environmental	P&K		#20 conc (5-15)	unknown			GVPC, colony 2	7/7/1995
1462	Environmental	P&K		#1 conc (5-15)	unknown			GVPC	7/7/1995
1463	Environmental	P&K		#10 conc (5-15)	unknown			AT & BCYE colony 3	7/7/1995
1464	Environmental	P&K		#9 conc (5-15)	unknown			BCYE, colony 2, ?spp	7/7/1995
1465	Environmental	P&K		#6 conc (5-15)	unknown			AT & BCYE, colony 3	7/7/1995
1466	Environmental	P&K		#6 conc (5-15)	unknown			DGVP, colony 3	7/7/1995
1467	Environmental	University Drive VAMC		fountain (5-15)	L pneumophila	1			7/7/1995
1468	Environmental	University Drive VAMC		fountain	L pneumophila	1		colony 2	7/7/1995
1469	Environmental	University Drive VAMC		fountain	L pneumophila	1		colony 4	7/7/1995
1470	Environmental	University Drive VAMC		fountain	L pneumophila	1			7/7/1995
1471	Environmental	St. Margaret's Hospital		faucet	L pneumophila	1	oxford		7/7/1995
1472	Environmental	St. Margaret's Hospital		shower	L pneumophila	1			7/7/1995
1473	Environmental	St. Margaret's Hospital		faucet	L pneumophila	1			7/7/1995
1474	Environmental	P&K		#20 conc (6-11)	unknown			GVPC, colony 1	7/7/1995
1475	Environmental	P&K		#20 conc				DGVP	7/7/1995
1476	Environmental	P&K		#20	red fl. Spp				7/7/1995
1477	Environmental	P&K		#18 conc	blue-white sp.			AT & BCYE	7/7/1995
1478	Environmental	Akron City Hosp		Tank A #1	L pneumophila	1		5-24-94	7/17/1995

Discarded Legionella Stock Collection

Record #	Culture type	Company Name	Source name	Site Option 3	species name	sg	sub type	Made source	Expires
1479	Environmental	Akron City Hosp		#2 ICU	L pneumophila	1		5-24-95	7/17/1995
1480	Environmental	Akron City Hosp		Tank C #4	L pneumophila	1		1-5-94	7/17/1995
1481	Environmental	Akron City Hosp		#10 room 565	L pneumophila	1		9-30-94	7/17/1995
1482	Environmental	Akron City Hosp		#18 room 565	L pneumophila	1		5-3-95	7/17/1995
1483	Environmental	Akron City Hosp		#11 room 556	red fl. Sp.			10-12-94	7/17/1995
1484	Environmental	Akron City Hosp		#12 room 553	L pneumophila	1		9-30-94	7/17/1995
1485	Environmental	Akron City Hosp		#19 ICU	L pneumophila	1		5-3-94	7/17/1995
1486	Environmental	Akron City Hosp		#20 Tank B	L pneumophila	1		5-3-95	7/17/1995
1487	Environmental	Akron City Hosp		Tank A #15	L pneumophila	1			7/17/1995
1491	Environmental	Sewickley Hospital		5-95)	L pneumophila	1	Philadelphia	sticky	9/14/1995
1492	Environmental	Sewickley Hospital		5)	L pneumophila	1		#2	9/14/1995
1493	Environmental	Sewickley Hospital		654 hall sink	L pneumophila	1		#3, smooth	9/14/1995
1494	Environmental	Akron City Hosp		Isolate #3	L pneumophila	6			9/14/1995
1495	Environmental	Akron City Hosp		Isolate #5	L pneumophila	1	Benidorm		9/14/1995
1496	Environmental	Akron City Hosp		Isolate #8	L pneumophila	1	Philadelphia		9/14/1995
1497	Environmental	Akron City Hosp		Isolate #13	L pneumophila	1	Bellingham		9/14/1995
1498	Environmental	Akron City Hosp		Isolate #16	L pneumophila	1	Philadelphia		9/14/1995
1499	Environmental	Akron City Hosp		Isolate #21	L pneumophila	1	Philadelphia		9/14/1995
1500	Environmental	Akron City Hosp		Isolate #22	L pneumophila	1	Philadelphia		9/14/1995
1501	Environmental	Akron City Hosp		Isolate #23	L pneumophila	1	Philadelphia		9/14/1995
1502	Environmental	Akron City Hosp		Isolate #24	L pneumophila	1	Philadelphia		9/14/1995
1503	Environmental	Akron City Hosp		Isolate #25	L pneumophila	1	Benidorm		9/14/1995
1504	Environmental	Akron City Hosp		Isolate #26	L pneumophila	1	Philadelphia		9/14/1995
1505	Environmental	Akron City Hosp		Isolate #27	L pneumophila	1	Philadelphia		9/14/1995
1506	Environmental	Turkey			L. rubrilucens			species unknown	9/14/1995
1507	Environmental	University Drive VAMC		fountain	L pneumophila	1	Bellingham		5
1508	Environmental	University Drive VAMC		fountain	L pneumophila	1	Bellingham		5
[illegible]	Environmental	University Drive VAMC		fountain	L pneumophila	1	Bellingham		5
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	Bellingham	[illegible]	5

Discarded Legionella Stock Collection

Record #	Source type	Company Name	Source pt name	Description	Species name	sg	Sub type	Miscellaneous	Frozen
1525	Environmental	University Drive VAMC	Ma11	7E-142	L pneumophila	1	Allentown	BCYE #1	12/4/1995
1526	Environmental	University Drive VAMC		7E-142	L pneumophila	1	Allentown	BCYE #2	12/4/1995
1527	Environmental	University Drive VAMC		7E-142	L pneumophila	1		DGVP	12/4/1995
1528	Environmental	University Drive VAMC		7E-114	L pneumophila	1			12/4/1995
1529	Environmental	Jefferson Hospital			L pneumophila	1	Oxford		12/4/1995
1530	Environmental	Jefferson Hospital			L pneumophila	2			12/4/1995
1531	Environmental	Jefferson Hospital			L pneumophila	1			12/4/1995
1532	Environmental	Jefferson Hospital			L pneumophila	2			12/4/1995
1533	Environmental	Jefferson Hospital			L pneumophila	2			12/4/1995
1534	Environmental	Jefferson Hospital			L pneumophila	1			12/4/1995
1535	Environmental	Jefferson Hospital			L pneumophila	2			12/4/1995
1536	Environmental	University Drive VAMC		4N210	unknown				12/9/1995
1537	Environmental	University Drive VAMC		6N vascular lab	L pneumophila	1			12/9/1995
1538	Environmental	University Drive VAMC		9E120	L pneumophila	1			12/9/1995
1539	Environmental	Sewickley Hospital		S. HWT	Legionella sp.				3/8/1996
1540	Environmental	Meadville Hospital		#4	L pneumophila	4			3/8/1996
1541	Environmental	Hospital		#9438	L pneumophila	5			3/8/1996
1542	Environmental	Aspinwall VAMC		1B106 sink	L pneumophila	1			3/8/1996
1543	Environmental	Highland Drive VAMC		2008	red fl. Sp.				3/8/1996
1544	Environmental	Highland Drive VAMC		Bldg 2 2015N	L pneumophila	1			3/8/1996
1545	Environmental	Highland Drive VAMC		Bldg 2 2015N	L pneumophila	6			3/8/1996
1546	Environmental	Highland Drive VAMC		Bldg 2 3036	L pneumophila	1			3/8/1996
1547	Environmental	University Drive VAMC		model laminar	L pneumophila	1			3/8/1996
1554	Environmental	Akron Cty Hosp		Isolate #58	L pneumophila	1	Bellingham		3/8/1996
1556	Environmental	University Drive VAMC			C. albicans			PAV not PAV-2	3/19/1996
1559	Environmental	Highland Drive VAMC		Bldg 2 1097E	? Spp				4/8/1996
1560	Environmental	Highland Drive VAMC		Bldg 2 2015N	Lp ?				4/8/1996
1561	Environmental	Highland Drive VAMC		Bldg 2 3036W	red fl sp				4/8/1996
1562	Environmental	Highland Drive VAMC		Bldg 2 3036W	red fl sp				4/8/1996
1563	Environmental	Highland Drive VAMC		Bldg 2 4059e	blue-white			?anisa	4/8/1996
1564	Environmental	Highland Drive VAMC		Bldg. 2 4077e	L pneumophila	1	Benidorm		4/8/1996

Discarded Legionella Stock Collection

Record #	Source type	Company Name	Source pt name	Description	Species name	sg	Sub type	Miscellaneous	Frozen
1565	Environmental	Highland Drive VAMC		Bldg 2 hall sink	spp?				4/8/1996
1566	Environmental	Highland Drive VAMC		#3	spp ?			remel +	4/8/1996
1567	Environmental	Highland Drive VAMC		Bldg 2 hall sink	blue-white				4/8/1996
1568	Environmental	Forbes Hospital		room	L pneumophila	1			4/18/1996
1569	Environmental	Forbes Hospital		room	Red fl. Sp.				4/18/1996
1571	Environmental	Highland Drive VAMC		model - bldg 2	L pneumophila	6		Sctx; proubernated col	4/18/1996
1572	Environmental	University Drive VAMC		model	L pneumophila	1			4/18/1996
1579	Environmental	McKeesport Hospital		room 324	L pneumophila	1	Olda		5/16/1996
1580	Environmental	McKeesport Hospital		Annex HWT	L pneumophila	1	Olda		5/16/1996
1581	Environmental	McKeesport Hospital		Annex HWT	L pneumophila	1			5/16/1996
1582	Environmental	McKeesport Hospital		Annex HWT	L pneumophila	1			5/16/1996
1583	Environmental	McKeesport Hospital		Annex HWT	L pneumophila	1			5/16/1996
1587	Environmental	Broudy home		apt. 514 sink	L pneumophila	1	Olda		4/5/1996
1588	Environmental	Broudy home		sink	L pneumophila	1	Olda		7/5/1996
1589	Environmental	Broudy home		apt 514 shower	L pneumophila	1	Olda		7/5/1996
1590	Environmental	Kennilworth Apts		310 shower	L pneumophila	1	Olda		7/5/1996
1591	Environmental	Kennilworth Apts		708 kitchen	L pneumophila	1	Olda		7/5/1996
1593	Environmental	Forbes Regional		25 Men's room	L pneumophila	1			7/21/1996
1594	Environmental	Forbes Regional		25 Men's room	L pneumophila	1			7/21/1996
1595	Environmental	Management		Tower - NY	L pneumophila	1			7/21/1996
1596	Environmental	West Penn Hospital		Tank ME H441	L pneumophila	1			7/18/1996
1597	Environmental	West Penn Hospital		Tank I H443	L pneumophila	3			7/18/1996
1598	Environmental	West Penn Hospital		Tank I H444	L pneumophila	3		green morph	7/18/1996
1602	Environmental	Wausau Hospital		CIC 1663 col 2	L pneumophila	8?		OFA + sg 4/5	8/4/1996
1603	Environmental	Wausau Hospital		CIC 1663 col 3	L pneumophila	8?			8/4/1996
1604	Environmental	Wausau Hospital		addition) col	L pneumophila	3			8/4/1996
1605	Environmental	Wausau Hospital		addition)	L pneumophila	3		CDC confirmed	8/4/1996
1606	Environmental	Wausau Hospital		MSICU 1847	L pneumophila				

Discarded Legionella Stock Collection

Record #	source type	company name	source name	description	species name	type	sub type	culture source	date
1610	Environmental	University Drive VAMC		model (7-7-96)	L pneumophila	6		turbulent	8/4/1996
1611	Environmental	University Drive VAMC		model	L pneumophila	1		turbulent	8/4/1996
1612	Environmental	University Drive VAMC		model	L pneumophila	6			8/4/1996
1613	Environmental	Institute		321 sink	L pneumophila	1			8/8/1996
1614	Environmental	St Francis Central		633 sink	L pneumophila	1			8/6/1996
1618	Environmental	Washington Hospital		room	L pneumophila	1			8/26/1996
1620	Environmental	Presby UPMC		PUH #1	L pneumophila	1	Allentown		9/11/1996
1621	Environmental	Presby UPMC		PUH #2	L pneumophila	1	Olda		9/11/1996
1622	Environmental	Presby UPMC		PUH #3	L pneumophila	1	Olda		9/11/1996
1623	Environmental	Presby UPMC		PUH #5	L pneumophila	1			9/11/1996
1624	Environmental	Presby UPMC		#5	L pneumophila	1	Olda		9/11/1996
1625	Environmental	Presby UPMC		PUH #6	L pneumophila	1			9/11/1996
1635	Environmental	University Drive VAMC		6W-33 sink	L pneumophila	1	Bellingham	col #1	11/1/1996
1636	Environmental	University Drive VAMC		6W-33 sink	L pneumophila	1	Bellingham	col #2	11/1/1996
1637	Environmental	University Drive VAMC		7W-33 sink	L pneumophila	1	Allentown	col #1	11/1/1996
1638	Environmental	University Drive VAMC		7W-33 sink	L pneumophila	1	Allentown	col #2	11/1/1996
1640	Environmental	Akron City Hosp	Ca4		L pneumophila	1	Philadelphia		11/1/1996
1643	Environmental	Togus VAMC			L pneumophila	2			11/7/1996
1654	Environmental	New Zealand		mix linked to 93-	L. longbeachae	1			5/27/1997
1655	Environmental	New Zealand		mix linked to pt	L. longbeachae				5/27/1997
1656	Environmental	Wausau Hospital		HWT #1	L pneumophila	3			5/27/1997
1657	Environmental	Wausau Hospital		CIC 1661	L pneumophila	5		w/4&5Scimedx	5/27/1993
1659	Environmental	Kennilworth Apts		Rm 408K	L pneumophila	1			7/14/1997
1660	Environmental	Kennilworth Apts		Rm 514K	L pneumophila	1			7/14/1997
1661	Environmental	Kennilworth Apts		Rm 912K	L pneumophila	1			7/14/1997
1662	Environmental	Kennilworth Apts		HW Rm 514K	L pneumophila	1			7/14/1997
1666	Environmental	Ohio Valley Med Ctr		HWT #2	L pneumophila	3			8/13/1997
1667	Environmental	Ohio Valley Med Ctr		HWT #2	L pneumophila	4			8/13/1997
1668	Environmental	Ohio Valley Med Ctr		5W Rm 414	L pneumophila	1		waxy	8/13/1997
1669	Environmental	Ohio Valley Med Ctr		5W Rm 511	L pneumophila	1			8/13/1997
1670	Environmental	Ohio Valley Med Ctr		5W Rm 511	L pneumophila	1		#3	8/13/1997

Discarded Legionella Stock Collection

Record #	source type	company name	source name	description	species name	type	sub type	culture source	date
1671	Environmental	County Medical Center		W wing	L pneumophila	6		CCVC	10/8/1997
1672	Environmental	County Medical Center		W wing	L pneumophila	6		BCYE	10/8/1997
1673	Environmental	Beaver Medical Center		CCU #16	L pneumophila	1			10/8/1997
1674	Environmental	Beaver Medical Center		HWT 2417	L pneumophila	1			10/8/1997
1675	Environmental	Beaver Medical Center		CCU #3	L pneumophila	12		+w/1&5Scimedx	10/8/1997
1676	Environmental	Beaver Medical Center		ER Rm #4	L pneumophila	5			10/8/1997
1677	Environmental	Beaver Medical Center		HWT 2418	L pneumophila	6			10/8/1997
1678	Environmental	St. Elizabeth's		Pavillion	L pneumophila	1			7
1680	Environmental	Beaver Medical Center		M105	L pneumophila	8		Scimedx	7
1681	Environmental	Klenzoid-Geisinger		Bush Tower	L pneumophila	1			7
1682	Environmental	County Hospital		W wing	L pneumophila	6			7
1683	Environmental	Klenzoid-Bryn Mawr		penthouse	L pneumophila	1			7
1684	Environmental	Klenzoid-Bryn Mawr		1&2	L pneumophila	6			7
1685	Environmental	Sewickley Hospital		518S sink	not Legionella				7
1686	Environmental	St. Joseph's		1 & 2	L pneumophila	1			7
1688	Environmental	Kennilworth Apts		Rm 514 sink	Mycobacterium				11/5/1997
1689	Environmental	Kennilworth Apts		(9-11-97)	M. gordonea				11/5/1997
1690	Environmental	Kennilworth Apts		(9-11-97)	M. kansasii				11/5/1997
1691	Environmental	Highland Drive VAMC			L pneumophila	1			7
1692	Environmental	Beaver Medical Center		2411	L pneumophila	1			7
1693	Environmental	Beaver Medical Center		2418	L pneumophila	1			7
1694	Environmental	Beaver Medical Center		C368	Leg sp (red fl)				7
1695	Environmental	Rehab Institute		307 shower	white)			BCYE	7
1699	Environmental	Aspinwall VAMC		machine	L pneumophila	1			7
1701	Environmental	St. Vincent		drainpipe	L pneumophila	1			1/22/1998
1702	Environmental	St. Vincent		drainpipe	L pneumophila	5			1/22/1998
1703	Environmental	St. Vincent		98) type 1	L pneumophila	5			2/3/1998
		St. Vincent		98) type 2	L pneumophila	5			2/3/1998
									2/3/1998

Discarded Legionella Stock Collection

Record #	Industry type	Company Name	Dept/Plant name	Description	Species name	bp	Subtype	Model/Version	Frozen
1710	Environmental	Cox Health System		south station	L pneumophila	1			2/5/1998
1711	Environmental	Cox Health System		held shower,	L pneumophila	1			2/8/1998
1712	Environmental	Cox Health System		wing	L pneumophila	1			2/5/1998
1715	Environmental	Aspinwall VAMC		Bldg 50 1A-120	L pneumophila	1			2/24/1998
1730	Environmental	Hospital		T61334-1	L pneumophila	3		Scimedx	3/6/1998
1731	Environmental	Hospital		T61334-2	not Legionella				3/6/1998
1732	Environmental	Hospital		H66797	L pneumophila	4		Scimedx	3/6/1998
1733	Environmental	Hospital		F55500	L pneumophila	*		*3 and 4	3/6/1998
1734	Environmental	Hospital		F55501	L pneumophila	5			3/6/1998
1735	Environmental	Oxford Development		Cooling	L pneumophila	1	Oxford		3/13/1998
1736	Environmental	Oxford Development		roof top puddle	L pneumophila	1			3/13/1998
1737	Environmental	Aspinwall VAMC		GA128	L pneumophila	1			3/13/1998
1738	Environmental	Aspinwall VAMC		1A143	L pneumophila	1			3/13/1998
1739	Environmental	Aspinwall VAMC		GA150	L pneumophila	1			3/13/1998
1740	Environmental	Aspinwall VAMC		2A118	L pneumophila	1			3/13/1998
1741	Environmental	Oxford Development		standguard	L pneumophila	*6		12-03; previously *4, 5	3/24/1998
1742	Environmental	Oxford Development		metal tech CT	L pneumophila	*5		12-0*waxy, +ve for 4, 5	3/27/1998
1743	Environmental	Oxford Development		metal tech CT	L pneumophila	*		*waxy, +ve for 4, 5 and 6	3/27/1998
1744	Environmental	Oxford Development		metal tech CT	L pneumophila	*5		*smooth?, +ve for 4, 5	3/27/1998
1745	Environmental	Oxford Development		metal tech CT	L pneumophila	*		and 6	3/27/1998
1746	Environmental	Oxford Development		Metal tech CT	L pneumophila	1	Oxford	confirmed, bright	3/27/1998
1747	Environmental	Oxford Development		metal tech CT	L pneumophila	1		confirmed,bright	3/27/1998
1748	Environmental	Oxford Development		metal tech CT	L pneumophila	1	Oxford	dim fluorescence	3/27/1998
1749	Environmental	Oxford Development		metal tech CT	L pneumophila	1		rare dim fluorescence	3/27/1998
1750	Environmental	Treatment Plant		HWT	BW positive*			*for boz, dem &anisa	3/27/1998
1751	Environmental	Treatment Plant		HWT	BW-not stained				3/27/1998
1785	Environmental	University Drive VAMC		ice machine 9E	L pneumophila	1			5/12/1998
1796	Environmental	University Drive VAMC	PC	room collected	Xanthomonas				3/19/1998
1797	Environmental	University Drive VAMC	PC	mask collected	Xanthomonas				3/19/1998
1798	Environmental	University Drive VAMC	PC	collected	Xanthomonas				3/19/1998
1799	Environmental	University Drive VAMC	BS	room collected	Xanthomonas				3/19/1998

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Record #	Industry type	Company Name	Dept/Plant name	Description	Species name	bp	Subtype	Model/Version	Frozen
1800	Environmental	University Drive VAMC		sink water room	Xanthomonas				3/19/1998
1801	Environmental	University Drive VAMC		tap water(7)	Xanthomonas				3/19/1998
1802	Environmental	University Drive VAMC		sink swab (9)	Xanthomonas				3/19/1998
1803	Environmental	University Drive VAMC		showerhead	Xanthomonas				3/19/1998
1804	Environmental	University Drive VAMC		sink swab (18)	Xanthomonas				3/19/1998
1805	Environmental	University Drive VAMC		swab(30) room	Xanthomonas				3/19/1998
1806	Environmental	University Drive VAMC		swab(38) room	Xanthomonas				3/19/1998
1807	Environmental	University Drive VAMC		(34) room 1-4	Xanthomonas				3/19/1998
1808	Environmental	University Drive VAMC	MD	table (40) room	Xanthomonas				3/19/1998
1809	Environmental	University Drive VAMC	Re	table (42) room	Xanthomonas				3/19/1998
1841	Environmental	University Drive VAMC		radiology dept.	L pneumophila	1			6/5/1998
1842	Environmental	Dacar Industries		WP19 CT	L pneumophila	1			6/19/1998
1843	Environmental	Dacar Industries		WP24 CT	L pneumophila	1*		*weak	6/19/1998
1844	Environmental	Industrial Chem. Corp		CT1-U153	L pneumophila	1			6/19/1998
1845	Environmental	Industrial Chem. Corp.		CT2-U153	L pneumophila	4			6/19/1998
1846	Environmental	St. Elizabeth's		showerhead	L pneumophila	1			7/3/1998
1847	Environmental	Asbury Heights		496	?				7/3/1998
1848	Environmental	Hospital		525	L pneumophila	*		with 6	7/6/1998
1849	Environmental	University Drive VAMC			aerogenes			for Ed	7/8/1998
1850	Environmental	Hospital		Rm 292	L pneumophila	*		*DFA 4, 5 and 6	7/30/1998
1851	Environmental	Hospital		HWT 2	L pneumophila	1			7/30/1998
1852	Environmental	Center		98B842	L pneumophila	*		*+ve for 4 and 5	8/4/1998
1853	Environmental	Center		98B860	L pneumophila	*		*+ve for 4, 5 and6	8/4/1998
1854	Environmental	Owens Illinois		98B911	L pneumophila	1*		*weak fluor.	8/7/1998
1855	Environmental	Owens Illinois		98B916	L pneumophila	1		strong fluor.	8/7/1998
1856	Environmental	Citizen's General		#5, 98B963	L pneumophila	1			8/7/1998
1857	Environmental	Citizen's General		98B973	L pneumophila	1		#1856	8/7/1998
1858	Environmental	Dacar Industries		SH CT, 98B955	L pneumophila	6			8/7/1998

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Record #	Culture type	Company Name	Source name	Description	Species name	sg	Sub type	Lyse	Frozen
1863	Environmental	Klenzoid		98B1088	L pneumophila	1			8/21/1998
1864	Environmental	Klenzoid		98B1088	Leg spp				8/21/1998
1865	Environmental	Klenzoid		Chestnut,	L pneumophila	1			8/21/1998
1867	Environmental	OSHA		98B1150	L pneumophila	1		ATCCVC-1	8/21/1998
1868	Environmental	OSHA		98B1150	L pneumophila	1		a little different	8/21/1998
1869	Environmental	OSHA		98B1151	Leg. Spp			DIR DGVP	8/21/1998
1870	Environmental	OSHA		98B1151	L. anisa			DIR CCVC	8/21/1998
1871	Environmental	OSHA		98B1151	L pneumophila	6		AT DGVP	8/21/1998
1872	Environmental	OSHA		98B1151	L pneumophila	1		AT CCVC	8/21/1998
1873	Environmental	Dr. Chang's Hospital		#2, BCYE	L pneumophila	1			9/4/1998
1874	Environmental	Dr. Chang's Hospital		#2, DGVP	L pneumophila	1			9/4/1998
1875	Environmental	Dr. Chang's Hospital		#3, BCYE	L pneumophila	1			9/4/1998
1876	Environmental	Dr. Chang's Hospital		#3, DGVP	L pneumophila	1			9/4/1998
1877	Environmental	Dr. Chang's Hospital		#4, BCYE	L pneumophila	1			9/4/1998
1878	Environmental	Dr. Chang's Hospital		#4, DGVP	L pneumophila	1			9/4/1998
1879	Environmental	Dr. Chang's Hospital		#6, BCYE	L pneumophila	1			9/4/1998
1880	Environmental	Dr. Chang's Hospital		#6, DGVP	L pneumophila	1			9/4/1998
1881	Environmental	Jefferson Hospital		98B1192	L pneumophila	1			9/4/1998
1882	Environmental	Industrial Chem		U2229CT,	L pneumophila	4		CCVC1	9/4/1998
1883	Environmental	CHP (Children's)		98B1170	L pneumophila	1			9/4/1998
1884	Environmental	OSHA		98B1245	L pneumophila	4		DIR DGVP1	9/4/1998
1885	Environmental	Oxford Development		East CT, Dir	L pneumophila	*		*4 or 5	9/15/1998
1886	Environmental	Oxford Development		East tower	L pneumophila	*		*4 or 5, AT DGVP	9/15/1998
1887	Environmental	OSHA		98B1321	L pneumophila	1			9/25/1998
1888	Environmental	OSHA		98B1323	L pneumophila	1			9/25/1998
1889	Environmental	OSHA		98B1324	Leg spp			type 1	9/25/1998
1890	Environmental	OSHA		98B1325	Leg sp			type 2	9/25/1998
1893	Environmental	Children's Institute		98B1480	L pneumophila	5			10/1/1998
1894	Environmental	Industrial Chem		98B1566	L pneumophila	1*		*weak, DGVP-AT	10/9/1998
1895	Environmental	PA Dept of Health		98B1571	Leg spp				10/9/1998
1896	Environmental	PA Dept of Health		side CT,	L pneumophila	6			10/9/1998

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Record #	Culture type	Company Name	Source name	Description	Species name	sg	Sub type	Lyse	Frozen
1897	Environmental	PA Dept of Health		CT, 98B1576	L pneumophila	5			10/9/1998
1898	Environmental	PA. Dept of Health		CT, 98B1582	L pneumophila	6		different than 1896	10/9/1998
1899	Environmental	Microbac Labs		98B1670	L pneumophila	1			10/9/1998
1900	Environmental	Microbac Labs		98B1671	L pneumophila	1			10/9/1998
1901	Environmental	OSHA		9/28/98	L pneumophila	1			8
1902	Environmental	OSHA		recirc.,	L pneumophila	3			8
1903	Environmental	OSHA		recirc., 98B-	L pneumophila	1			8
1904	Environmental	OSHA		98B1619	L pneumophila	1			8
1905	Environmental	University Drive VAMC		98A1653	L pneumophila	1			8
1906	Environmental	University Drive VAMC		shower,	L pneumophila	1			8
1907	Environmental	University Drive VAMC		98A1694	L pneumophila	1			8
1908	Environmental	Jefferson Hospital		CT, 98B1756	L pneumophila	1			8
1909	Environmental	Industrial Chem		98B1729	L pneumophila	4			8
1912	Environmental	Klenzoid		98B1826	L pneumophila	6			8
1913	Environmental	St. Francis		98B1835	L pneumophila	1		strain 1	8
1914	Environmental	St. Francis		98B1835	L pneumophila	1		strain 2	8
1915	Environmental	Penn State Geisinger		10, 98B1941	L pneumophila	1			11/3/1998
1916	Environmental	Penn State Geisinger		CT, 98B1948	L pneumophila	1			11/3/1998
1917	Environmental	AUH Forbes		room, 98B1932	Leg sp				11/3/1998
1954	Environmental	Penn State Geisinger		98B1993	L pneumophila	1			11/5/1998
1955	Environmental	Coastline		98B2048	L pneumophila	4			11/5/1998
1956	Environmental	Coastline		98B2049	L pneumophila	1			11/5/1998
1960	Environmental	Mayview		98B2427	L pneumophila	1			8
1967	Environmental	Penn State Geisinger		98B2759	L pneumophila	1			1/11/1999
1968	Environmental	Penn State Geisinger		98B2763	L pneumophila	1			1/11/1999
1969	Environmental	Industrial Chem		RH-1-4357 CT	L pneumophila	1			1/11/1999
1970	Environmental	Industrial Chem		RH-1-4357 CT	L pneumophila	4			1/11/1999
[illegible]	Environmental	Industrial Chem		RH-1-4357 CT	Leg spp				1/11/1999
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	L pneumophila	*		CCVC1, purple	1/14/1999

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Record	Source Type	Company Name	Source Name	Description	Species	Serotype	Strain	Miscellaneous	Date
1975	Environmental	Johns Hopkins		99B3007	L pneumophila	1		AT-DGVP	1/19/1999
1976	Environmental	Johns Hopkins		98B3007	L pneumophila	5		Dir CCVC 3	1/20/1999
1977	Environmental	Hospital		W56468 isolate	Leg spp				1/28/1999
1978	Environmental	Hospital		W56470	Leg spp				1/28/1999
1980	Environmental	Togus VAMC		99A3240	L pneumophila	2			1/29/1999
1982	Environmental	C&E/Nasa		sump, 99B3279	L pneumophila	1		colony type 1	2/4/1999
1983	Environmental	C&E/Nasa		sump, 99B3279	L pneumophila	1		colony type 2	2/4/1999
2003	Environmental	Center		water tap,	L pneumophila	1			2/25/1999
2004	Environmental	Center		water tap,	L pneumophila	1			2/25/1999
2005	Environmental	Center		tap, 99B3480	L pneumophila	1			2/25/1999
2006	Environmental	Togus VAMC		99A3588	L pneumophila	2			2/25/1999
2007	Environmental	Togus VAMC		73 nhcu #20	L pneumophila	2			2/25/1999
2011	Environmental	Reserve Base		99A3757	L pneumophila	1			3/5/1999
2012	Environmental	Reserve Base		99A3759	L pneumophila	1			3/5/1999
2013	Environmental	Reserve Base		99A3760	L pneumophila	1			3/5/1999
2014	Environmental	Fed Bldg		men's	L pneumophila	5		colony #1	3/5/1999
2015	Environmental	Fed Bldg		men's	L pneumophila	1		colony #2	3/5/1999
2016	Environmental	Fed Bldg		sink, 97A3751	L pneumophila	1		type 1	3/5/1999
2017	Environmental	Fed Bldg		sink, 99A3751	L pneumophila	1		type 2	3/5/1999
2018	Environmental	Fed Bldg		CT, 99A3756	L pneumophila	5			3/5/1999
2020	Environmental	Office of Compliance		NorthWest,	L pneumophila	1			3/10/1999
2021	Environmental	Office of Compliance		Northwest,	L pneumophila	1			3/10/1999
2022	Environmental	Office of Compliance		science,	L pneumophila	1			3/10/1999
2023	Environmental	Mayview		99B3788	L pneumophila	3			3/10/1999
2024	Environmental	Mayview		99B3796-1	L pneumophila	1			3/10/1999
2025	Environmental	Mayview		99B-3796-2	L pneumophila	1		site	3/10/1999
2026	Environmental	Mayview		99B3799	L pneumophila	1			3/10/1999
2027	Environmental	Center		water tap,	L pneumophila	1			3/12/1999
2031	Environmental	Chemway/CMU		CT, 99B3951	L pneumophila	1			3/12/1999
2032	Environmental	Chemway/CMU		99B3952	L pneumophila	1			3/12/1999
2033	Environmental	Chemway/CMU		99B3853	L pneumophila	1			3/12/1999

Discarded Legionella Stock Collection

Record	Source Type	Company Name	Source Name	Description	Species	Serotype	Strain	Miscellaneous	Date
2034	Environmental	Fed Bldg		99B3750	L. bozemanii				3/15/1999
2035	Environmental	Hospital		faucet,	L pneumophila	1			3/19/1999
2036	Environmental	Hospital		faucet,	L pneumophila	5?			3/19/1999
2037	Environmental	C&E		sump, 99B4080	L pneumophila	?			3/26/1999
2038	Environmental	C&E		sump, 99B4083	L pneumophila	?			3/26/1999
2041	Environmental	Sewickley Hospital		99B4507	L pneumophila	6		strain #1?	4/28/1999
2042	Environmental	Sewickley Hospital		sink, 99B4515	L pneumophila	6		strain #2?	4/28/1999
2043	Environmental	Sewickley Hospital		sink, 99B4515	L pneumophila	1			4/28/1999
2044	Environmental	Center		99B4602	L pneumophila	1			5/6/1999
2045	Environmental	Citizens General		99B4642	L pneumophila	1		strain 1	5/7/1999
2046	Environmental	Citizens General		99B4642	L pneumophila	1		strain 2	5/7/1999
2049	Environmental	Tucson VAMC		dining room ice	L pneumophila	4			5/20/1999
2050	Environmental	Tucson VAMC		dining room ice	L pneumophila	1			5/20/1999
2051	Environmental	Wausau Hospital		shower,	L pneumophila	5			5/24/1999
2052	Environmental	Wausau Hospital		HW, 99B4921	L pneumophila	3			5/24/1999
2053	Environmental	McGuire VAH		99C4996	L pneumophila	1			5/24/1999
2054	Environmental	Ohio Valley Med Ctr		99B5018	L pneumophila	1			5/24/1999
2055	Environmental	West Penn Hospital		across from	L. anisa				5/24/1999
2056	Environmental	Vim Beaumont		HW, 99C5278	L pneumophila	1		strain 1	5/24/1999
2057	Environmental	Vim Beaumont		tower, 99C5282	L pneumophila	1		str2, CDC confirmed	5/24/1999
2058	Environmental	Coastline		99B5090	L pneumophila	1			5/24/1999
2060	Environmental	Lehigh Valley Hospital		99C5098	M. fortuitum				5/24/1999
2061	Environmental	Sewickley Hospital		99B5304	Leg spp				6/18/1999
2062	Environmental	Condor Industries		University,	L pneumophila	1			6/18/1999
2063	Environmental	Auburn NY		99B5418	L pneumophila	1			6/23/1999
2065	Environmental	Conemaugh		99B5459	L pneumophila	1		AT-DGVP	6/28/1999
2066	Environmental	Conemaugh		99B5459	L pneumophila	*		*not 1-6, Dir CCVC	6/30/1999
2067	Environmental	Conemaugh		[illegible]					

Discarded Legionella Stock Collection

Record #	Culture Type	Company Name	Location Name	Specimen	Species Name	Serotype	Sub-type	Stock Comments	Date
2071	Environmental	IL		99B5504	L pneumophila	1			6/28/1999
2072	Environmental	US Micro Solutions		99B5644	L. anisa			CDC confirmed	7/9/1999
2073	Environmental	Calgon, WV		CT, 99B5622	L pneumophila	1			7/9/1999
2074	Environmental	Coastline		99B5536	L pneumophila	1			7/9/1999
2075	Environmental	Hospital		99B5585	L pneumophila	5*		strongest with 5	7/9/1999
2076	Environmental	Hospital		99B5587	L pneumophila	5*		strongest with 5	7/9/1999
2077	Environmental	Hospital		99B5589	L pneumophila	5*		strongest with 5	7/9/1999
2078	Environmental	AUH Forbes		4, 99B5566	L pneumophila	1			7/9/1999
2079	Environmental	AUH Forbes		99B5569	L pneumophila	1			7/9/1999
2080	Environmental	Wash DC		Plant, W	L pneumophila	1			7/11/1999
2081	Environmental	JNB Labs, NJ		CT, 99B5679	L pneumophila	1			7/14/1999
2082	Environmental	JNB Labs, NJ		CT, 99B5679	L pneumophila	4			7/14/1999
2083	Environmental	Wash DC		W. cooling	Leg. Spp			Dir CCVC	7/11/1999
2084	Environmental	Wash DC		CT meter,	unknown			AT CCVC	7/11/1999
2085	Environmental	Wash DC		CT meter	L pneumophila	3		AT CCVC	7/11/1999
2086	Environmental	Wash DC		CT meter,	L pneumophila	6		AT CCVC	7/11/1999
2087	Environmental	Vermont Boiler		Tower,	L pneumophila	1			7/9/1999
2088	Environmental	Polyseal		direct, 99B5796	L pneumophila	5			7/15/1999
2089	Environmental	Microbac Labs		99B5863	Leg sp				7/21/1999
2090	Environmental	Klenzoid		Tower,	L pneumophila	1		AT DGVP	7/23/1999
2091	Environmental	Klenzoid		tower, 99B5871	L pneumophila	1	Olda		7/23/1999
2092	Environmental	Klenzoid		Gen tower,	L pneumophila	1			7/23/1999
2093	Environmental	US Microsolutions		99B5956	Leg sp				7/23/1999
2094	Environmental	Industrial Chem		1A, 99B5918	L pneumophila	6			7/23/1999
2095	Environmental	Highland Drive VAMC		99B5854	L pneumophila	6			7/23/1999
2096	Environmental	Coastline		99B5922	L pneumophila	1*		reactive, CCVC1	7/23/1999
2097	Environmental	Coastline		99B5922	L pneumophila	1*		reactive, CCVC2	7/23/1999
2098	Environmental	Conemaugh		CT-A, 99B5837	L pneumophila	1*		OLDA, Knox and Bell	7/23/1994
2099	Environmental	Klenzoid		99B5865	L pneumophila	1*		culture as #2090	7/26/1999
2100	Environmental	Dacar Industries		Johnstown	L pneumophila	5			7/27/1999
2101	Environmental	Development/Union		99B6039	unknown				7/28/1999

Discarded Legionella Stock Collection

Record #	Culture Type	Company Name	Location Name	Specimen	Species Name	Serotype	Sub-type	Stock Comments	Date
2102	Environmental	Industrial Chemical		99B6015	L pneumophila	1			7/30/1999
2103	Environmental	Industrial Chem		99B6033	L pneumophila	1			7/30/1999
2104	Environmental	Industrial Chem		99B6033	L pneumophila	*		*not 1-6	7/30/1999
2105	Environmental	Penisula Regional		99B6051	L pneumophila	6			7/30/1999
2106	Environmental	Penisula Regional		99B6057	L pneumophila	1			7/30/1999
2107	Environmental	West Penn Hospital		99N6147	L pneumophila	3			7/30/1999
2108	Environmental	Chemway		ladies room,	L pneumophila	1			8/12/1999
2109	Environmental	Chemway		Pump Tower,	L pneumophila	1*		from isolate #2108	8/12/1999
2110	Environmental	Chemway		Common Loop	L pneumophila	4			8/12/1999
2111	Environmental	Jefferson Hospital		center CT,	L pneumophila	1		CDC confirmed	8/12/1999
2112	Environmental	Industrial Chem		99B6112	L pneumophila	4			8/12/1999
2113	Environmental	Conemaugh		99B6210	L pneumophila	1			8/12/1999
2115	Environmental	Titus Station		99B6256	L pneumophila	1			8/19/1999
2116	Environmental	Keystone Station		996184	L pneumophila	*		*4 and 5	8/19/1999
2117	Environmental	Keystone Station		99B6184	L pneumophila	1			8/19/1999
2118	Environmental	Keystone Station		1SW, 99B6185	L pneumophila	7		ID by CDC	8/19/1999
2119	Environmental	Klenzoid		99B6241	L pneumophila	1			8/19/1999
2125	Environmental	Keystone Station		tower, 99B6706	L pneumophila	10		ID by CDC	9/24/1999
2126	Environmental	SHHS		Center,	L pneumophila	1	Olda	sg, CDC confirmed	9/24/1999
2128	Environmental	Salisburg Center, MD		shower,	L pneumophila	6			9/27/1999
2129	Environmental	US Steel Clairton		CT, 99B6742	L pneumophila	1			9/27/1999
2130	Environmental	Wash DC		sump, 99B6799	L pneumophila	1	Bellingham		9/27/1999
2131	Environmental	Microbac Labs		99B6874	L pneumophila	1			9/27/1999
2132	Environmental	Microbac Labs		#1053-2,	L pneumophila	1			9
2133	Environmental	Microbac Labs		#1053-4,	L pneumophila	1			9
2134	Environmental	Microbac Labs		99B7133	L pneumophila	1			9
2135	Environmental	Microbac Labs		99B7134	L pneumophila	1			9
[illegible]	[illegible]	Cnsr Path Lab	Ro2	(Jackson)	L pneumophila	1			9

Discarded Legionella Stock Collection

Record #	Culture type	Company Name	Sub-Compt. name	Description	Species name	Sg	Serotype	Misc. Info	Discard
2140	Environmental	Titus Station		99B6918	L pneumophila	1		green; CDC confirmed	9
2141	Environmental	Microbac Labs		99B7258	L pneumophila	1			9
2142	Environmental	Microbac Labs		99B7259	L pneumophila	1			9
2143	Environmental	Microbac Labs		99B7260	L pneumophila	1			9
2145	Environmental	Sunrise Nursing Home		room sink	L. anisa			CDC confirmed	9
2146	Environmental	Sunrise Nursing Home		room sink	L. anisa				9
2147	Environmental	US Steel Clairton		CT, 99B7186	L. sainthelensi	1		ID by CDC	9
2148	Environmental	ENSR		99B7249	L pneumophila	1	Olda	strain 1	9
2149	Environmental	ENSR		99B7249	L pneumophila	1	Olda	strain 2	9
2150	Environmental	Seward Station		CT, 99B7198	L pneumophila	1			9
2151	Environmental	Klenzoid		99B7245	L pneumophila	1	Bellingham		9
2152	Environmental	Adena Technologies		CT, 99B7390	L pneumophila	1			11/1/1999
2153	Environmental	US Microsolutions		#3, 99B7610	L. anisa			CDC confirmed	9
2154	Environmental	US Microsolutions		#12,	L. anisa			CDC confirmed	9
2155	Environmental	Highland Drive VAMC		2333SW	L. anisa			CDC confirmed	9
2156	Environmental	Adena Technologies		Residence	L pneumophila	1			12/2/1999
2157	Environmental	Adena Technologies		Tower	L pneumophila	1			12/2/1999
2159	Environmental	Aspinwall VAMC		99A8223	L pneumophila	1		#1	9
2160	Environmental	Aspinwall VAMC		99A8223	L pneumophila	1		#2	9
2161	Environmental	Wash DC		99B9201	L pneumophila	4			9
2162	Environmental	Wash DC		99B8197	L pneumophila	1		#2	9
2163	Environmental	US Microsolutions		99B8276	L pneumophila	1			1/3/2000
2164	Environmental	California Schools		#1,	L pneumophila	1			1/6/2000
2165	Environmental	California Schools		#2, 99B8260	L pneumophila	1			1/6/2000
2166	Environmental	West Penn Hospital		99B8255	L pneumophila	1			1/6/2000
2167	Environmental	Johns Hopkins		faucet	L pneumophila	3			1/14/2000
2168	Environmental	Johns Hopkins		faucet	Leg. Spp			not pneumophila	1/14/2000
2169	Environmental	Johns Hopkins		00B8386	L pneumophila	3			1/14/2000
2170	Environmental	Johns Hopkins		00B8388	Leg. Spp				1/14/2000
2172	Environmental	Hospital		00B8268	Leg spp			not pneumophila	1/17/2000
2173	Environmental	Wilmington DE VA		CT, 00C8621	L pneumophila	1			1/28/2000

Discarded Legionella Stock Collection

Record #	Culture type	Company Name	Sub-Compt. name	Description	Species name	Sg	Serotype	Misc. Info	Discard
2175	Environmental	Aspinwall VAMC		0A8783	L pneumophila	1		strain 1	2/7/2000
2176	Environmental	Aspinwall VAMC		Bldg 2, 0A8783	L pneumophila	1		strain 2	2/7/2000
2177	Environmental	St. Peter's Albany NY		0B8814	L pneumophila	5		strain 1 (blue)	2/11/2000
2178	Environmental	St. Peter's Albany NY		0B8814	L pneumophila	5		strain 2 (pink)	2/11/2000
2179	Environmental	US Microsolutions		0B9128	L. anisa				2/24/2000
2180	Environmental	US Microsolutions		0B9129	L. dumoffii				2/24/2000
2181	Environmental	Binax		processing CT	L pneumophila	1			3/13/2000
2182	Environmental	Binax		Compressor CT	L pneumophila	1			3/13/2000
2183	Environmental	Klenzoid-Bryn Mawr		0B10177	L pneumophila	1			3/13/2000
2184	Environmental	Inalab, Inc		CT, 00B10288	Leg. Spp				3/17/2000
2185	Environmental	Inalab, Inc		00B10289	L pneumophila	1		clumpy	3/17/2000
2186	Environmental	Inalab, Inc		bath, 00B10290	L pneumophila	1		clumpy	3/17/2000
2187	Environmental	Inalab, Inc		bath, 00B10290	L pneumophila	1		smooth	3/17/2000
2188	Environmental	St. Peter's Albany, NY		CT, 0B10090	L pneumophila	1			3/19/2000
2191	Environmental	Applied Bldg, MD		CT, 0A10422	L pneumophila	1			4/2/2000
2192	Environmental	Applied Bldg, MD		0A10425	L pneumophila	1			4/2/2000
2193	Environmental	Johns Hopkins		0B10622	L pneumophila	1		gummy, isolate #1	4/14/2000
2194	Environmental	Johns Hopkins		#1	L pneumophila	1		smooth, isolate #2	4/14/2000
2195	Environmental	Johns Hopkins		0B10622	L pneumophila	1		gummy, isolate #2	4/14/2000
2196	Environmental	Johns Hopkins		0B10631	L pneumophila	1		smooth, isolate #2	4/14/2000
2199	Environmental	Johns Hopkins		771	L. anisa				4/21/2000
2200	Environmental	Johns Hopkins		MICU Rm 2	Leg spp			not pneumophila	4/21/2000
2201	Environmental	Johns Hopkins		MICU Rm 2	L pneumophila	3		**10621	4/21/2000
2202	Environmental	Johns Hopkins		Osler 4 sink	L pneumophila	3			4/21/2000
2203	Environmental	Nalco		PCT-A	L pneumophila	1			4/29/2000
2204	Environmental	Nalco		PCT-A	L pneumophila	5		**10759	4/29/2000
2205	Environmental	FRANCE		bath	L pneumophila	6		no VA record #	5/5/2000
2206	Environmental	FRANCE		bath	L pneumophila	3		no VA record #	5/5/2000

Discarded Legionella Stock Collection

Record #	Affinity Type	Company Name	Hospital Name	Product	Organism Name	Serg	Strain Type	Place	Miscellaneous	Entered
2210	Environmental	US Microsolutions		water	L pneumophila	1				5/10/2000
2211	Environmental	Aspinwall VAMC		(smooth)	L pneumophila	1				5/10/2000
2212	Environmental	Aspinwall VAMC		(gummy)	L pneumophila	1				5/10/2000
2214	Environmental	WaterPro		cooling tower	L pneumophila	1	Olda		confirm by MAB	5/28/2000
2215	Environmental	WaterPro		Elcott City CT	L pneumophila	1	Bellingham			5/28/2000
2216	Environmental	WaterPro		Belair CT	L pneumophila	1	Olda		confirm by MAB	5/28/2000
2217	Environmental	WaterPro		Crownsville CT	L pneumophila	1	Olda		confirm by MAB	5/28/2000
2219	Environmental	Spec Path Lab	Tu	9E114 sink	L pneumophila	1				5/31/2000
2220	Environmental	Spec Path Lab	Tu	9W Ice	L pneumophila	1				5/31/2000
2221	Environmental	Klenzoid		restroom	L pneumophila	1				5/31/2000
2222	Environmental	Klenzoid		IVF rec room	L pneumophila	6				5/31/2000
2223	Environmental	Klenzoid		Tank - C wing	L pneumophila	1				6/1/2000
2226	Environmental	VGH-Taiwan		MICU-2	Legionella spp.				Taiwan isolate	6/25/2000
2227	Environmental	VGH-Taiwan		VICU-11	L pneumophila	1			Taiwan isolate	6/25/2000
2228	Environmental	VGH-Taiwan		Water	L pneumophila	4			Taiwan isolate	6/23/2000
2229	Environmental	VGH-Taiwan		tower)	L pneumophila	4			Taiwan isolate	6/23/2000
2230	Environmental	VGH-Taiwan		storage tank	other				)	6/30/2000
2231	Environmental	Adena Technologies	cooling tower	Mound	L pneumophila	1				6/30/2000
2234	Environmental	University		Wing	L pneumophila	6				7/5/2000
2235	Environmental	Inalab, Inc		Royal Sea Cliff	L pneumophila	1				7/5/2000
2236	Environmental	Inalab, Inc		by the Sea	L pneumophila	1				7/5/2000
2237	Environmental	Binax		tower	L pneumophila	1			tobe Lp1	7/10/2000
2238	Environmental	Binax		tower	L pneumophila	1			to be Lp1	7/10/2000
2239	Environmental	GLA consultants		Binax study	L pneumophila	1				7/22/2000
2240	Environmental	GLA consultants		Binax study	L pneumophila	1				7/22/2000
2241	Environmental	Binax		CT, isolate 1	L pneumophila	1				7/22/2000
2242	Environmental	Binax		CT, isolate 2	L pneumophila				not 1-6	7/22/2000
2248	Environmental	HC Info	isolate 1	shower	Legionella spp.				St. Joseph's Med Ctr.	9/7/2000
2249	Environmental	HC Info	isolate 2	shower	L pneumophila	6			St. Joseph's Med Ctr.	9/7/2000
2250	Environmental	HC Info	isolate 3	shower	L.anisa				St. Joseph's Med Ctr.	9/7/2000
2251	Environmental	HC Info		6W Pt shower	L pneumophila				Med Ctr.	9/7/2000

Discarded Legionella Stock Collection

Record #	Affinity Type	Company Name	Hospital Name	Product	Organism Name	Serg	Strain Type	Place	Miscellaneous	Entered
2252	Environmental	HC Info		6W shower	L pneumophila	6			St. Joseph's Med.Ctr.	9/11/2000
2253	Environmental	HC Info		4N MSICU	L pneumophila	6			St. Joseph's Med Ctr.	9/11/2000
2254	Environmental	HC Info		6W cardiac RC	L pneumophila	6			St. Joseph's Med Ctr.	9/11/2000
2255	Environmental	HC Info		water	L pneumophila	6			St. Joseph's Med Ctr.	9/11/2000
2258	Environmental	Klenzoid		cooling tower	not legionella				Ram(-);mTech+?	0
2259	Environmental	Palo Alto VAMC		DGVP 1	L pneumophila	1				11/4/2000
2260	Environmental	Palo Alto VAMC		HWT Bldg 100	L pneumophila	1				11/4/2000
2261	Environmental	Palo Alto VAMC		Plant (F. DGVP	L pneumophila	1			str.1?	11/4/2000
2262	Environmental	Palo Alto VAMC		Plant (F DGVP	L pneumophila	1			str 2?	11/4/2000
2263	Environmental	Palo Alto VAMC		faucet	L pneumophila	1				11/4/2000
2264	Environmental	Wm Beaumont		tower (D DGVP	L pneumophila	1				11/4/2000
2265	Environmental	Wm Beaumont		tower (D DGVP	L pneumophila				not 1-6	11/4/2000
2266	Environmental	Wm Beaumont		DGVP 1)	L pneumophila	3			str 1?	11/4/2000
2267	Environmental	Wm Beaumont		DGVP 2)	L pneumophila	3			str 2?	11/4/2000
2268	Environmental	Wm Beaumont			L bozemanii					11/4/2000
2269	Environmental	Wm Beaumont		BCYE 1)	L pneumophila				not 1-6	11/4/2000
2270	Environmental	Nashville VAMC		Dialysis room	L pneumophila	6				0
2271	Environmental	Nashville VAMC		Main CT	L pneumophila	5				0
2272	Environmental	Nashville VAMC		Main CT	L bozemanii					0
2273	Environmental	Nashville VAMC		Main CT	L anisa					0
2274	Environmental	West Penn Hospital		apt.9 kitchen	L pneumophila	1				0
2275	Environmental	West Penn Hospital		apt.9 bathroom	L pneumophila	1				0
2276	Environmental	West Penn Hospital		2, sample 1	L pneumophila	1				0
2277	Environmental	West Penn Hospital		1, sample 1	L pneumophila	1				0
2278	Environmental	Cleveland VAMC		4225	L pneumophila	5				0
2279	Environmental	Cleveland VAMC		4225	L anisa					0
2280	Environmental	Butler VAMC		Cl, rm CA01	L pneumophila	1				0
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	L pneumophila	1				0

Discarded Legionella Stock Collection

Record #	Sample Type	Company Name	Location/Item	Description	Isolate Identification	Sg	Subtype 1	Subtype 2	Date Received
2285	Environmental	Omaha VAMC		12 th floor BR	L anisa				12/4/2000
2286	Environmental	Omaha VAMC		#1	L pneumophila	1		strain 1?	12/4/2000
2287	Environmental	Omaha VAMC		#1	L pneumophila	1		strain 2?	12/4/2000
2288	Environmental	Chesterton		spike sample	unknown gnr			backgr cont.	12/4/2000
2292	Environmental	St. Peter's Hospital		Tank 7 isolate 1	L pneumophila	5		(+/-) mTech	0
2293	Environmental	St. Peter's Hospital		Tank 7 isolate 2	L pneumophila	5		(+/-)mTech	0
2294	Environmental	Chesterton		0 pass	gnr 1				0
2295	Environmental	Chesterton		spiked	gnr 2				0
2296	Environmental	VAMC Syracuse		isolate 1	L pneumophila			not 1-6	0
2297	Environmental	VAMC Syracuse		isolate 2	L pneumophila	1	Olda?		0
2298	Environmental	VAMC Syracuse		C846	L pneumophila			not 1-6 #2	0
2299	Environmental	VAMC Syracuse		A332	L pneumophila	1	Olda?		0
2300	Environmental	VAMC Huntington		1 C150 sink	L anisa			Stout-Muder study	0
2301	Environmental	VAMC Huntington		isolate 1	L pneumophila	1		Stout-Muder study	0
2302	Environmental	VAMC Huntington		isolate 2	L pneumophila	1		Stout-Muder study	0
2303	Environmental	Scottsdale HC		sink	L pneumophila	5		(+/-)mTech	0
2304	Environmental	Austin, City of		Pilot CT	L pneumophila	6			1/2/2001
2305	Environmental	Coastline		condensor	L pneumophila	4			1/2/2001
2306	Environmental	Center		BP 732 faucet	L pneumophila	1			1/2/2001
2307	Environmental	Iowa VAMC		#1	L pneumophila	1		str 1?	1/2/2001
2308	Environmental	Iowa VAMC		#2	L pneumophila	1		str 2?	1/2/2001
2309	Environmental	Iowa VAMC		7W 31, is#1	L pneumophila	1			1/2/2001
2310	Environmental	Iowa VAMC		7W 31, is#2	L pneumophila	1			1/2/2001
2311	Environmental	Iowa VAMC		is#1	L pneumophila	1			1/2/2001
2312	Environmental	Iowa VAMC		is#2	L pneumophila	1		str 3?	1/2/2001
2313	Environmental	Iowa VAMC		is#3	Legionella spp.			not pneumo	1/2/2001
2314	Environmental	Albany VAMC		sink, isolate 1	L pneumophila	1		1st col.type?	1/12/2001
2315	Environmental	Albany VAMC		sink, isolate 2	L pneumophila	1		2nd col.type?	1/12/2001
2316	Environmental	Albany VAMC		isolate 1	L pneumophila	1		1 col type?	1/12/2001
2317	Environmental	Albany VAMC		isolate 2	L pneumophila	1		2nd col.type?	1/12/2001
2318	Environmental	Albany VAMC		813B Shower	L pneumophila	1			1/12/2001

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Record #	Sample Type	Company Name	Location/Item	Description	Isolate Identification	Sg	Subtype 1	Subtype 2	Date Received
2319	Environmental	St. Peter's Hospital		tank 4	L pneumophila	1			1/29/2001
2320	Environmental	Elmhurst		Nursery	L pneumophila	3			1/29/2001
2321	Environmental	Elmhurst		Nursery A 835	L pneumophila	3			1/29/2001
2322	Environmental	SHHS		2415 W	L pneumophila	3			1/29/2001
2323	Environmental	SHHS		Serving line	L pneumophila	3			1/29/2001
2324	Environmental	ACHD		maintenance	L pneumophila	1			1/31/2001
2325	Environmental	ACHD		men's shower	L pneumophila	1			1/31/2001
2326	Environmental	Beford VAMC		B25A	L pneumophila	3			2/9/2001
2327	Environmental	R2J Chemical Services		Pavillion CT	L pneumophila	1			2/9/2001
2328	Environmental	Service		3E Rm 3017	L pneumophila	1			2/9/2001
2329	Environmental	NRG Energy Center		Millers CT	L pneumophila	1			2/16/2001
2330	Environmental	NRG Energy Center		Plant CT	L pneumophila	1			2/16/2001
2332	Environmental	VAMC Huntington		cooling tower	L pneumophila	1			2/26/2001
2333	Environmental	R2J Chemical Services		spectrum CT	L pneumophila	1			2/23/2001
2334	Environmental	Longbeach VAMC		#1	L pneumophila	1			2/23/2001
2335	Environmental	US Microsolutions		sample	L pneumophila	1			2/23/2001
2338	Environmental	Center		Lg CT Basin	L pneumophila	1			3/2/2001
2339	Environmental	Center		Sm CT	L pneumophila	1			3/2/2001
2342	Environmental	International Chemstar		NGA CT	L pneumophila	1			3/5/2001
2386	Environmental	VAMC Dayton		8N pat room	L pneumophila	1			3/15/2001
2387	Environmental	VAMC Dayton		room	L pneumophila	1			3/15/2001
2388	Environmental	VAMC Dayton		room	L pneumophila	1			3/15/2001
2411	Environmental	Chemway		Hosp. HWT 1	L pneumophila	5		str 1	3/29/2001
2412	Environmental	Chemway		Hosp. HWT 2	L pneumophila	5		str 2	3/29/2001
2416	Environmental	ACHD		336 faucet	L pneumophila	1			4/12/2001
2417	Environmental	ACHD		337	L pneumophila	1			4/12/2001
2418	Environmental	ACHD		Return line	L pneumophila	1			4/12/2001
2419	Environmental	Hosp		showerhead	L pneumophila	6			4/17/2001

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Record #	Culture type	Company Name	Source	Description	Species name	Sg	Study type	Mycobacterium	Date
2423	Environmental	Albany VAMC		+ patient	L pneumophila	1		VA study	4/19/2001
2428	Environmental	Tucson VAMC		207 sink	L pneumophila	6			5/11/2001
2436	Environmental	Klenzoid		Hospital, 6C	L pneumophila	1			5/17/2001
2437	Environmental	Web Aruba		sample #5	L pneumophila	1			5/23/2001
2438	Environmental	Web Aruba		Sample 11A	L pneumophila	6			5/23/2001
2439	Environmental	Web Aruba		Sample 3	L pneumophila	*		not 1-6	5/23/2001
2442	Environmental	Cleveland VAMC			L pneumophila	5		str 1	5/24/2001
2443	Environmental	Cleveland VAMC			L pneumophila	5		str 2	5/24/2001
2471	Environmental	UPMC McKeesport		showerhead	L pneumophila	1			5/31/2001
2472	Environmental	Butler VAMC		114	L pneumophila	5			5/31/2001
2473	Environmental	VGH-Taiwan		3-1, 4 C1	L pneumophila			confirm ID	
2474	Environmental	VGH-Taiwan		3-10, 24C1				confirm ID	
2475	Environmental	VGH-Taiwan		3-24, 1 - 8C2	L pneumophila			confirm ID	
2476	Environmental	VGH-Taiwan		209	L pneumophila			confirm ID	
2477	Environmental	VGH-Taiwan		248	L pneumophila			confirm ID	
2478	Environmental	Longbeach VAMC		M131 A faucet	L pneumophila	1		VA study	6/3/2001
2479	Environmental	West Penn Hospital		N311 shower	L pneumophila	3		str1	6/4/2001
2480	Environmental	West Penn Hospital		E 625 sink	L pneumophila	3		str 2	6/4/2001
2481	Environmental	SHHS		heater #3	L pneumophila	2			6/6/2001
2482	Environmental	USAF		cooling tower	L pneumophila	1			6/6/2001
2483	Environmental	Center		HWT preflush	L pneumophila	6			6/13/2001
2484	Environmental	ACHD		Ave.,HW	L pneumophila	1		str 1	6/13/2001
2485	Environmental	ACHD		Ave.,HW	L pneumophila	1		str 2	6/13/2001
2486	Environmental	ACHD		Ave., HW	L pneumophila	1		str 3	6/13/2001
2488	Environmental	Blossom View		Rm 272 faucet	L pneumophila	1			6/20/2001
2489	Environmental	Syracuse VAMC		A332 restroom	L pneumophila	6			6/22/2001
2490	Environmental	Spec Path Lab		residence HWT	L pneumophila	5			6/27/2001
2492	Environmental	US Microsolutions		6749-6	L pneumophila	1			7/12/2001
2493	Environmental	US Microsolutions		6749-8	L pneumophila	1			7/12/2001
2494	Environmental	US Microsolutions		6754-1	L pneumophila	5			7/12/2001
2495	Environmental	St.Clair Hospital		Tower Tech	L pneumophila	1			7/13/2001

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Record #	Culture type	Company Name	Source	Description	Species name	Sg	Study type	Mycobacterium	Date
2498	Environmental	Kingman MC		PCV 342	L pneumophila	5			8/8/2001
2499	Environmental	Kingman MC		PCV 342	L pneumophila	1			8/8/2001
2500	Environmental	St. Joseph MC, RI		resp)	L pneumophila	1		for PFGE	8/10/2001
2501	Environmental	Ellenville Reg Hosp		HWT	L pneumophila	6			8/13/2001
2502	Environmental	St. Peter's Albany NY		immed.	L pneumophila	5			8/15/2001
2518	Environmental	Ellenville Reg Hosp		HWT	L pneumophila	6			8/22/2001
2519	Environmental	SHHS		CT	L pneumophila	1			8/23/2001
2520	Environmental	Tucson VAMC		ICU, 235 sink	L pneumophila	1			8/30/2001
2521	Environmental	(Orange,CA)		shower head	L pneumophila	6			8/29/2001
2522	Environmental	(Orange,CA)		faucet	L pneumophila			not 1-6	8/29/2001
2523	Environmental	(Orange,CA)		EV-1806-1 CT	L pneumophila	1			8/29/2001
2524	Environmental	(Orange,CA)		EV-1807 HWT	L pneumophila	6			8/29/2001
2525	Environmental	Spec Path Lab		kitchen sink	L pneumophila	1			9/7/2001
2526	Environmental	Spec Path Lab		8632 BRSF	L pneumophila	1			9/10/2001
2527	Environmental	Center		CT	L pneumophila	1			9/12/2001
2528	Environmental	ACHD		515 kitchen	L pneumophila	1			9/12/2001
2529	Environmental	ACHD		515 bath	L pneumophila	1			9/12/2001
2530	Environmental	ACHD		1216 kitchen	L pneumophila	1			9/12/2001
2531	Environmental	ACHD		1216 bath	L pneumophila	1			9/12/2001
2532	Environmental	Mercy Hospital		rm 612	L pneumophila	1			9/14/2001
2533	Environmental	Hosp		kitchen sink	L pneumophila	5			9/20/2001
2534	Environmental	Hosp		Blood bank sink	L pneumophila	6			9/20/2001
2535	Environmental	Hosp		600 ton CT	L pneumophila	1			9/20/2001
2536	Environmental	Washington Hospital		sink	L pneumophila	3			9/26/2001
2538	Environmental	Spec Path Lab		Kerestury's	L pneumophila	6			1
2539	Environmental	Spec Path Lab		Kerestury's	L pneumophila	1			1
2540	Environmental	Enrich Products		Parasitology	Mycobacterium			avium	1
				Family Center	Mycobacterium			gordonae	1
									1

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Record #	Facility Type	Company Name	Sample Location	Species	Serotype	Isolated From	Date Found
2548	Environmental	Harmarville (GLA)	central shower	L species		no pneumo	11/9/2001
2549	Environmental	Harmarville (GLA)	Central Shower	L anisa			11/9/2000
2550	Environmental	Harmarville (GLA)	Central Shower	L pneumophila	5		11/9/2001
2551	Environmental	Harmarville (GLA)	Rm 112 sink	L pneumophila	1		11/9/2001
2552	Environmental	Harmarville (GLA)	Pool Shower	L pneumophila	1		11/9/2001
2553	Environmental	Harmarville (GLA)	HW Tank	L pneumophila	1		11/9/2001
2554	Environmental	UPMC Passavant	Trane Sump	L anisa			11/9/2001
2555	Environmental	UPMC Passavant	Trane Sump	L pneumophila	1		11/9/2001
2556	Environmental	Oaklawn Hospital	HWT	Legionella Spec.		not pneumo	1
2557	Environmental	Center	Room	Legionella Spec.		no pneumo	12/6/2001
2558	Environmental	Butler VAMC	W Faucet	L pneumophila	1	from patient's room	12/6/2010
2559	Environmental	Enrich Products	Family Ctr	M.avium			1
2560	Environmental	Enrich Products	Family Ctr	M. gordonae			1
2561	Environmental	Wausau Hospital	Break Rm	L pneumophila	1		1
2562	Environmental	Butler VAMC	Faucet	L pneumophila		not 1-6	1
2563	Environmental	Meadville Hospital	Mechanical Rm	L pneumophila	4		1
2564	Environmental	Butler VAMC	Bathroom	L pneumophila	5		1
2565	Environmental	NSU Hospital	MR1 CT	L pneumophila	5		1
2566	Environmental	NSU Hospital	MR1 CT	L pneumophila	6		1
2567	Environmental	JSI Industries	Bldg D Rm 301	L pneumophila	4	a hospital sample	1
2568	Environmental	Center	West HWT	L pneumophila	1		1
2569	Environmental	Tucson VAMC	ICU #13	L pneumophila	1		1
2570	Environmental	Tucson VAMC	ICU #13	L pneumophila	6		1
2571	Environmental	JK, Inc.	Faucet	L pneumophila	1		1
2572	Environmental	JK, Inc.	350 Faucet	L pneumophila	1		1
2573	Environmental	JK, Inc.	Faucet	L pneumophila	1		1
2574	Environmental	VGH-Taiwan	Bldg. "A"	L pneumophila	1		1/14/2002
2575	Environmental	VGH-Taiwan	CICU-5,6	L pneumophila	1		1/4/2002
2576	Environmental	VGH-Taiwan	VICU-10	L pneumophila	1		1/4/2002
2578	Environmental	VGH-Taiwan	Bldg. A (A-2)	L pneumophila	6		1/7/2002
2579	Environmental	VGH-Taiwan	Bldg. B (A-4)	L pneumophila	6		1/7/2002

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2580	Environmental	VGH-Taiwan	B (A-5)	L pneumophila	6			1/7/2002
2581	Environmental	VGH-Taiwan	CICU-10 (A-6)	L pneumophila	6			1/7/2002
2582	Environmental	VGH-Taiwan	VICI-3,5 (A-7)	L pneumophila	6			1/7/2002
2583	Environmental	VGH-Taiwan	BICU-6 (A-8)	L pneumophila	6			1/7/2002
2585	Environmental	VGH-Taiwan	NICU-8 (B-2)	L pneumophila	6			1/7/2002
2586	Environmental	VGH-Taiwan	RICU-8 (B-3)	L pneumophila	6			1/7/2002
2589	Environmental	Hospital	W4300	Legionella spec.			not pneumophila	1/8/2002
2590	Environmental	Hospital	ER	L pneumophila	6			1/9/2002
2592	Environmental	Enrich Products	Recovery	M.xenopi				1/30/2002
2593	Environmental	IL	Rm. 2120	L pneumophila	1			2/13/2002
2594	Environmental	Butler VAMC	Audiology 116	L pneumophila	4			2/13/2002
2595	Environmental	Butler VAMC	Audiology 116	L species			not pneumophila	2/15/2002
2596	Environmental	West Penn Hospital	555-SGH	L pneumophila	5			2/22/2002
2597	Environmental	John J. Kane Hospital	swab #4	L pneumophila	1			3/5/2002
2598	Environmental	John J. Kane Hospital	2A-216 Shower	L pneumophila	1		Janet's sample	3/6/2002
2599	Environmental	John J. Kane Hospital	hydrotherapy	L pneumophila	1		Janet's sample	3/13/2002
2600	Environmental	John J. Kane Hospital	swab #5	L anisa				3/13/2002
2604	Environmental	Hospital	230 Faucet	L pneumophila	6			4/12/2002
2606	Environmental	Phoenix Baptist Hospital	Water-Pretest	L pneumophila	5			4/18/2002
2607	Environmental	Phoenix Baptist Hospital	Cooling Tower	L pneumophila	1			4/18/2002
2610	Environmental	Beaver Medical Center	C-340 Shower	L pneumophila	5			5/3/2002
2611	Environmental	Beaver Medical Center	C-322 Sink	L pneumophila	1		strain 1?	5/3/2002
2612	Environmental	Beaver Medical Center	M-103 Sink	L pneumophila	2		strain 2?	5/3/2002
2613	Environmental	Beaver Medical Center	Occ. Therapy	L pneumophila	1		strain 1?	5/3/2002
2614	Environmental	Beaver Medical Center	HWT	L pneumophila	6			5/3/2002
2615	Environmental	Stout/Aerator Study	2A 104 #2	species			not pneumophila	5/6/2002
2616	Environmental	EPA Study	Heitzenrater	L pneumophila	1			5/8/2002
2617	Environmental	EPA Study	Heitzenrater	L pneumophila	1			5/8/2002

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Record #	Culture type	Company Name	Source Name	Description	Species name	Serg	Subtype	Strain/group	Isolate
2621	Environmental	Metro Health		1	L pneumophila	5		strain 1	5/25/2002
2622	Environmental	Metro Health		2	L pneumophila	5		strain 2	5/25/2002
2623	Environmental	Center		ER Room	L pneumophila	1			5/25/2002
2624	Environmental	Iowa VAMC		7W 31 Shower	L pneumophila	1		strain 1?	5/31/2002
2625	Environmental	Iowa VAMC		7E 30 Shower	L pneumophila	1		strain 2?	5/31/2002
2627	Environmental	Center		Machine	L species			not pneumo	6/10/2002
2632	Environmental	WI Veterans Home		460	1 species			not serogroup 1-6	6/21/2002
2633	Environmental	Klenzoid		Menonite Home-	L pneumophila	1			6/21/2002
2634	Environmental	Klenzoid		Menonite Home-	L pneumophila	1			6/20/2002
2635	Environmental	Klenzoid		Continuing	L pneumophila	1		strain 1?	6/20/2002
2636	Environmental	Klenzoid		Continuing	L pneumophila	1		strain 2?	6/20/2002
2637	Environmental	Birmingham		P608 Faucet	L pneumophila	1		isolate	7/1/2002
2638	Environmental	Birmingham		Faucet	L pneumophila	1		isolate	7/1/2002
2641	Environmental	Management, Inc.		Center for	L pneumophila	1			7/9/2002
2642	Environmental	Management, Inc.		Center for	L pneumophila	1			7/9/2002
2643	Environmental	Mercy Hospital		Providence	L pneumophila	5			7/18/2002
2644	Environmental	Mercy Hospital		MHP, Main	L pneumophila	1			7/18/2002
2645	Environmental	Mercy Hospital		MHP, Main	L pneumophila	1			7/18/2002
2647	Environmental	ACHD - EPA Study		Gilleland Home	L pneumophila	1			7/24/2002
2648	Environmental	ACHD - EPA Study		(Gilleland	L pneumophila	1			7/24/2002
2650	Environmental	ACHD - EPA Study		Housing Auth.,	L pneumophila	1			8/13/2002
2651	Environmental	ACHD - EPA Study		Housing Auth.,	L pneumophila	1		str.1?	8/13/2002
2652	Environmental	ACHD - EPA Study		Housing Auth.,	L pneumophila	1		str. 2?	8/13/2002
2653	Environmental	Beaver Medical Center		test w/pt	L pneumophila	1			8/15/2002
2654	Environmental	Beaver Medical Center		C323 shower	L pneumophila	6			8/15/2002
2656	Environmental	J.H. Bayview		2A	L pneumophila	6			8/14/2002
2657	Environmental	J.H. Bayview		24A	L pneumophila			not 1-6	8/14/2002
2658	Environmental	J.H. Bayview		25A	L pneumophila	1			8/14/2002
2661	Environmental	Spain HUGTIP	67/2 Return B,	date: 10/90)	L pneumophila	1		strain 2?	8/21/2002
2662	Environmental	Spain HUGTIP	69 Return A	date: 10/90	L pneumophila	1		strain 1?	8/21/2002
2663	Environmental	Spain HUGTIP	70 2nd Fl,	date: 11/90	L pneumophila	1		strain 2? (Neg axoid)	8/21/2002

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Record #	Culture type	Company Name	Source Name	Description	Species name	Serg	Subtype	Strain/group	Isolate
2664	Environmental	Spain HUGTIP	80 7th Fl,	date: 11/90	L pneumophila	1		strain 1?	8/21/2002
2665	Environmental	Spain HUGTIP	209 Return B,	date: 1/96	L pneumophila	1		strain 1?	8/21/2002
2666	Environmental	Spain HUGTIP	210 Return A,	date: 1/96	L pneumophila	1		strain 1?	8/21/2002
2667	Environmental	Spain HUGTIP	582 2nd Fl.	date: 4/99	L pneumophila	1		strain 2? (Neg axoid)	8/21/2002
2668	Environmental	Spain HUGTIP	676 Return B,	7/2000	L pneumophila	1		strain 1?	8/21/2002
2669	Environmental	Spain HUGTIP	684 Return B,	7/2000	L pneumophila	1		strain 1?	8/21/2002
2670	Environmental	Spain HUGTIP	897 1st Fl,	5/2001	L pneumophila	1		strain 1?	8/21/2002
2671	Environmental	Spain HUGTIP	951 13th Fl,	9/2001	L pneumophila	1		strain 1?	8/21/2002
2672	Environmental	Spain HUGTIP	1044 7th Fl,	4/2002	L pneumophila	1		strain 2? (Neg axoid)	8/21/2002
2673	Environmental	Spain HUGTIP	1049 1st Fl,	4/2002	L pneumophila	1		strain 1?	8/21/2002
2674	Environmental	Spain HUGTIP	1056 8th Fl,	4/2002	L pneumophila	1		strain 2? (Neg axoid)	8/21/2002
2675	Environmental	Spain HUGTIP	1060 2nd Fl,	4/2002	L pneumophila	1		strain 1?	8/21/2002
2676	Environmental	Spec Path Lab		#2	L pneumophila	5			8/30/2002
2677	Environmental	Cuyahoga-EPA		717 Sink	L. micdadei				9/5/2002
2678	Environmental	Beaver Medical Center		C323 Sink	L pneumophila	1			9/5/2002
2679	Environmental	J.H. Bayview		A242 Tub	L pneumophila	5			9/8/2002
2680	Environmental	Metro Health		#1-Rm 942	Scotochromogen				9/9/2002
2681	Environmental	Aspinwall VAMC		Study.#1A-2A	Scotochromogen				9/9/2002
2682	Environmental	Aspinwall VAMC		Study.#1Ba 103	Scotochromogen				9/9/2002
2683	Environmental	VAMC Cleveland		#1 H102	Scotochromogen				9/9/2002
2684	Environmental	Keystone Station		6 DFA-	L pneumophila			not 1-6	9/12/2002
2686	Environmental	CHP (Children's)		CHP# 1331	L pneumophila	1		CuAg Resist.study	9/13/2002
2687	Environmental	CHP (Children's)		CHP# 1332	L pneumophila	1		CuAg Resist.study	9/13/2002
2688	Environmental	CHP (Children's)		CHP# 1335	L pneumophila	1		CuAg Resist.study	9/13/2002
2689	Environmental	CHP (Children's)		CHP# 1336	L pneumophila	1		CuAg Resist.study	9/13/2002
2690	Environmental	CHP (Children's)		CHP# 1341	L pneumophila	1		CuAg Resist.study	9/13/2002
2691	Environmental	CHP (Children's)		CHP# 1339	L pneumophila	1		CuAg Resist.study	9/13/2002
[illegible]	[illegible]	CHP (Children's)		CHP# 1342	L pneumophila	1		CuAg Resist.study	9/13/2002
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	9/15/2002

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Record #	Sample Type	Site Company Name	Hospital Alpha	Description	Species Found	LP1	LP6 Type	Culture Method	Date Found
2696	Environmental	ACHD - EPA Study	RD	kitchen sink	L pneumophila	5		confirmed by CDC	9/15/2002
2697	Environmental	ACHD - EPA Study	RD	kitchen sink	pneumo				9/15/2002
2698	Environmental	VA Huntington		Faucet	L pneumophila	1			9/30/2002
2699	Environmental	VAMC Cleveland		Faucet	L pneumophila	5			9/20/2002
2708	Environmental	VA Tucson		Machine	L pneumophila	1			10/9/2002
2709	Environmental	VA Tucson		Machine	L pneumophila	4			10/9/2002
2711	Environmental	Wm Beaumont		Tower	L pneumophila	1			2
2712	Environmental	Wm Beaumont		Faucet	L pneumophila	3			2
2718	Environmental	Cuyahoga-EPA		drain 3 at work	L pneumophila	1			2
2719	Environmental	Cuyahoga-EPA		bathroom at	L pneumophila	1			2
2720	Environmental	Cuyahoga-EPA		tower at work	L pneumophila	3			2
2721	Environmental	Wm Beaumont		tower	L pneumophila			not 1-6	2
2723	Environmental	Phoenix Baptist Hospital		water	L pneumophila	6			11/6/2002
2732	Environmental	Omaha VAMC		8E B 204 sink	L pneumophila	1	2+4+4+4+	pink	2
2733	Environmental	Omaha VAMC		shower	L pneumophila	1	2+4+4+4+	blue col	2
2734	Environmental	Omaha VAMC		5W E 605 sink	L pneumophila	1		blue	2
2735	Environmental	Omaha VAMC		5W E 605 sink	L pneumophila	1		pink col	2
2736	Environmental	Iowa VAMC		#1 7w 31 sink	L pneumophila	1			2
2737	Environmental	Iowa VAMC		#1 5S 14 sink	L pneumophila	1			2
2741	Environmental	ACHD - EPA Study		Sink	L pneumophila	1			2
2742	Environmental	ACHD - EPA Study		Shower	L pneumophila	1			2
2744	Environmental	St. Francis, NY		CT2 Basin	L pneumophila	1		Bellingham	2
2746	Environmental	(Orange,CA)		CT EV 297	L pneumophila	1		Bellingham	2
2749	Environmental	Cuyahoga-EPA		Wheel Chair	L pneumophila	1			1/16/2003
2750	Environmental	Cuyahoga-EPA		Carbon Black	L pneumophila	1			1/16/2003
2751	Environmental	Cuyahoga-EPA		Turntable	L pneumophila	1			1/16/2003
2752	Environmental	ACHD - EPA Study	JC	HWT	L pneumophila	1			1/29/2003
2753	Environmental	ACHD - EPA Study	JC	Kitchen Sink	L pneumophila	1			1/29/2003
2754	Environmental	ACHD - EPA Study	JC	Bathroom Sink	L pneumophila	1			1/29/2003
2755	Environmental	ACHD - EPA Study	JC	Bathroom Sink	L pneumophila	1			1/29/2003
2756	Environmental	Metro Health		Faucet	L pneumophila				2/13/2003

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Record #	Sample Type	Site Company Name	Hospital Alpha	Description	Species Found	LP1	LP6 Type	Culture Method	Date Found
2757	Environmental	ACHD - EPA Study	Du	HWT	L pneumophila			not 1-6	2/20/2003
2758	Environmental	ACHD - EPA Study	JC	HWT	L pneumophila	5			2/20/2003
2768	Environmental	Center	JC	Bathroom Sink	L pneumophila			not 1, positive w/ 5 & 8	3/6/2003
2770	Environmental	Seton MC		showerhead	L pneumophila	1		for PFGE	3/7/2003
2771	Environmental	Seton MC		ink faucet	L pneumophila	1		for PFGE	3/7/2003
2772	Environmental	Seton MC		CLU water	L pneumophila	1		for PFGE	3/7/2003
2773	Environmental	Seton MC		HWT	L pneumophila	1		for PFGE	3/7/2003
2774	Environmental	Seton MC		CCU/CUI HWT	L pneumophila	1		for PFGE	3/7/2003
2776	Environmental	Titan Station		cooling tower	L pneumophila	5		3+ with LP5, 2+ w/ LP8	3/28/2003
2777	Environmental	Surburban General		RM 446 sink	L pneumophila	5		3+ with Lp5, 2+ with LP8	4/3/2003
2778	Environmental	Klenzoid		6- RM 107 sink	L pneumophila	1			4/11/2003
2779	Environmental	Klenzoid		Bldg 8- RM 306	L pneumophila	6			4/11/2003
2780	Environmental	Klenzoid		8- Rm 306	L pneumophila	1			4/11/2003
2783	Environmental	(Orange,CA)		EV766 HWT	L pneumophila	6			4/17/2003
2788	Environmental	UAB		Faucet	L pneumophila	1			4/25/2003
2789	Environmental	UAB		Faucet	L pneumophila	1			4/25/2003
2793	Environmental	Medical Center		Discharge	L.species			not pneumophila	5/5/2003
2794	Environmental	Oaklawn Hospital		Station	Ps. aeruginosa			mucoid	5/6/2003
2795	Environmental	Oaklawn Hospital		Station	Ps. aeruginosa			flat	5/6/2003
2796	Environmental	Iowa VAMC		7E 12-Shower	Ps. aeruginosa				5/6/2003
2797	Environmental	Tucson VAMC		Machine-Ice	Ps. aeruginosa				5/6/2003
2798	Environmental	Oaklawn		Boiler HWT	Ps. stutzeri				5/6/2003
2799	Environmental	VA Huntington		Faucet	Sten.maltophilia				5/6/2003
2800	Environmental	Metro Health		Table Hose	Ps. aeruginosa			#1	5/6/2003
2801	Environmental	Metro Health		Table Hose	Ps. aeruginosa			#2	5/6/2003
2802	Environmental	Parma Hospital		708 Sink	Ps. stutzeri				5/6/2003
2803	Environmental	VAMC - Cleveland L.S.		Faucet	Ac.junii/johnsonii				5/6/2003

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Record #	Isolate Type	Site Company Name	Room Number	Description	Species Name	Serotype	Subtype	Misc. Info	Date Isolated
2810	Environmental	Family House		Janitor Sink	L pneumophila	1			5/15/2003
2812	Environmental	HC Info		flush	L pneumophila	1		strain #1?	5/21/2003
2813	Environmental	HC Info		flush	L pneumophila	1		strain #2?	5/21/2003
2814	Environmental	HC Info		flush	L pneumophila	3			5/21/2003
2815	Environmental	HC Info		126, Post-flush	L pneumophila	3			5/23/2003
2816	Environmental	HC Info		126, Post-flush	L pneumophila	1			5/23/2003
2817	Environmental	HC Info		Pre-flush	L pneumophila	1	strain #1?		5/23/2003
2818	Environmental	HC Info		Pre-flush	L pneumophila	1	strain #2?		5/23/2003
2819	Environmental	HC Info		Ice Machine	L pneumophila	1	strain #1?		5/23/2003
2820	Environmental	HC Info		Ice Machine	L pneumophila	1	strain #2?		5/23/2003
2821	Environmental	HC Info		Rm.	L pneumophila	8			5/23/2003
2822	Environmental	EPA Study		TH: HWT #3	L pneumophila	1			5/29/2003
2823	Environmental	EPA Study		TH: HWT #4	L pneumophila	1			5/29/2003
2824	Environmental	ACHD - EPA Study		drinking ft	L pneumophila	1			5/30/2003
2826	Environmental	Mercy Hospital - Buffalo		1-819 Faucet	L pneumophila	6			6/11/2003
2827	Environmental	Mercy Hospital - Buffalo		Faucet	L pneumophila	1			6/11/2003
2828	Environmental	Mercy Hospital - Buffalo		near elevator	L pneumophila	1			6/11/2003
2829	Environmental	Lackland AFB		"Blinded"	M. simiae			for CulAg study	
2830	Environmental	Lackland AFB		"blinded"	M. simiae			for CulAg study	
2831	Environmental	Lackland AFB		"blinded"	M. simiae			for CulAg study	6/11/2003
2832	Environmental	Lackland AFB		"blinded"	M. simiae			for CulAg study	6/11/2003
2834	Environmental	Mercy Hospital - Buffalo		#1 409 Mop rm.	L pneumophila	12			6/19/2003
2840	Environmental	Oak Forest Hospital		Dispenser	L pneumophila	1			7/3/2003
2841	Environmental	ACHD - EPA Study	MD	HWT	L pneumophila	1		from previous residence	7/3/2003
2842	Environmental	ACHD - EPA Study	MD	HWT	L pneumophila			residence	7/3/2003
2843	Environmental	Phoenix Baptist Hospital		Domestic HWT	L pneumophila			not 1-6	7/9/2003
2844	Environmental	EPA Study	KC	HWT	L pneumophila			not 1-6	7/16/2003
2847	Environmental	University Drive VAMC		water survivors	unknown			Eason's project	7/22/2003
2848	Environmental	University Drive VAMC		water survivors	unknown			Eason's project	7/22/2003
2849	Environmental	University Drive VAMC		water survivors	unknown			Eason's project	7/22/2003
2850	Environmental	Spain HUGTIP		stock #2668	L pneumophila	1			7/25/2003

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2851	Environmental	UHGTip Spain		#2668 (subtle	L pneumophila	1			7/25/2003
2852	Environmental	Canadigua VAMC		118A faucet	L pneumophila			not 1-6	7/30/2003
2853	Environmental	Canadigua VAMC		118A faucet	L pneumophila			not 1-6	7/30/2003
2854	Environmental	Canadigua VAMC		118A faucet	L pneumophila	1			7/30/2003
2855	Environmental	Syracuse VAMC		Centrical	L pneumophila			not 1-6	8/6/2003
2856	Environmental	Hospital		flush	L pneumophila			not 1-6	8/6/2003
2862	Environmental	West Penn Hospital		Tank 1 S wing	L pneumophila	3			8/14/2003
2863	Environmental	West Penn Hospital		N311 sink	L pneumophila	3			8/14/2003
2864	Environmental	West Penn Hospital		Rehab	L pneumophila	3			8/14/2003
2865	Environmental	West Penn Hospital		E910 sink	L pneumophila	3			8/14/2003
2866	Environmental	West Penn Hospital		2 Bathroom tub	L pneumophila	1		for PFGE	8/14/2003
2867	Environmental	West Penn Hospital		6, Bathroom	L pneumophila	1		for PFGE	8/14/2003
2870	Environmental	Ohio EPA		Kitchen sink	L pneumophila	1		isolate 1	8/21/2003
2871	Environmental	Ohio EPA		kitchen sink	L pneumophila	1		isolate 2	8/21/2003
2872	Environmental	Ohio EPA		MT: Work HWT	L pneumophila	1			8/21/2003
2874	Environmental	Lackland AFB		colony of 630	M.simiae			630a	8/25/2003
2875	Environmental	Lackland AFB		colony type of	M.simiae			630b	8/25/2003
2876	Environmental	Lackland AFB		colony of 682	M.simiae			682a	8/25/2003
2877	Environmental	Lackland AFB		colony of 682	M.simiae			682c	8/25/2003
2878	Environmental	Lackland AFB		colony of 722	M.simiae			722a	8/25/2003
2879	Environmental	Lackland AFB		colony of 722	M.simiae			722b	8/25/2003
2880	Environmental	Lackland AFB		colony of 922	M.simiae			922a	8/25/2003
2881	Environmental	ACHD - EPA Study		bathroom sink	L pneumophila	1			8/29/2003
2882	Environmental	ACHD - EPA Study		E.Stang HWT	L pneumophila	1		strain 1?	8/29/2003
2883	Environmental	ACHD - EPA Study		E.Stang HWT	L pneumophila	1		strain 2?	8/29/2003
2884	Environmental	ACHD - EPA Study		bathroom tub	L pneumophila	1			8/29/2003
2885	Environmental	Mercy Hospital - Buffalo		409	L pneumophila	12		strain ?	8/29/2003
		Hospital - Buffalo		471	Legionella sp			not pneumo	8/29/2003
									9/4/2003

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Record #	Facility Type	Facility Name	Source/Plant	Site Description	Species Name	Sg	Site Type	Serogroup	Frozen
2892	Environmental	Care- Bridgeton		160 Ton C.T.	L pneumophila	1			9/18/2003
2893	Environmental	Blessing Home		Campus	L pneumophila	1			9/18/2003
2894	Environmental	JSI	Isolate 1		L pneumophila			Not 1-6	9/25/2003
2895	Environmental	JSI	Isolate 2		other			Legionella Species	9/26/2003
2896	Environmental	JSI	Rec Room C, 421		L pneumophila	4			9/24/2003
2897	Environmental	JSI	Rec Room C 421		L pneumophila	6			9/24/2003
2900	Environmental	Klenzoid		Hospital	L pneumophila	6			10/1/2003
2901	Environmental	St. Clair Hospital		Water	L pneumophila	4			10/2/2003
2905	Environmental	Rhode Island Hospital		HWT Immed.	L pneumophila	1			10/9/2003
2906	Environmental	Rhode Island Hospital		HWT Immed	L pneumophila	3			10/9/2003
2907	Environmental	Rhode Island Hospital		HWT Immed.	L pneumophila	1			10/9/2003
2909	Environmental	ACHD - EPA Study	WP	Faucet	L pneumophila	1			3
2910	Environmental	ACHD - EPA Study	WP	Faucet	L pneumophila	1			3
2911	Environmental	ACHD - EPA Study	WP	Faucet	L anisa	1			3
2912	Environmental	ACHD - EPA Study	WP	Faucet	L pneumophila	1			3
2913	Environmental	ACHD - EPA Study	WP	Faucet	L pneumophila	1			3
2914	Environmental	ACHD - EPA Study	JK	Faucet	L anisa				3
2915	Environmental	ACHD - EPA Study	WP	Kit Sink Faucet	L anisa				3
2916	Environmental	Togus VAMC		63E Shower	L pneumophila	2			3
2917	Environmental	ACHD - EPA Study	Mason Building	Hot Water Tank	L pneumophila	1			3
2918	Environmental	ACHD - EPA Study	DS	Faucet	L anisa				3
2919	Environmental	ACHD - EPA Study		Unit 1304	L pneumophila	1			11/3/2003
2920	Environmental	St Joe. Org. Gly		Faucet	L pneumophila	1			11/3/2003
2921	Environmental	St Joe. Org. Gly		Showerhead	L anisa				3
2922	Environmental	St Joe. Org. Gly		EV 2572 HWT	L pneumophila	6			11/3/2003
2923	Environmental	St Joe. Org. Gly		EV 2573 HWT	L pneumophila	6			11/3/2003
2924	Environmental	St Joe. Org. Gly		Cooling Tower	L pneumophila	1			11/3/2003
2925	Environmental	ACHD - EPA Study	JG	Faucet	L pneumophila	1			11/5/2003
2926	Environmental	ACHD - EPA Study	JG	Shower	L pneumophila	1			11/5/2003
2927	Environmental	ACHD - EPA Study	JG	Hot Water Tank	L pneumophila	1			11/5/2003
2928	Environmental	ACHD - EPA Study	JG	Faucet	L pneumophila	1			11/5/2003

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Record #	Facility Type	Facility Name	Source/Plant	Site Description	Species Name	Sg	Site Type	Serogroup	Frozen
2929	Environmental	ACHD - EPA Study	JG	Faucet	L pneumophila	1			11/5/2003
2930	Environmental	Guardian		Hosp. Tower 4	L pneumophila	1			3
2931	Environmental	Maryvale		Post	L pneumophila	6			3
2938	Environmental	US Microsolutions		Fnt.	L pneumophila	1			3
2939	Environmental	US Microsolutions		3088-02 CT	L pneumophila	1			3
2940	Environmental	US Microsolutions		3090-01 CT	L pneumophila	1			3
2941	Environmental	Health-EPA	BM	HWT.	L pneumophila			not 1-6	3
2945	Environmental	Buffalo Psych. Center		Sink Basement	L pneumophila	1			1/22/2004
2946	Environmental	Buffalo Psych. Center		20U- 2nd Floor	L pneumophila	1			1/22/2004
2961	Environmental	University Drive VAMC		Fountain	L pneumophila	1			2/6/2004
2962	Environmental	EPA	CR	HWT.	L pneumophila	1			2/18/2004
2963	Environmental	EPA	CR	Faucet	L pneumophila	1			2/18/2004
2964	Environmental	EPA	CR	Faucet	L pneumophila	1			2/18/2004
2965	Environmental	EPA	CR	Faucet	L pneumophila	1			2/18/2004
2966	Environmental	Ruhr Universitat		Ionization	L pneumophila			serogroup	2/27/2004
2967	Environmental	Ruhr Universitat		Ionization	L pneumophila	6			2/27/2004
2968	Environmental	Ruhr Universitat		Ionization	L pneumophila	6			2/27/2004
2969	Environmental	Ruhr Universitat		Ionization	L pneumophila	6			2/27/2004
2970	Environmental	Ruhr Universitat		Ionization	L pneumophila	6			2/27/2004
2971	Environmental	Howard Nowman Co.	Med.	Boiler RM HWT	L pneumophila	1			3/3/2004
2972	Environmental	Yaropai Reg. M.C.		Center	L pneumophila	4			3/17/2004
2973	Environmental	JSI		Water Sink	L pneumophila	5			3/17/2004
2974	Environmental	Klenzoid		306	L bozemanii				3/18/2004
2975	Environmental	WaterPro		Hotel C Shower	L pneumophila	5			3/24/2000
2976	Environmental	Osteopathic M.C.		Pump Rm	L pneumophila	1			4/7/2004
2977	Environmental	Beverly Health Care		Faucet	L pneumophila	5			5/6/2004
2978	Environmental	Beverly Health Care		Faucet	L pneumophila	1			5/6/2004
[illegible]	Environmental	Beverly Health Care		Faucet	L pneumophila	1			5/6/2004

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Record #	Culture Type	Company Name	Source of Isolate	Description	Species Name	Gr	Subtype	Additional	Date
2998	Environmental	Beverly Health Care		Rm 214 faucet	L pneumophila			not 1-6	6/3/2004
2999	Environmental	St. Peters Albany NY		#314 Tower	L pneumophila	1			6/16/2004
3000	Environmental	DCH Regional		sample 1 tank	L pneumophila	1			6/16/2004
3005	Environmental	Metro Health		514H spray	P.aeruginosa				6/23/2004
3006	Environmental	Metro Health		spray table #2	P.aeruginosa			small colony	6/23/2004
3007	Environmental	Metro Health		spray table #2	P.aeruginosa			large colony	6/23/2004
3008	Environmental	Metro Health		spray table #2	P.aeruginosa			isolate (b)	6/23/2004
3009	Environmental	Metro Health		spray table #1	P.aeruginosa				6/23/2004
3010	Environmental	Metro Health		524H Spray	P.aeruginosa				6/23/2004
3011	Environmental	Metro Health		Spray table #2	P.aeruginosa			small colony	6/23/2004
3012	Environmental	Metro Health		Spray table #2	P.aeruginosa			large colony	6/23/2004
3013	Environmental	Metro Health		cockroach #1	P.aeruginosa				6/23/2004
3014	Environmental	Metro Health		cockroach #3	P.aeruginosa				6/23/2004
3015	Environmental	Metro Health		cockroach #5	P.aeruginosa				6/23/2004
3016	Environmental	Metro Health		cockroach	E.cloacae?				6/23/2004
3024	Environmental	EPA Study	RK	Towers	L pneumophila	1			7/29/2004
3025	Environmental	Chemway		213 HWT Int.	L pneumophila	1			7/29/2004
3026	Environmental	Chemway		213 HWT- 2nd	L pneumophila	1			7/29/2004
3027	Environmental	Chemway		CT	L pneumophila			not 1-6	7/29/2004
3029	Environmental	Clevelan, City of		floor drain	Legionella spp			not pneumophila	8/20/2004
3030	Environmental	Medical Center		# 121	L pneumophila	1			8/25/2004
3031	Environmental	EPA Study	Gr3	HWT	L pneumophila	5			8/25/2004
3032	Environmental	EPA Study	Gr3	Kitchen Sink	L pneumophila	5			8/25/2004
3033	Environmental	EPA Study	Gr3	Bathroom sink	L pneumophila	5			8/25/2004
3034	Environmental	EPA Study	Gr3	Bathroom tub	L pneumophila	5			8/25/2004
3035	Environmental	U of Utah MC		data7/15/04	L pneumophila	1		UDH#70401343	8/26/2004
3036	Environmental	Washington Hospital		sink by rom 598	L pneumophila	1			8/26/2004
3037	Environmental	Summit County HD		Hot tub dip #1	L pneumophila	1			9/10/2004
3038	Environmental	Summit County HD		hot tub dip #2	L pneumophila	1			9/10/2004
3040	Environmental	Beverly Manor		A	L pneumophila	1			9/23/2004
3041	Environmental	University Drive VAMC		control water	L pneumophila	1		str.1; greenish	9/29/2004

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Record #	Culture Type	Company Name	Source of Isolate	Description	Species Name	Gr	Subtype	Additional	Date
3042	Environmental	University Drive VAMC		control water	L pneumophila	1		str.2; pinkish	9/29/2004
3043	Environmental	Highland Drive VAMC		Nurs Station	L pneumophila	6			9/29/2004
3045	Environmental	Buffalo VAMC		913A-01-48	L pneumophila	1			10/7/2004
3046	Environmental	Buffalo VAMC		233D-01-57	L pneumophila	6			10/7/2004
3047	Environmental	Buffalo VAMC		514C-02-53	L pneumophila	1			10/7/2004
3048	Environmental	Buffalo VAMC		211D-04-62	L pneumophila	6			10/7/2004
3049	Environmental	Buffalo VAMC		233D-04-63	L pneumophila	6			10/7/2004
3050	Environmental	Buffalo VAMC		516C-04-64	L pneumophila	6			10/7/2004
3051	Environmental	Buffalo VAMC		613D-04-65	L pneumophila	6			10/7/2004
3052	Environmental	Buffalo VAMC		913A-04-66	L pneumophila	6			10/7/2004
3055	Environmental	Family House		McKee - HWT	L pneumophila	1			4
3056	Environmental	Family House		Machine	L pneumophila	1			4
3057	Environmental	Water Science		Shower	L pneumophila	3			11/3/2004
3058	Environmental	Spec Path Lab		1(Dr.	L pneumophila	1			11/3/2004
3059	Environmental	Spec Path Lab		(Dr. Greenburg)	L pneumophila	1			11/3/2004
3060	Environmental	Beverly Manor		Faucet	L pneumophila	1			11/3/2004
3062	Environmental	St. Vincent Rehab		Immediate	L pneumophila	1			4
3063	Environmental	St. Vincent Rehab		2nd fl fountain	L pneumophila	1			4
3064	Environmental	U of Utah MC		bldg at UUMC	L pneumophila	1		UDH#70402072	12/7/2004
3065	Environmental	U of Utah MC		bldg at UUMC	L pneumophila	1		UDH#70402073	12/7/2004
3066	Environmental	CHP (Children's)	KK	back Nit;	L pneumophila	1			12/7/2004
3067	Environmental	CHP (Children's)	KK	Rm 9737	L pneumophila	1			12/7/2004
3068	Environmental	CHP (Children's)	KK	CHP#H59854	L pneumophila	1			12/7/2004
3069	Environmental	Lutheran Gen		collected	L pneumophila	1		for Cu-Ag testing	12/7/2004
3070	Environmental	Lutheran Gen		11/17/04	L pneumophila	3		for Cu-Ag testing	12/7/2004
3072	Environmental	U of Utah MC		Med Tower 453	L pneumophila	1		for Cu-Ag testing	1/4/2005
3079	Environmental	EPA Study		Anthony home,	L pneumophila	5			1/12/2005
[illegible]	[illegible]	[illegible]		#2	Legionella sp			not pneumo	1/14/2005
[illegible]	[illegible]	[illegible]		[illegible]	[illegible]	1			2/2/2005

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Record #	Culture Type	Company Name	Source Name	Sample Description	Species Name	tag	Sub Type	Status Reason	Thawed
3088	Environmental	EPA Study	An3	faucet	L pneumophila	1			2/2/2005
3095	Environmental	US Micro Solutions		faculty B.R.	L pneumophila	1			2/24/2005
3096	Environmental	US Micro Solutions		girl's room	L pneumophila	1			2/24/2005
3097	Environmental	US Micro Solutions		sink	L pneumophila	1			2/24/2005
3099	Environmental	NCRA		shower	L pneumophila	4		neg with Oxoid 2-14	3/16/2005
3100	Environmental	Hague		Immed.	L pneumophila	1			3/17/2005
3101	Environmental	Hague		shower	L pneumophila	1			3/17/2005
3105	Environmental	Cleveland VAMC		Bldg 5 - CT	L pneumophila	1			3/23/2005
3106	Environmental	Hague		Rm 82	L pneumophila	1			3/31/2005
3107	Environmental	VAMC Phoenix		HW -10 A 2416	Legionella sp			not pneumophila	4/7/2005
3108	Environmental	VAMC Phoenix		HW- 10 A 2416	L pneumophila	1			4/7/2005
3109	Environmental	VAMC Phoenix		8	L pneumophila	6			4/7/2005
3110	Environmental	Beaver Medical Center		A 316 Faucet	L pneumophila			not 1 - 6	5/9/2005
3111	Environmental	CSL Water Quality		789991 faucet	L pneumophila	1			5/17/2005
3112	Environmental	Kienzoid		clin.	L pneumophila	6			5/26/2005
3113	Environmental	HC Info		401 HW pre	L pneumophila			not 1-6	5/26/2005
3114	Environmental	HC Info		424 HW pre	L pneumophila	6			5/26/2005
3115	Environmental	University Drive VAMC		sink	L pneumophila	6			5/26/2005
3116	Environmental	Magee Hospital		Faucet	L pneumophila	1			6/2/2005
3117	Environmental	Lyon, France		Subcul.C3	L pneumophila	1	strain		6/8/2005
3118	Environmental	Lyon, France		Subcul.C3	L pneumophila	1	strain		6/8/2005
3120	Environmental	University Drive VAMC		6W 138 Shower	L pneumophila	1			6/15/2005
3121	Environmental	University Drive VAMC		A wing HWT #1	L pneumophila	1			6/15/2005
3122	Environmental	Clinic		Rm. 370 Faucet	L pneumophila	1			6/15/2005
3123	Environmental	Clinic		Rm 368 Faucet	L pneumophila	1			6/15/2005
3124	Environmental	Clinic		Faucet	L pneumophila	1			6/15/2005
3125	Environmental	Clinic		Shower	L pneumophila	1			6/15/2005
3126	Environmental	Clinic		Faucet	L pneumophila	1			6/15/2005
3127	Environmental	Univ. Iowa Hosp.		Faucet	L pneumophila	1			6/15/2005
3128	Environmental	Hague		1 Rm 320 Hot	L pneumophila	1			6/17/2005
3129	Environmental	Hague		3 Rm 319 Hot	L pneumophila	1			6/17/2005

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Record #	Culture Type	Company Name	Source Name	Sample Description	Species Name	tag	Sub Type	Status Reason	Thawed
3133	Environmental	Washington Hospital		8th Fl CT	L pneumophila	5			7/28/2005
3134	Environmental	Highland Drive VAMC		Wms Rm sink	L pneumophila	6			8/2/2005
3135	Environmental	Highland Drive VAMC		Men's Rm sink	L pneumophila	6			8/2/2005
3136	Environmental	VAMC Phoenix		tank	L pneumophila	1			8/3/2005
3137	Environmental	International Chemstar		St. Agnes CT	L pneumophila	1			8/11/2005
3139	Environmental	HC Info		525: B151,	L pneumophila	1			8/18/2005
3140	Environmental	HC Info		529: PACU sink	L pneumophila	1			8/18/2005
3141	Environmental	HC Info		Huntsman CT	L pneumophila	1			8/18/2005
3142	Environmental	Kienzoid		1st Fl Stroke	L pneumophila	6			8/18/2005
3143	Environmental	Kienzoid		Duncan Tower	L pneumophila	1			8/18/2005
3144	Environmental	Spec Path Lab		pot.water; yel.	unknown				8/18/2005
3145	Environmental	Spec Path Lab		pot.water; yel.	unknown				8/18/2005
3146	Environmental	Kienzoid		Hosp - South	L pneumophila	6			8/19/2005
3147	Environmental	Good Sam Hosp		BD line	L pneumophila	1			8/25/2005
3148	Environmental	Good Sam Hosp		BD line	L pneumophila	6			8/25/2005
3149	Environmental	Kienzoid		OCC Tower	L pneumophila	1			8/25/2005
3150	Environmental	Univ MO Hosp		6W-48 Faucet	L pneumophila	1			8/31/2005
3151	Environmental	Univ MO Hosp		4W-27 faucet	L pneumophila	1			8/31/2005
3153	Environmental	Sentry		pot.water# 17	L pneumophila	6		did not grow on DGVP	9/7/2005
3154	Environmental	S.D. State Lab		CT	L pneumophila	1			9/14/2005
3155	Environmental	S.D. State Lab		CT	L pneumophila	1			9/14/2005
3156	Environmental	S.D. State Lab		Tower	L pneumophila	1			9/14/2005
3157	Environmental	S.D. State Lab		Tower	L pneumophila	1			9/14/2005
3158	Environmental	S.D. State Lab		Chiller #1	L pneumophila	1			9/14/2005
3159	Environmental	S.D. State Lab		Chiller #2	L pneumophila	1			9/14/2005
3160	Environmental	S.D. State Lab		CT	L pneumophila			not 1-6	9/14/2005
3161	Environmental	S.D. State Lab		Tower to	L pneumophila	1			9/14/2005
3162	Environmental	S.D. State Lab		Tower to	L pneumophila	1			[illegible]

Discarded Legionella Stock Collection

Record #	Culture type	Company Name	Location Indentifier	Description	Species name	Sg	Subtype	Misc. Info	Frozen
3166	Environmental	S.D. State Lab		CT	L pneumophila	1		isolate 1	9/14/2005
3167	Environmental	S.D. State Lab		CT	L pneumophila	1		isolate 2	9/14/2005
3168	Environmental	S.D. State Lab		Small Tower	L pneumophila	1		isolate 1	9/21/2005
3169	Environmental	S.D. State Lab		small tower	L pneumophila	1		isolate 2	9/21/2005
3170	Environmental	S.D. State Lab		small tower	Legionella spp			not pneumo.	9/21/2005
3171	Environmental	S.D. State Lab		tower	L pneumophila	1		isolate 1	9/21/2005
3172	Environmental	S.D. State Lab		tower	L pneumophila	1		isolate 2	9/21/2005
3173	Environmental	S.D. State Lab		Tower	L pneumophila	1			9/21/2005
3174	Environmental	S.D. State Lab		Tower	L pneumophila	1		isolate 2	9/21/2005
3175	Environmental	S.D. State Lab		Tower	L pneumophila	1		isolate 3	9/21/2005
3176	Environmental	S.D. State Lab		Swamp Cooler	L pneumophila	1		isolate 1	9/21/2005
3177	Environmental	S.D. State Lab		Swamp Cooler	L pneumophila	1		isolate 3	9/21/2005
3178	Environmental	S.D. State Lab		Tower	L pneumophila	1		isolate 2	9/21/2005
3179	Environmental	S.D. State Lab		Tower	L pneumophila	1		isolate 4	9/21/2005
3180	Environmental	S.D. State Lab		Tower	L pneumophila	1		isolate 1	9/21/2005
3181	Environmental	S.D. State Lab		Tower	L pneumophila	1		isolate 3	9/21/2005
3182	Environmental	S.D. State Lab		America Tower	L pneumophila	1		isolate 1	9/21/2005
3183	Environmental	S.D. State Lab		America Tower	L pneumophila	1		isolate 5	9/21/2005
3184	Environmental	S.D. State Lab		West	L pneumophila	1		isolate 4	9/22/2005
3185	Environmental	S.D. State Lab		West	L pneumophila	1		isolate5	9/22/2005
3186	Environmental	S.D. State Lab		Tower	L pneumophila	1		isolate2	9/22/2005
3187	Environmental	S.D. State Lab		Tower	L pneumophila	1		isolate 6	9/22/2005
3188	Environmental	S.D. State Lab		Tower	L pneumophila	1			9/23/2005
3191	Environmental	Mercy Hospital	RB	Room 8005	L pneumophila	1			9/30/2005
3192	Environmental	Mercy Hospital	RB	Ice Machine	L pneumophila	1			9/30/2005
3193	Environmental	University Drive VAMC		#2 Immediate	L pneumophila	1			9/30/2005
3194	Environmental	Rapid City Reg. Hospital		Tower	L pneumophila	1			5
3195	Environmental	Rapid City Reg. Hospital		Tower	L pneumophila	1			5
3196	Environmental	Rapid City Reg. Hospital		Tower	L pneumophila	1			5
3197	Environmental	Rapid City Reg. Hospital		Tower	L pneumophila	1			5
3198	Environmental	Huntington Mem Hosp		Rm 624 faucet	L pneumophila	1			11/4/2005

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Record #	Culture type	Company Name	Location Indentifier	Description	Species name	Sg	Subtype	Misc. Info	Frozen
3199	Environmental	Huntington Mem Hosp		Ice machine	L pneumophila	1			11/4/2005
3200	Environmental	Huntington Mem Hosp		faucet	L pneumophila	1			11/4/2005
3201	Environmental	Aspinwall VAMC		Sink	L pneumophila	1			11/9/2005
3202	Environmental	Enrich Products		R/R Faucet; for	L pneumophila	5		xreacts w/8	5
3203	Environmental	Peter Becker		Dentist sink	L pneumophila	1	MAB2+		5
3204	Environmental	Peter Becker		Dentist sink	L anisa				5
3205	Environmental	Peter Becker		PC Rm 7	L pneumophila	1	MAB2+	MAB2+	5
3206	Environmental	Peter Becker		isolate 4	L pneumophila	1	MAB2+	col type 1	5
3207	Environmental	Peter Becker		isolate 5	L pneumophila	1	MAB2+	col type 2	5
3208	Environmental	Peter Becker		isolate 4	L pneumophila	1	MAB2+	col type 1	5
3209	Environmental	Peter Becker		isolate 5	L pneumophila	1	MAB2+	col type 2	5
3210	Environmental	Peter Becker		Beauty Parlor	L pneumophila	5			5
3211	Environmental	Peter Becker		Room 41	L pneumophila	1	MAB2+		5
3212	Environmental	Spec Path Lab		CT GNR	unknown			str 1	5
3213	Environmental	Spec Path Lab		CT GNR	unknown			str 2	5
3214	Environmental	Metro Health		Hose	P.aeruginosa				5
3215	Environmental	Metro Health		Hose B	P.aeruginosa				5
3216	Environmental	PLPH Calgary		Hospital	L pneumophila	1		Pre-ionization	5
3217	Environmental	PLPH Calgary		Hospital (install	L pneumophila	1		Post-ionization	5
3218	Environmental	PLPH Calgary		(install date	L pneumophila	1		Pre-ionization	5
3219	Environmental	PLPH Calgary		(install date	L pneumophila	1		Post-ionization	5
3220	Environmental	PLPH Calgary		date 10/12/04)	L pneumophila	1		Pre-ionization	5
3221	Environmental	PLPH Calgary		date 10/12/04)	L pneumophila	1		Post-ionization	5
3223	Environmental	Nursing Home		5 Faucet	L pneumophila	6		Col 1	1/20/2006
3224	Environmental	Nursing Home		5 Faucet	L pneumophila	6		Col 2	1/20/2006
3225	Environmental	Nursing Home		5 Faucet	L pneumophila	6		Col 3	1/20/2006
3226	Environmental	VAMC - Phoenix, AZ		w/ Lp8					1/20/2006
		VAMC - Phoenix, AZ		w/ Lp8					1/20/2006
								Green Strain	1/25/2006

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Record #	Culture type	Company/Name	source/pt.name	Description	species/serotype	SG	Subtype	Mab/Mab2	Date
3231	Environmental	The Friendly Home		Ladies' Room	L pneumophila	3		Pink Strain	1/25/2006
3232	Environmental	Center		Faucet	L pneumophila	5			2/8/2006
3233	Environmental	Univ MO Hosp		Faucet	L pneumophila	6			2/15/2006
3234	Environmental	Univ MO Hosp		C3036 Faucet	L pneumophila	1		Str 1	2/15/2006
3235	Environmental	Univ MO Hosp		C5027 shower	L pneumophila	1		str 2	2/15/2006
3236	Environmental	Center		machine	Legionella spp.			not pneumo	3/1/2006
3237	Environmental	EICC		Building, 2.9092	L pneumophila			not 1-6	3/17/2006
3239	Environmental	Magee Hospital		Rm 3293 sink	L pneumophila	1		pink, Mab2 neg	3/17/2006
3240	Environmental	Magee Hospital		Rm 3293 sink	L pneumophila	1		blue, Mab2 neg	3/17/2006
3242	Environmental	Magee Hospital		Sink	L pneumophila	6			3/31/2006
3243	Environmental	Ellis Hospital		North Feed	L pneumophila	4			3/31/2006
3244	Environmental	Ellis Hospital		Ceramic CT	L pneumophila	1			4/5/2006
3245	Environmental	Ellis Hospital		Ceramic CT	L pneumophila	1			4/5/2006
3246	Environmental	Ellis Hospital		Ceramic CT	L pneumophila	1			4/5/2006
3247	Environmental	Chemaqua Baldwinsville		Hospital AC	L pneumophila	5			4/7/2006
3250	Environmental	Lincoln Hospital Center		Sink	L pneumophila	6			5/10/2006
3251	Environmental	Lincoln Hospital Center	Nursing St.		L pneumophila	6			5/10/2006
3252	Environmental	Lincoln Hospital Caner		Sink	L pneumophila	6			5/10/2006
3253	Environmental	Lincoln Hospital Center		Sink	L pneumophila	6			5/10/2006
3254	Environmental	Magee Hospital		Faucet	L pneumophila	1		pink	
3255	Environmental	Magee Hospital		Faucet	L pneumophila	1		green	
3256	Environmental	Mercerville		Faucet	L pneumophila	1			5/15/2006
2605	isolate	Hospital		General #	Legionella spec.			not pneumophila	4/12/2002
567	Other	University Drive VAMC			Resistant			from Micro	1/16/1986
126	Unknown	University Drive VAMC		667-AP80					7/1/1980
585	Unknown	Highland Drive VAMC		Unknown	L pneumophila	1			5/28/1986
904	unknown	Togus VAMC			L pneumophila	2			2/24/1989
943	unknown	Togus VAMC		493	L pneumophila	1			2/9/1990
956	unknown	Togus VAMC		2866	L pneumophila	1		Brucella broth	8/22/1990
957	unknown	Togus VAMC		2869	L pneumophila	2		Brucella broth	8/22/1990
958	unknown	Togus VAMC		2873	L pneumophila	1		Brucella broth	8/22/1990

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Record #	Culture type	Company/Name	source/pt.name	Description	species/serotype	SG	Subtype	Mab/Mab2	Date
2247	unknown	Michigan	Unknown	Michigan-GISA	Staph. Aureus	NA	NA	Dr. Zervos	9/1/2000

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No.	Name	Sg/spp	DateColl.	Date Froz.	# Vials*	Record#	Test date	RTN	NOW	Confirm.	Comments
1	St	Lp1		4/22/96	2			Neg		No	
2	Ro	Lp3		3/10/97	2			Neg		Culture	
3	JTA 01053	L. feelei		11/19/96	2			Neg		Culture	
4	Ca	Lp1		5/10/96	5			25.8		Culture	
5	Ka	Lp1		10/3/96	3		10/2/96	12		Serology	Sero. >512 IgM
6	Hu	Lp1		2/13/97	1		2/12/97	38		No	
7	Ma	Lp1		7/15/96	4		7/11/96	8		Culture	
8	Zi	Lp1		10/14/96	1			Neg		Culture	
9	Di	Lp1		10/9/96	3		10/10/96	7.7		Culture	
10	Br	Lp1		3/11/97	5		3/6/97	46.6		?	
11	Ku	Lp1		11/5/97	13			6		No	
12	JPR 03032	Lp1		9/5/97	3		8/29/97	24		Serology	
13	Wi	Lp1		2/25/97	2		12/26/96	12.7		?	
14	Lo	Lp1		6/11/97	2		6/9/97	3.7		No	
15	Ol	Lp1		9/5/97	5		9/4/97	33		No	
16	Mi	Lp1		4/23/98	14		4/20/98	7.14		Serology	
17	Po	Lp1		4/28/98	7		4/27/98	11.8		Culture	
18	Ga	Lp1		7/16/98	20			4.8		?	
19	Ni	Lp1		7/16/98	20			11		?	
20	W	Lp1		7/16/98	20			16.8		?	
21	We	Lp4		8/25/98	24			Neg		Culture	
22	BH	Lp1		10/8/98	18		10/6/98	8.3			
23	Po	Lp1		10/8/98	12		10/6/98	12			
24	Se	Lp1		10/8/98	14		10/6/98	7.7			
25	Sz	Lp1		10/8/98	15		10/6/98	5.3			
26	RP	Lp1		10/8/98	6		10/6/98	> 20.0			
27	ZCR	Lp1		10/23/98	11			10.6		Culture	
28	TDE	Lp1		10/23/98	8			7.5		Culture	
29	OLH	Lp1		12/15/98	10			9.5		Culture	3-50 ml aliquots (Box 3,4)
30	M-G	Lp4		2/2/99	6			Neg		Culture	
31	Tr	Lp1		2/25/99	6		2/18/99	12.3		Culture	4-50 ml aliquots (Box 1)
32	Ha	Lp1		2/24/99	10		2/18/99	30.6		Culture	4 serum vials frozen;2-50 ml aliquots(Box2
33	Ha	Lp1		2/24/99	10		2/18/99	26.5		Culture	2-50 ml aliquots (Box 2)

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No.	Name	Sg/spp	DateColl.	Date Froz.	# Vials*	Record#	Test date	RTN	NOW	Confirm.	Comments
34	Wi	Lp1		2/24/99	10		2/18/99	36.1		Culture	
35	Wi	Lp1		2/24/99	10		2/18/99	19.6		Culture	
36	Dw	Lp1		2/24/99	10		4/9/99	21.5		Culture	5 serum vials;2-50 ml aliquots (Box3)
37	Ho	Lp1		4/26/99	10		4/27/99	3.1		no	4 serum vials ;4-50 ml aliquots(Box4,5)
38	Ni	Lp1		5/12/99	8		5/7/99	10.4			1-50 ml aliquots(Box4)
39	Ad	Lp1		7/22/99	10	99A5934	7/19/99	21			3 sputum vials
40	Ad	Lp1		7/22/99	10		7/22/99	17			4-50 ml aliquots (Box 6)
41	PMM	Lp1		8/26/99	7			4.3		Culture	3 sputum vials
42	Ha	Lp1		9/8/99	9	99A6636	9/6/99	10		Culture	5 sputum vials; 1-50 ml aliquot
43	Ha	Lp1		9/8/99	10	99A6633	9/6/99	13.6		Culture	1-50 ml aliquot
44	Ha	Lp1		10/21/99	10	99A7338		17		Culture	4-50 ml aliquots
45	Bu	Lp1		9/8/99	3		9/6/99	6.5		Culture	1 BAL vial
46	Sc	Lp1		10/20/99	9	99A7201		23		Culture	3 sputum vials; 1-50 ml aliquot(Box7)
47	Sc	Lp1		10/20/99	8	99A7320		12		Culture	
48	Br	Lp3		9/9/99	9					Culture	1-50 ml aliquot (box9)
49	Tu	Lp1		6/1/00	3	11078	5/15/00	22		Culture	spt vials also froz
50	Ob	Lp1		10/13/00	10	13220		24		Culture	spt vials also froz
51	MH	Lp1		12/8/00	3	14417	11/29/00	8.6		Culture	spt vials also froz
None	Ar		2/15/01	2/??/01	10	15839	2/26/01	neg		Culture	Mercy pt
52	Ba	Lp1		3/??/2001	10	15818	2/21/01	Neg		Culture	extra 50 ml in box 10
53	Albany pt 001	Lp1		4/20/01	4	16638	4/13/01	10			
None	GWJ (OM057001)	Lp1	6/9/01	6/??/01	9	17986	6/13/01	43.7			culture neg
None	Pe	Lp1	6/18/01	6/??/01	5	18106	6/14/01	23			AGH pt
None	Bo		8/16/01	8/??/01	5	20102	8/21/01	Neg			Tucson VA Leg. Study pt
None	RR		6/27/01	7/??/01	1	19091	7/16/01	neg			Tucson VA Leg. Study pt
54	HJS (OM 003006)	Lp9		7/10/01	9	18705	6/29/01	Neg		Culture	CAPSS 150
55	MLG (OM 073005)	???		7/16/01	9	18968	7/16/01	3.2			CAPSS 150
56	RR	Lp4		7/25/01	1	19091	7/16/01	Neg		Culture	< 0.5 ml
57	AS	???		12/6/01	10	20721	9/10/01	4		no	false pos?
58	MS	L.longb.		10/3/01	9	21301	not done	ND		Culture	Mercy patient;2 x 25 ml, 1 x 40 ml in box 1(
59	PD	Lp1		12/6/01	8	21569	11/??/01	22		no	Mercy patient, deceased
60	DM	Lp1		12/6/01	9	33319	10???/01	29		Culture	1 x 50ml in box 10
61	RT	Lp1		12/6/01	10	33805	11/??/01	5		no	1 x 50ml in box 10

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No.	Name	Sg/spp	DateColl.	Date Froz.	# Vials*	Record#	Test date	RTN	NOW	Confirm.	Comments
62	RS	Lp1		12/14/01	5	34379	12/12/01	20			
63	JK	Lp1		1/29/02	5	35173	1/4/02	5.5		no	no spt culture
64	AB	Lp1		1/29/02	3	35810	1/25/02	59		Culture	10 spt vials also
65	SM (OM 021003)	Lp1		4/8/02	8	38110	4/5/02	16.8		no	CAPSS 150
66	EB (OM 015018)	L.dum.		5/8/02	10	38836	4/26/02	Neg		Culture	CAPSS 150
67	SG	Lp1		6/12/02	5	40387	6/12/02	25.4		Culture	EPA: >300cfu/plate Lp1
68	JD			6/12/02	6	40388	6/12/02	Neg			1 col in Blood proved to be Lactobacillus
69	DW			6/14/02	10	39591	5/19/02	Neg		no	Negative EPA pt
70	Br	Lp5		6/19/02	8	40427	6/13/02	Neg		Culture	1 spt vial saved
71	DF	Lp1	11/12/02	11/15/02	5	45528	11/13/02	51	ND	no	
72	TW (Iowa City)	Lp1	11/2/02	11/15/02	5	45391	11/8/02	5.2	ND	no	
73	LH	Lp1	11/21/02	12/6/02	9	45719	11/21/02	8.4	pos	no	pt has pl.fld.&spt saved;both are cult.neg
74	TL	Lp1	2/17/03	2/19/03	2	47250	2/19/03	43	pos	no	resp.cult neg
75	WC	Lp1	5/19/03	5/21/03	3	48828	5/20/03	3.6	±	no	2 resp.samples saved;both cult.neg
76	CM	Lp1	5/22/03	5/23/03	5	48956	5/23/03	4.8	pos	no	1 negative spt. Saved
77	JG	Lp1	9/15/03	9/16/03	3	52088	9/16/03	49	pos	Culture	pos sputum and isolate saved.
78	JB	Lp1	9/26/03	10/1/03	5	52562	9/29/03	neg	ND	no	resp.cult neg; false + DFA
79	CR	Lp1	12/19/03	12/29/03	4		12/22/03	Neg	?	Culture	pos sputum; none saved
80	RC	Lp1	6/11/04	6/14/04	1	58141	6/11/04	11	±	no	re-test RTN=3.9
81	HW	Lp1	6/15/04	6/18/04	5	58575	6/17/04	4.5	±	no	post-treat spt saved; RTN post boiling=5
82	HW	Lp1	6/17/04	6/17/04	5	58690	6/21/05	4.2	±	no	RTN=5.2 on repeat
83	SC	Lp1	6/29/04	6/30/04	10	59022	6/30/04	53.7	pos	Culture	spt samples saved
84	JC	Lp1	7/2/04	7/6/04	5	59145	7/2/04	8.6	pos		
85	MJ	Lp1	7/5/04	7/7/04	1	59162	7/7/04	8.7	pos		
86	AG	Lp5	7/25/04	7/29/04	12	59704	7/26/04	Neg	ND	Culture	1 sputum vial saved
87	AB	Lp1	7/31/04	8/5/04	6	60058	8/5/04	9.3	pos	no	Wilmington VA
88	RF	Lp1	8/6/04	8/10/04	5	60144	8/9/04	17.9	pos	no	
89	RF	Lp1	8/7/04	8/10/04	3	60146	8/10/04	21.6	pos	no	
90	MM	Lp1	8/9/04	8/10/04	3	60164	8/10/04	10.1	pos		Wilmington VA
91	AB	Lp1	9/3/04	9/18/04	5	61045	7/8/04	9.5	pos		Wilmington VA
92	KK	Lp1	11/5/04	11/8/04	4	62769	11/8/04	28	pos	Culture	culture pos by CHP
93	KK	Lp1	11/8/04	11/11/04	5	62863	11/11/04	31	pos	"	
94	KK	Lp1	11/15/04	11/16/04	4	62918	11/16/04	28.5	pos	"	

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LD patient urines at -70°C

No.	Name	Sg/spp	DateColl.	Date Froz.	# Vials*	Record#	Test date	RTN	NOW	Confirm.	Comments
95	KB	Lp1	11/21/04	11/24/04	8	63052	11/22/04	36.7	pos	no	no spt saved
96	KK	Lp1	12/13/04	12/15/04	12	63632	12/15/04	14.5	pos	"	
97	KK	Lp1	12/20/04	12/21/04	1	63752	12/21/04	10.6	pos	"	
98	KK	Lp1	1/4/05	1/5/05	15	63952	1/5/05	14	pos	"	
99	KK	Lp1	1/25/05	1/26/05	0	64397	1/26/05	7	pos	"	50 ml conical saved
100	EL	Lp1	3/7/05	3/8/05	1	65249	3/8/05	16.8	pos	Culture	pos. BAL at CHP
101	KK	Lp1	4/29/05	5/4/05	16	66365	5/4/05	15.6	pos	"	
102	HP	Lp1	6/14/05	6/15/05	3	67381	6/15/05	13	pos	no	
103	HL	Lp1	7/1/05	7/5/05	3	68011	7/5/05	26.1	pos	n	
104	MB	Lp1	8/3/05	8/4/05	5	68996	8/4/05	54.8	pos	Culture+	
105	MW	Lp1	9/7/05	9/7/05	5	69883	9/7/05	4.4	±	no	
1 0	BS	Lp1	9/8/05	9/9/05	2	69985	9/9/05	22	pos		
					788						

788
124
912

RIA to EIA after 9
ND=Not d

Special Pathogens Laboratory

Date Updated: 5/5/05

Frozen respiratory samples: Positive LD patients

Pt or vial #	Patient	serogr.	Date coll.	Date Froz.	Lab#	Cult. result	# vials	Comments
1	Ko	Lp1	6/13/94	5/1/96			1	
2	Ma	Lp1	11/1/95	5/1/96			4	
3	Ve	Lp1	9/9/93	5/1/96			2	
4	St	Lp1	8/1/94	5/1/96			2	
5	Ni	Lp1	?	12/18/97			3	
6	St	Lp1	?	5/3/96			4	
7	Ma		?	7/29/96			2	
8	DK	Lp1	?	10/5/96			3	
9	Ma	Lp1	6/11/96	7/10/96			2	urine RTN8.1;lab#10287; **2 vials to BD3/02**
10	Bu	Lp1	?	10/25/95			3	
11	Zi	Lp1	10/14/96	10/1/98			2	
12	Di	Lp1	?	10/10/96			2	
13	Ca	Lp1	?	5/2/96			2	
14	JHG	Lp1	2/15/97	2/24/97		heavy sg1	6	tested 2/18/97; urine RTN=17.3; **1 vial to BD 3/02**
15	B-P	L. spp?	?	2/13/97			3	stock # 1646
16	Po	Lp1	?	5/7/98			3	
17	ZCR	Lp1	?	10/27/98			2	
18	Ha	Lp1	?	2/24/99			2	
19	M-G	Lp4	?	2/2/99			2	**1 vial to BD 3/02**
20	PMM	Lp1	?	8/26/99			2	**1 vial to BD 3/02**
21	Ha	Lp1	?	9/8/99			3	**1 vial to BD 3/02**
22	Bu	Lp1	?	9/8/99			1	BAL
23	Dw	Lp1	3/25/02	4/16/99			6	BAL; **1 vial to BD 3/02**
24	Tr	Lp1	?	2/1/99			2	collected/froz.? Two different dates
25	Ad		?	7/22/99			3	Negative culture?
26	Wi	Lp1	1/24/99	2/24/99			1	
27	Sc	Lp1	?	10/20/99			2	**1 vial to BD 3/02**
28	Tu	Lp1	?	1/1/00			2	Pos. urine Ag.; negative culture
29	Tu	Lp1	5/12/00	5/14/00			8	Pos DFA and EIA (22.0);**1 vial to BD 3/02**
30	Ob	Lp1	?	10/13/00			1	
31	Ha	Lp1	?	12/8/00			3	**1 vial to BD 3/02**
32	Albany pt 001	Lp1		4/4/01			1	diluted in sterile water. 0.2 ml
33	Pe (ACHD)	Lp1	?	6/19/01			1	

Special Pathogens Laboratory

Date Updated: 5/5/0!

Frozen respiratory samples: Positive LD patients

Pt or vial #	Patient	serogr.	Date coll.	Date Froz.	Lab#	Cult. result	# vials	Comments
34	HJS(003006)	Lp9	?	7/10/01			2	
35	RD	Lp1?	?	12//6/01			1	Mercy pt; bronchbrush,NEGATIVE
36	RM	Lp1?	?	12//6/01			2	Mercy pt; bronchbrush, NEGATIVE
37	DS	Lp1?	?	12/6/01			1	NEGATIVE
38	RS	Lp1		12/14/01			2	**1 vial to BD 3/02**
39	AB	Lp1		1/29/02			9	**1 vial to BD 3/02**
40	DK	Spn	4/10/02	4/11/02			3	vials moved to non-etiology stock
41	A-H (EPA pt)	Lp1	4/17/02	4/26/02	38866		1	>300 CFU on BCYE
42	A-H (EPA pt)	Lp1	4/23/02	4/26/02			1	Negative culture
43	DH (EPA pt)	Lp1					2	
44	MGF (EPA pt)	Lp1		5/29/02			1	
45	SJB (EPA pt)	Lp1	5/28/02	5/30/02			2	
46	RPH (EPA pt)	Lp1	5/29/02	5/31/02			4	
47	SG (EPA pt)	Lp1	6/9/02	6/12/02			3	
48	RH (EPA pt)	Lp1	5/30/02	6/14/02			1	
49	LB	Lp5	6/17/02	6/19/02	Micro 9807		1	VA patient
50	JM (EPA pt)	Lp1	6/24/02		40915		1	< 100 ul
51	JM (EPA pt)	Lp1	6/26/02		40917		1	
52	FP (EPA pt)	Lp1	?		40741		2	Negative culture
53	DB (EPA pt)	Lp1	7/11/02	7/18/02	41710		5	
54	Ko	?	10/16/02	10/31/02	45150	Neg	1	BAL; neg by submitting lab
55	LH	Lp1	11/20/02	12/6/02	45794	Neg	2	spt negative; urine RTN=8.4
56	LH	Lp1	11/20/02	12/6/02	45721	Neg	9	pleural fld negative by culture, EIA and NOW
57	TL	Lp1		3/./03	47347	Neg	1	
58	TL	Lp1		3/3/03	47348	Neg	1	
59	WC	Lp1	5/19/03	5/21/03	48876	Neg	2	
60	WC	Lp1	5/22/03	5/23/03	49003	Neg	4	
61	CM	Lp1	5/21/03	5/23/03	49002	Neg	5	
62	RN	Lp1		7/31/03	50679	Not done	2	pleural fluid RTN = 21 and NOW +
63	CM	Lp1		8/13/03	50931	?	1	pleural fluid
64	CM	Lp1		8/13/03	50936	?	4	pleural fluid; NOW pos but EIA neg
65	JG	Lp1	9/15/03	9/16/03	52117	Positive	4	DFA pos
66	JB	Lp1	9/26/03	10/1/03	52578	Neg	3	DFA false positive

Special Pathogens Laboratory

Date Updated: 5/5/05

Frozen respiratory samples: Positive LD patients

Pt or vial #	Patient	serogr.	Date coll.	Date Froz.	Lab#	Cult. result	# vials	Comments
67	HW	Lp1	6/21/04	6/24/04	58829	Neg	3	post-treatment
68	SC	Lp1	6/29/04	7/2/04	59141	Positive	3	
69	WA	?	6/28/04	7/7/04	59143	Neg	4	BAL
70	JS	Lp1	?	7/7/04	59167	Not done	2	pos blood culture
71	AG	Lp5	7/24/04	7/29/04	59856	Positive	1	Lp5
72	RD	Lp1?	8/2/04	8/16/04	60205	Neg	2	BAL; urine Ag + at Lutheran Hosp
73	RW	Lp1	?	9/7/04	61038	Positive	4	
74	CAP 104 - Omaha	Lp1	?	10/1/04	61930	Positive	1	
							124	

Minus 70 Revco Freezer- Autoclave Room 4/

Mary Lee (?) and **Megan** UTI **G. Fong** UTI	**Megan and Joe** S. aureus checkerboard **J. Chow** Staph Cipro study **Muder** Misc. PA & EC isolates Strep isolates Staph Isolates Muder Staph 1-18	**Chang** NHS Chang 1994 20- complete rack	Fluconazole Study ATCC CL 929 Cell Line HL60 P20 GDF	**Hong** Candida Isolates HN Bacteriodes	Legionella serology antigens ELISA III PPA antigen Biorad Aspergillus	**Singh**: Liver QC Sera Rack #1	**Paterson**: Klebsiella Complete
Chang NHS Chang #20- **Ying** CHP Cystic Fibrosis PGH ZOO Box1 PGH ZOO Box2	MOE Study S. aureus Cipro hemodialysis **Ying** CHP Study	**Ortho McNeil-1** Sera 171 151 complete rack	**Dr. Yu** Fuo Sera Misc. isolates **Marrie** Legionella Serology	**MOE** (JR) serum Cap Isolates **Chang** S. aureus sera Minocycline/Rif	**Joe Chow** : MGH Enterobacter **Quinn**: Enterobacter	**Singh**: Liver QC Sera Rack #2	Klebsiella 1-241 **Hong**: Ca Isolates **Muder**: is -X. mal - Candi **Yu**: eye isolates
Ying's Stuff Special Pathogens PA#141- Staph 101-200	Singh- Fluconozole study Serum samples still in specimen bags (Angio seal study) HL-60 cells	**Ortho McNeil-2** Sera 171 151 complete rack	**Ortho McNeil-3** Sera 171 151 complete rack	**Ying** Isolates Misc. Legionella Isolates S. viridans	**MRSA** Complete rack	**Singh**: Liver QC Sera Rack #3	**Yu/Chiu**: Pneumo Study Isolates

* I think they belong to Cardiology

File: C/Lab Documents/Freezer locations/Revco freezer autoclave room

4/21/2(

Upright Revco – 80 ° Freezer Map

discard? what do samples

Shelf					
1	"New" Pseudos "Old" Pseudos Eason's Environmental and Blood Isolates		RWJohnson—1997-1998 Serology 33-48	RWJohnson—1997-1998 Serology 17-32 Patterson-HIV sera	RWJohnson—1997-1998 Serology 1-16
2	Legionella Stock Rack 5	Legionella Stock Rack 4	Legionella Stock Rack 3	Legionella Stock Rack 2	Legionella Stock Rack 1
3	←	←	Dr. Singh's Galactomannan Study samples Sera and BAL	→	Positive L. pneumophila Cooling towers Cooling Tower QC samples
4	Miscellaneous: *HHV-6 (Singh) *antibiotic stocks *MIC QC Working stocks *SA isolates 201-300 Oakland/Asp. MRSA 1-64	Miscellaneous:	Enterococcus (Muder/Vergis)	Dry ice storage	
5	*DM/HIV sera *Singh -Crypto CSF/Sera/ Isolates Singh-fungal isolates	Positive LD urine: 50 ml conicals	Positive urines: Sarstedt vials	EPA respiratory specimens (1 vial/specimen) *CSF-S.pneumo isolates (Yu)	LD positive serum and sputum Non-LD etiology samples

File: Main lab computer C/Lab Documents/Freezer Locations/Upright Revco -80

1 Background and Overview by Dr. Stou

2 Destruction of the SPL Collection of Isolates and Specimens – the Petitio

3 Documents Related to the Request to Transfer the Collection

4 Procedure for Storing Bacterial in the Special Pathogens Laboratory

5 The Functions of the Special Pathogens Laboratory – Janet E. Stout, Ph.D. PD & Research Documents

6 Documentation of Legionella-related Isolates and Specimens

7 Examples of Use of the Collection and Requests by Scientists

8 Stout CV and Relevant Publications

Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

Legionella strains

Yousef Abu-Kwaik <abukwaik@louisville.edu> **Fri, Mar 9, 2007 at 9:15 AM**
To: jes20@pitt.edu

Hello Janet, I would like to get a ~12 strains of clinical isolates of Legionella pneumophila serogroup 1, preferably isolated at distant times from each other and from different areas. We are doing some phylogeny studies on acquisition of some eukaryotic genes. We will give you credit on the publication that will result from this. Thank you. Yousef

Yousef Abu Kwaik, Professor
Bumgardner Chair in
Molecular Pathogenesis
Director of Graduate Studies
Department of Microbiology and Immunology
U of L Health Sciences Center
319 Abraham Flexner Way 55A
Room 412
Louisville, KY 40292

Phone # (502) 852-4117 (office), (502) 852-4118 (lab)
FAX # (502) 852-7531
email <abukwaik@louisville.edu>

Yousef Abu-Kwaik.vcf
1K

Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

Letter of protest on destruction of microorganisms-Final

Victor Yu <victorlyu@gmail.com> **Sun, Mar 18, 2007 at 7:59 AM**
To: Yousef Abu-Kwaik <abukwaik@louisville.edu>
Cc: Janet Stout <jes20micro@gmail.com>

Dear Yousef

I apologize for my delay in replying. There are 2 reasons for the delay:

1. I am in Portugal giving lectures on legionnaires'' disease. The Portuguese see many cases in their ICUs.

2. I have been quite depressed at the recent turn of events as described in the 2 attached emails. So, it is evident that we cannot assist you at this time.

Sadly, Victor

Victor L Yu MD
Professor of Medicine
University of Pittsburgh
Pittsburgh, PA

Telephone:
Cell: 412-901-7707
Fax: 412-343-4764
Home: 412-343-7429

---------- Forwarded message ----------
Date: Fri, 09 Mar 2007 08:12:40 -0500
From: Yousef Abu-Kwaik < abukwaik@louisville.edu>
To: victoryu@legionella.org
Subject: Legionella strains

Hello Victor, I would like to get a ~12 strains of clinical isolates of Legionella pneumophila serogroup 1, preferably isolated at distant times from each other and from different areas. We are doing some phylogeny studies on acquisition of some eukaryotic genes. We will give you credit on the publication that will result from this. Thank you. Yousef

Yousef Abu Kwaik, Professor
Bumgardner Chair in
Molecular Pathogenesis
Director of Graduate Studies
Department of Microbiology and Immunology
U of L Health Sciences Center

Retrospective Surplus Sample Collection Protocol for BDProbe Tec ET Assay Development

Abstract/Final Report

OBJECTIVE: To provide surplus frozen sputum, brochoalveolar lavage or bronchial wash specimens that have tested positive for Legionella pneumophila to Becton Dickinson & Company for the development of a Legionella pneumophila assay to be performed on the BDProbeTec ET system.

RESEARCH DESIGN: Approximately 10 lower respiratory specimens positive for Legionella pneumophila that have been stored at -20 C or lower will be recorded on the BD Data Report Form and then sent to BD on dry ice.

METHODOLOGY: Becton Dickinson and Co. will use the retrospective surplus sample collection to help with internal assay development of amplified DNA assays for atypical pneumonia on the BDProbeTec ET System.
A unique BD identification number will be assigned to each specimen in the protocol which is a traceable number to laboratory records. The number will be attached to the Data Report Form and to each sample collection tube. Any patient identifier will be removed from the specimen tube. The L. pneumophila testing method, results and test date will be recorded on the Specimen Collection data Report Form. Antimicrobial therapy and duration of treatment for atypical pneumonia prior to sample collection will be recorded also.

FINDINGS: A total of 11 specimens were sent to BD. 5/11 samples were tested by the ProbeTec system, the remaining samples will be tested at a later time. 5/5 were positive by the ProbeTec assay. These specimens were culture positive for L. pneumophila serogroup 1 in concentrations ranging from single colony isolation to heavy growth on culture.

CLINICAL RELATIONSHIPS: Patients infected with L. pneumophila will benefit in the future by a more timely confirmation of disease if the Becton Dickinson and Co. is successful in developing an L. pneumophila assay.

IMPACT/SIGNIFICANCE: The results from this limited sample set suggest that the ProbeTec assay is a sensitive test for the detection of L. pneumophila in clinical specimens. These data will be included in FDA approval for this application which may result in the availability of the assay for use in VA healthcare facilities.

Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

Request for Staphyococcus and MRSA isolates for VA patients - destruction !

Victor Yu <victorlyu@gmail.com> **Fri, Jun 27, 2008 at 8:19 PM**
To: "Peter C. Appelbaum M.D." <pappelbaum@hmc.psu.edu>
Cc: "Stull, Josh (Specter)" <Josh_Stull@specter.senate.gov>, "Boos, Scott (Sen Specter)" <scott_boos@specter.senate.gov>, "Bayer, Bill (Specter)" <Bill_Bayer@specter.senate.gov>, Stan Caldwell <stan_caldwell@specter.senate.gov>, "Smith, Alan (Rep Mike Doyle)" <alan.smith@mail.house.gov>, "Holleman, Edith" <Edith.Holleman@mail.house.gov>, James Paul <James.Paul@mail.house.gov>, "joel. kupersmith" <Joel.Kupersmith@va.gov>, "Roselle, Gary, VHACIN" <Gary.Roselle@va.gov>, Bill Brew - Akaka <bill_brew@svac.senate.gov>, "Kauinui, Kelli (Akaka)" <Kelli_Kauinui@akaka.senate.gov>, "Sakai, James (Akaka)" <james_sakai@akaka.senate.gov>, "Hamerschlag, Arthur" <arthur.hamerschlag@va.gov>

Peter

Your study is important to VA patients since MRSA is a major hospital-acquired problem. Incredibly, administrators at the Pittsburgh VA wantonly destroyed our collection of MRSA and Staph aureus isolates. These isolates were collected assiduously over several decades in the anticipation that they would be of value to science. With the advent of MRSA, this collection would have yielded valuable info for VA patients

You can read about this horrifying scenario in the attachment.

Sorry.

Victor L Yu MD
Professor of Medicine
University of Pittsburgh
Pittsburgh, PA

Telephone:
Cell: 412-901-7707
Fax: 412-281-7445
Home: 412-343-7429
---------- Forwarded message ----------
From: **Peter C. Appelbaum M.D.** <Pappelbaum@hmc.psu.edu>
Date: Tue, Jun 17, 2008 at 11:34 AM
Subject: Request
To: victor.l.yu@gmail.com

Dear Victor

I am writing to you to request use of your valuable collection of S.aureus isolates collected as part of your VA collaborative study. As can be seen from my protocol, they are exactly what I need because they include vancomycin history and have also been collected from patients with end-stage renal diseases.

I am convinced that these strains exist amongst patients in the VA system and that their isolation and identification would improve patient care.

Sincerely yours

Peter C. Appelbaum MD PhD
Professor of Pathology & Director of Clinical Microbiology
Hershey Medical Center
Hershey, PA 17033

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2 attachments

New Pfizer VA hVISA and VISA concept study.doc
33K

CIDLDPetition.pdf
179K

Janet Stout

From: Jepson, Anne [Anne.Jepson@invmed.com]
Sent: Wednesday, August 13, 2008 5:32 PM
To: jstout@specialpathogenslab.com
Subject: Legionella Urinary Antigen Test

Hi Janet,

"Long time – no speak"!!! I hope this email finds you well and enjoying the summer!

Roger Piasio asked me to contact you because Binax / Inverness is undertaking some "product improvement / next generation" work in R&D that involves the use of an instrument to generate test results on some of our rapid tests, and the Legionella urinary antigen test is on the list as a potential candidate for this new format. Assuming that the project moves forward, R&D will need urine samples, ideally from culture confirmed positive patients, for development work, and eventually we would have to run clinical trials using culture as the "gold standard" to support a 510k filing with FDA. We will be seeking out experts and clinical investigators, and we are hopeful that you might be interested in working with us at some point and / or that you can suggest other people who might be as well. Please understand that nothing significant will be taking place in the near future – we are just trying to plan ahead a bit and put some "feelers" out.

I realize the information I have provided above is a bit "sketchy", to say the least, but we can certainly provide you with more detail, etc. depending on your level of interest. I look forward to hearing from you – in the meantime, take care.

With best regards,

Anne

Anne Jepson

Manager, Clinical Affairs

Inverness Medical

207-730-5739

Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

Positive Legionella urine specimens

Mortimer, Karen <Karen.Mortimer@invmed.com> Thu, Aug 16, 2007 at 1:54 PM

To: jes20micro@gmail.com

Dear Dr. Stout,

My name is Karen Mortimer and I work in the Clinical Affairs department at Binax. Norm Moore and Anne Jepson gave me your name as someone who may be able to help me acquire urine samples that are positive for *Legionella* urinary antigen. I would also be interested in obtaining urine specimens positive for *S. pneumo* urinary antigen. I am wondering if you have any such specimens banked or if you could point me in the direction of someone who may.

We would only need 0.5 – 1 ml per sample and would of course be willing to pay for each sample and shipping. I look forward to your reply.

Best regards,

Karen

Karen Mortimer, MT(ASCP)SM

Clinical Affairs Specialist

Binax, Inc.

Inverness Medical Professional Diagnostics

Gmail by Google BETA

Janet Stout <jes20micro@gmail.com>

Remel request for urine specimens

Victor L Yu <vly+@pitt.edu> **Sun, Oct 22, 2006 at 10:15 PM**
To: victorlyu@gmail.com
Cc: janet stout <jes20@pitt.edu>

Date: Mon, 16 Oct 2006 16:05:40 -0500
From: "Hsiung, Andre" <Andre.Hsiung@Remel.com>
To: vly@pitt.edu
Subject: Legionella Publication

Hello Dr. Yu,

How are you? My name is Andre Hsiung and I am in charge of Technical Projects at Remel Inc. We are specialized in diagnostic microbiology products.

I read the paper you published in 2002 about the Distribution of Legionella species and thought your findings were interesting. Being a former bench microbiologist myself, I understand many positive cases can be under reported and see the importance of constant reminder to the microbiology community about the importance of this pathogen.

I am currently involved in a diagnostic product for Legionella. With this in mind, I was wondering if you are interested in providing positive urine specimen for the development of this product. I understand positive specimens aren't seen on daily basis and I do not expect a lot of positive cases.

Please let me know if you are willing to consider my request. If positive, I will be happy to send a draft of agreement to you and discuss compensation details with you.

If you are not the right person from your institution to discuss about this matter, please feel free to forward this email to the appropriate party or to your colleagues from other institutions.

Gmail -talk BETA

Janet Stout <jes20micro@gmail.com>

Cethromycin susceptibilitiy for Legionella

Victor L Yu <vly+@pitt.edu> **Tue, Feb 27, 2007 at 6:09 AM**
To: jes20micro@gmail.com
Cc: victorlyu@gmail.com

Date: Mon, 26 Feb 2007 14:04:00 -0600
From: Marci English <MEnglish@advancedlifesciences.com>
To: Victor L Yu <vly@pitt.edu>
Subject: Cethromycin discussion

Dear Dr. Yu:

Thank you again for your time. I have attempted to outline the highlights of our conversation below. Please correct anything that I have inadvertently misinterpreted. I will be briefing our clinical team in the next few days about our discussion.

To summarize, Advanced Life Sciences is currently developing cethromycin (ABT-773) for community-acquired pneumonia. To supplement our program, we are looking for a laboratory that has a geographically diverse (world-wide) library of Legionella pneumophila isolates that are also temporally relevant (2005-onward). A proposed study would evaluate a limited number of these isolates and their susceptibility to cethromycin (as well as other selected antibiotics to be determined). The surveillance could encompass both broth dilution susceptibility testing and assays to show intracellular activity (such as the HL-60 assay described in your 2005 J. Antimicrobial Agents publication). Your laboratory has the capability to perform these studies.

It is also my understanding that your lab previously performed assays with ABT-773 for Abbott. This data is published (see aforementioned reference). The existence of this data may eliminate the need to perform the studies proposed above. The raw data may also be available, if needed. As a leader in the field of Legionella research, you commented that there have been no significant changes in resistance patterns for Legionella in a number of years. This would therefore make the Abbott data useful and would satisfy the need for temporally relevant data.

I appreciate your candid and positive comments about cethromycin. I look forward to your comments on the summary. As I stated during the

call, if you are interested in these proposed studies we can arrange for a CDA to be signed so that further discussion can take place with our team.

Kind regards,

Marci English

Marci English | Senior Manager of Clinical Research | Advanced Life Sciences

Office:

(630) 754-4339

Cell:

(630) 956-0774

Fax:

(630) 739-6754

Email:

menglish@advancedlifesciences.com

1440 Davey Road | Woodridge, IL 60517 | (630) 739-6744 | www.advancedlifesciences.com

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Globe 7/10/13/05 + 13,

Ontario lab warned years ago legionnaires test not sensitive enough

The Pittsburgh VA made the diagnosis of Legionnaires' disease in a mysterious illness in a Toronto nursing home

HELEN BRANSWELL

TORONTO (CP) - Ontario's provincial health laboratory was warned more than five years ago the in-house test it developed to detect legionnaires' disease wasn't sensitive enough, the U.S. expert who issued the caution said Thursday.

True to Dr. Victor Yu's warning, the same test failed to detect legionella pneumophila as the source of the outbreak at the Seven Oaks nursing home that has claimed 17 lives in Toronto. After the lab detected the bacteria in lung tissue taken during autopsy from some of the victims of the outbreak, a commercially available test confirmed the outbreak was indeed legionnaires'.

Yu, a legionnaires' expert at the University of Pittsburgh, said he warned the lab a number of years ago their test wasn't accurate enough. At the time, Yu was at an Ontario medical school as a visiting professor. He diagnosed a patient as suffering from legionnaires' but was told the provincial lab had run its test on the patient, and ruled out the disease.

Yu sent a specimen to Pittsburgh for testing with the commercial test, called the Binax Now test. It came back positive.

"I'm sure the people who did (developed) it were well meaning and extraordinarily capable. It just happens that sometimes the Lexus does better than the Cadillac in some areas," Yu said in an interview.

"And this particular case was the Lexus versus a Camry, I think. Or a Corolla. Or a Yugo. Because I think when you miss that many, I'm sure a lot of people were very, very disappointed."

Infectious disease expert Dr. Donald Low took over as medical director of the provincial lab this past July. He was unaware of Yu's earlier warning about the test, but he readily admitted it failed to do the job.

"This test wasn't working, especially in this situation," said Low, who is also chief microbiologist at Toronto's Mount Sinai Hospital.

"I guess in hindsight now, looking at the results we've seen with this outbreak, (I'm) not happy with the results."

Legionnaires' was always on the radar screen for public health investigators scrambling to figure out what was behind the outbreak at the long-term care facility.

The clustering of the onset of cases - producing an epidemiologic curve that resembled a sharp spike as opposed to the sweeping curve of something like influenza, for instance - made it a natural suspect.

Even from the start, the lab wanted to run the Binax test on samples from the affected patients, Low said. But the manufacturer had recently reformulated the test; the new version hadn't yet been approved for use in Canada. And the lab couldn't get its hands on any of the old version, he said.

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NEWS & COMMENTARY: REGIONS

The Toronto Health Dept confirms Dr Yu's findings

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Toronto Deaths Are Probably From Legionnaires Disease (Update1)

Oct. 6 (Bloomberg) -- Toronto health officials identified Legionnaires Disease, a form of pneumonia, as the probable cause of death of 16 people at a nursing home in the city.

Autopsy results on three of the dead residents of the Seven Oaks Home for the Aged showed Leg pneumophila, the bacterium that causes Legionnaires, Toronto Public Health said in statement to

``The Legionnaires Disease at Seven Oaks is confined to the nursing home,'' David McKeown, To officer of health, said in the statement. ``Because Legionnaires Disease is not transmitted from p person, there is no risk to the general community.''

Legionnaires Disease is a form of pneumonia caused by bacteria formed naturally in the environr water, Toronto Public Health said. The pneumonia takes its name from an outbreak of the diseas Philadelphia convention of the American Legion in 1976.

During the past two days, there have been no new cases of infection, and transmission of the illn have has subsided, McKeown said. There have been no further deaths from the outbreak that be said.

Gil Hardy, a spokesman for the Toronto public health agency, said Oct. 3 that officials had ruled respiratory syndrome, or SARS, which killed 44 people in the Toronto area in 2003.

To contact the reporter on this story:
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Christopher Donville in Vancouver cjdonville@bloomberg.net

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MORE NEWS

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SAN ANTONIO EXPRESS-NEWS
THURSDAY
JUNE 8, 2006
SECTION B

METRO

Disease source eyed in 10 cases

North Central Baptist Hospital
San Antonio, TX

VA Pittsburgh Special Pathogens Lab isolated Legionella from the hospital water

Patients at 2 North Side hospitals have been diagnosed with Legionnaires' in past 2 months.

BY DON FINLEY
EXPRESS-NEWS MEDICAL EDITOR

Health officials are investigating 10 cases of Legionnaires' disease in people from Bexar and Comal counties over the past two months to determine if they were infected from a single source.

Two of the 10 have died, although one death involved a patient suffering from advanced colon and lung cancer. All were older adults — the youngest was over 50 — and all had some medical condition including cancer and chronic lung disease that weakened their immune systems and increased their risk of contracting the bacterial pneumonia. One patient had recently undergone cosmetic surgery.

Healthy people generally are not at risk from Legionnaires' disease. The illness is not spread through person-to-person contact, but by inhaling contaminated droplets.

Seven of the patients live in Bexar County which normally sees a handful of cases each year — mostly in warmer months. The fact that all 10 cases were diagnosed in two North Side hospitals, and took place over the past two months, prompted the concern.

"We're looking to see if there's some sort of nosocomiality" said Roger Sanchez, an epidemiologist with the Metropolitan Health District, which is heading the probe with help from state health authorities and a four-person team from the Centers for Disease Control and Prevention in Atlanta. The CDC team arrived

See 2 hospitals, 8A

2 hospitals see Legionnaires' cases

CONTINUED FROM 1B

on Monday.

Investigators are interviewing patients, going over hospital medical records and testing water sources for the bacteria. In past years, Sanchez said, Legionnelle bacteria has been found on hotel shower heads, in hot tubs and even the automated vegetable sprayers in a grocery store.

But the bacteria is also found readily in nature, and it might well be that no common exposure took place, said Dr. Sandra Guerra-Cantu, regional medical director with the Texas Department of State Health Services.

"At this point we don't know for sure that there is a common exposure," said Guerra-Cantu. "Even if we find a common exposure, usually it's easily corrected. I wouldn't want the public to panic about this."

Each year, thousands of people nationwide are hospitalized with Legionnaires' disease, which was named for an outbreak at the 1976 American Legion conference in Philadelphia. The disease is fatal in about a third of cases, although the bacteria can also cause a milder illness with cold-like symptoms called Pontiac fever. Both illnesses are treated with antibiotics.

The CDC team was sent in part because its laboratory is one of the few places that can process some of the tests, Guerra-Cantu said. The team also uses events like this to train its epidemiologists, she added.

Investigators will ask patients about possible sources of exposure — commercial cooling towers, fountains, outdoor water sources — even the mist sprayers used on patios.

"Anywhere the investigation will lead us that more than one person lists as a possible exposure, we'll investigate further," Guerra-Cantu said.

The two North Side hospitals weren't identified by health authorities, but the Baptist Health System released a written statement that two of their facilities had cared for Legionnaires' patients. "Staff and physicians have a heightened awareness and are working closely with public health officials to deal with this influx," the statement read.

Baptist operates three North Side hospitals: Northeast Baptist, North Central Baptist and St. Luke's Baptist. Although the hospitals are being tested as possible sources of the infection, investigators also are going over records at those and other local hospitals to see if any other cases were missed.

A San Antonio outbreak in 1996 included 16 people. The source of that infection was never found, Sanchez said.

dfinley@express-news.net

Legionnaires' disease

What is it?

Legionnaires' disease is a type of pneumonia caused by the Legionnella bacteria. The bacteria got its name in 1976, when many people attending an American Legion convention suffered from an outbreak.

What are the symptoms?

Usually begin within 2 to 14 days of exposure to the bacteria and are similar to those caused by other forms of pneumonia: fever, chills and a cough.

How common is it?

Most healthy people do not get sick when exposed to the bacteria but people with chronic lung diseases or compromised immune systems are at risk. Between 8,000 and 18,000 people are hospitalized with the disease in the United States annually.

How do people get it?

By breathing in a mist or vapor contaminated with the bacteria. It is not spread by person-to-person contact.

Source: Centers for Disease Control and Prevention

HARRY THOMAS/STAFF

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2 Destruction of the SPL Collection of Isolates and Specimens – the Petitio

3 Documents Related to the Request to Transfer the Collection

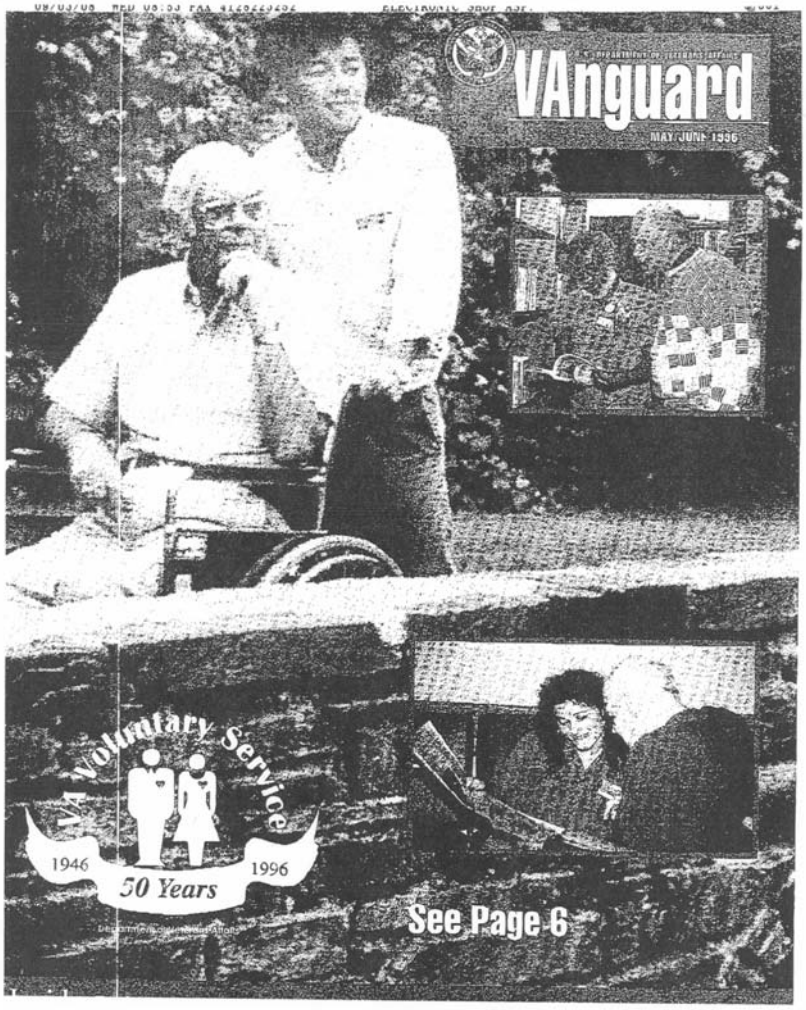
4 Procedure for Storing Bacterial in the Special Pathogens Laboratory

5 The Functions of the Special Pathogens Laboratory – Janet E. Stout, Ph.D. PD & Research Documents

6 Documentation of Legionella-related Isolates and Specimens

7 Examples of Use of the Collection and Requests by Scientists

8 Stout CV and Relevant Publications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20-year anniversary

VA Researchers, Experts on Legionnaire's

In 1976, 200 Legionnaires fell ill after attending the 58th annual convention of the American Legion in Philadelphia. A form of pneumonia later named Legionnaire's Disease claimed 34 lives.

Dr. Victor Yu, chief, Infectious Disease Division at the Pittsburgh (University Drive) VAMC, and his colleagues already know a lot about the legionella bacterium when the Centers for Disease Control officially named the bacteria Legionnaire's Disease in 1980. Since then, they have made significant discoveries about legionella and are recognized as experts in the field. These discoveries have lessened the risk of contracting the disease; however, Legionnaire's Disease remains a health threat to those with weakened immune systems.

Richard M. Vickers, supervisor of the Special Pathogen Laboratory at the Pittsburgh VAMC, discovered a way for hospitals to test easily for legionella. Using Vickers' test, Janet Stout, a Pittsburgh VAMC microbiologist, found the legionella organism lives in drinking water, particularly water systems of large buildings. Prior to their discovery, it was thought that legionella was transmitted via air conditioners or cooling towers.

The Special Pathogen Laboratory has set the standard for legionella testing in the country, and lab personnel and medical scientists in this country and around the world receive training there in detecting the legionella organism.

It was the first hospital in the world to test every patient admitted with pneumonia for Legionnaire's Disease, and the first to test its water supply routinely for the legionella bacterium. Now the Allegheny County Health Department requires all area hospitals to routinely test their water supplies.

Yu and his team had also determined the potential for in-home exposure to legionella. After analyzing data collected from Legion members and their home water supplies, the researchers were able to conclude the legionella bacterium was present in less than 25 percent of the homes tested. They also found the risk of contracting Legionnaire's Disease from exposure to contaminated water supplies was low.

They are now testing a new drug used to treat the disease. Azithromycin may provide physicians with a more effective treatment for Legionnaire's with fewer side effects. ❑

By Katie Sharon
Pittsburgh (Univ. Dr.) VAMC

MEDICAL advances

Infant Immune Study Disputed

A research team at the Baltimore VAMC was one of three U.S. teams whose studies dispute a conclusion about the immune system made more than 30 years ago. The findings could eventually lead to childhood vaccinations starting within days of birth.

Researchers led by immunologist Marcella Sarzotti-Kelsoe and her colleagues, virologists Deanna Robbins, Ph.D., and Dr. Paul Hoffman, report their findings in the March 22 issue of the journal Science.

"Our data indicate that the dose of virus encountered by a newborn's immune system determines the immune system response," said Sarzotti-Kelsoe. "Given the correct dose, newborns can respond like adults."

The researchers found that given a greatly reduced viral dose, newborn mice are fully capable of developing protective immunity. In contast, newborn mice receiving a high dose of virus develop a non-protective immune response and succumb to disease.

Studies at Case Western Reserve University in Cleveland and the National Institutes of Health point to the same conclusion.

Werner's Syndrome Gene Discovered

VA scientists have discovered a gene that causes premature aging known as Werner's Syndrome. Although that disorder is very rare, the discovery of the first human gene associated with aging should have broader implications for understanding the genetic underpinnings of the human aging process and the diseases that strike older people, such as coronary artery disease, cancer, diabetes and osteoporosis.

"We are interested in the aging process itself — not necessarily to arrest it but to help people age in a healthier way," said Gerard Schellenberg, Ph.D., associate director of the Geriatric Research, Education and Clinical Center in Seattle and leader of the study appearing in the April 12 issue of the journal Science.

Researchers of the VA Puget Sound Health Care System in Seattle, the Darwin Molecular Corporation and the University of Washington collaborated with an international team of researchers.

The scientists believe the cloning of the Werner's Syndrome gene, called WRN, offers clues to the cases of "normal aging" and related susceptibility. They found four different WRN mutations in a group of Werner's Syndrome patients from Japan and Syria.

Werner's Syndrome has long intrigued researchers, Schellenberg said, because people who develop the syndrome seem to be caught in a fast-forward time warp. Even though they are typically in their 30s, their hair grays and thins, their skin wrinkles and their cells show changes typical of the aged.

Even more importantly, they develop diseases associated with aging. ❑

UBIQUITOUSNESS OF *LEGIONELLA PNEUMOPHILA* IN THE WATER SUPPLY OF A HOSPITAL WITH ENDEMIC LEGIONNAIRES' DISEASE

JANET STOUT, M.S.,
VICTOR L. YU, M.D.,
R. M. VICKERS, B.S.,
JEFFREY ZURAVLEFF, M.S.,
MICHELE BEST, B.A.,
ARNOLD BROWN, M.D.,
ROBERT B. YEE, PH.D.,
AND ROBERT WADOWSKY, M.S.

SINCE 1977 there have been numerous outbreaks of nosocomial Legionnaires' disease; however, in only one was a reservoir established for *Legionella pneumophila*. Dondero and his colleagues have suggested that the organisms were spread from a contaminated cooling tower adjacent to a hospital with 39 cases of Legionnaires' disease.[1] *L. pneumophila* has also been isolated from showerheads and mixing valves of hospitals in the United States and England.[2,3] The two largest sustained outbreaks of nosocomial Legionnaires' disease have been at the Wadsworth Veterans Administration Hospital in Los Angeles and here at the Pittsburgh Veterans Administration Medical Center.[4,5] Although a definitive epidemiologic link has not been established, the potable water supply of both these medical centers has been shown to be contaminated with *L. pneumophila*.[2,6]

The isolation of *L. pneumophila* from the potable water to which five of six patients with nosocomial Legionnaires' disease were directly exposed prompted an extensive, ongoing environmental survey for *L. pneumophila* within our hospital. Fortuitously, the initial survey was performed just before an outbreak of 14 culture-confirmed cases of nosocomial Legionnaires' disease over a three-week period. In this report we demonstrate that *L. pneumophila* is more widely distributed within the hospital than previously realized and that the water-distribution system is the reservoir for the organism.

METHODS

Sites Associated with Legionnaires' Disease

Between November 1980 and March 1981, six nosocomial cases of Legionnaires' disease were diagnosed; all were due to *L. pneumophila*, serogroup 1. Environmental sampling of faucet and shower sites in the rooms and ward of these patients was performed immediately after diagnosis to determine whether the patients had been exposed to water contaminated with *L. pneumophila*.

From the Veterans Administration Medical Center and the School of Medicine and the Graduate School of Public Health, University of Pittsburgh. Address reprint requests to Dr. Yu at the Infectious Disease Section, Veterans Administration Hospital, University Drive C, Pittsburgh, PA 15240.

Supported by the Health Research and Service Foundation (United Way) and the Medical Research Service of the Veterans Administration.

Survey of Entire Hospital

Specimens for culture were taken from showers and faucets at each of 13 nursing units and five nonpatient areas (offices or laboratories). A total of 15 showers and 35 faucets were included in this survey (Fig. 1).

Monthly Surveillance Sites

Five showers and five faucets were selected as surveillance sites for monthly culture. These sites were selected to provide a representative mix of patient and nonpatient areas as well as east and west hospital wings. The purpose of this periodic surveillance was to monitor the extent, duration, and degree of *L. pneumophila* contamination in our hospital. We anticipated that we might also be able to correlate environmental surveillance data with the occurrence of nosocomial outbreaks of Legionnaires' disease.

Specimen Collection and Preparation

Samples were obtained by swabbing the water outlet with a Dacron swab (dislodging the sediment within the fixture) and then collecting 100 to 200-ml aliquots of water. A 0.1-ml aliquot of each sample was inoculated onto selective differential medium, which is a modification of previously described mediums used for isolation of *L. pneumophila*.[7-12]

Screening Suspected Isolates

Colonies morphologically similar to those of *L. pneumophila* were subcultured to buffered charcoal-yeast extract and five per cent sheep-blood agar plates. If growth did not occur on blood agar after two days of incubation, the isolate was tested by slide agglutination against antiserum for serogroups 1 and 5, as previously described[13]; positive results were considered presumptive identification of *L. pneumophila*. All suspected isolates were also confirmed by direct immunofluorescence testing with antiserums against six serogroups of *L. pneumophila*.[14,15]

RESULTS

Sites Associated with Legionnaires' Disease

L. pneumophila (serogroup 1) was isolated from the showers or faucets used by five of six patients with Legionnaires' disease (serogroup 1) within one week of the onset of their nosocomial pneumonia.

Survey of Entire Hospital

Nine of 15 showers and 24 of 35 faucets yielded the organism. Figure 1 shows that the organism was virtually ubiquitous throughout the hospital's water system.

Of the 51 *L. pneumophila* organisms isolated from environmental specimens, 46 were in serogroup 1 and five were in serogroup 5. Organisms from serogroups 2, 3, 4, and 6 were not isolated. All suspected isolates that were positive according to slide agglutination testing against either serogroup 1 or 5 were also positive against either serogroup 1 or 5 when tested by direct immunofluorescence.

Monthly Surveillance Sites

Of the 10 sites from which specimens were obtained for culture, all were positive for *L. pneumophila* in the April sampling, which fortuitously preceded an outbreak of 14 cases of culture-confirmed Legionnaires' disease over a three-week period. The concentration of *L. pneumophila* at these sites ranged from 5 to

Legionnaires' Disease: New Clinical Perspective from a Prospective Pneumonia Study

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In an attempt to ascertain the incidence of Legionnaires' disease at our hospital, a prospective case-control pneumonia study was conducted for 11 months. Specialized diagnostic tests for Legionella pneumophila, including serologic study, direct immunofluorescent examination, and selective culture, were made routinely available in our hospital. To our surprise, L. pneumophila was the most common cause of pneumonia (22.5 percent) attributable to a single pathogen, followed by Streptococcus pneumoniae (10.6 percent). In 68.8 percent of the cases, Legionnaires' pneumonia was hospital-acquired. In contrast to other investigators, we found that abdominal pain, diarrhea, neurologic signs, abnormal liver function results, hypophosphatemia, and hematuria did not occur significantly more frequently in pneumonia caused by L. pneumophila than in that caused by other microorganisms. However, hyponatremia within five days of onset of pneumonia occurred significantly more frequently in Legionnaires' disease ($p < 0.0001$). Since the clinical presentation is nonspecific, specialized laboratory tests are necessary to make the diagnosis. As a result of our experience, we suggest an approach using serologic tests as a screen to determine whether more specialized tests for Legionnaires' disease should be introduced into a hospital without previously recognized cases of Legionnaires' disease.

Since 1976 when the clinical syndrome of Legionnaires' disease was first defined, investigators have identified suggestive or even distinctive clinical features in pneumonia caused by Legionella pneumophila [1–9]. Any clinical or laboratory parameter shown to aid in the early diagnosis of Legionnaires' disease would be useful, since specialized laboratory tests are currently required. Presumably, earlier diagnosis would lead to earlier therapy with a concomitant improvement in outcome.

From February 1979 to August 1979, 12 sporadic cases of nosocomial and community-acquired Legionnaires' disease were observed at the Pittsburgh Veterans Administration Medical Center. Initially, most cases were diagnosed retrospectively using serologic tests; since the requests for specialized tests depended on the clinical acumen of individual physicians, we had little grasp of the incidence of Legionnaires' disease and the actual magnitude of the problem at our Medical Center. With these points in mind, we initiated a prospective study of all cases of pneumonia occurring at our hospital over an 11-month period. Specialized tests for Legionnaires' disease were made routinely available for all cases of pneumonia so as to uncover occult cases of Legionnaires' disease. In addition, we prospectively evaluated

From the Veterans Administration Medical Center and the University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania. This study was supported in part by grants from the Health Research and Services Foundation (United Way), Pittsburgh, Pennsylvania, and the Veterans Administration General Medical Research Service. Portions of this work were presented at the Plenary Session, Association of American Physicians Meeting, Washington, D.C., 1980, and American Epidemiological Society Meeting, Hershey, Pennsylvania, 1980. Requests for reprints should be addressed to Dr. Victor L. Yu, Infectious Disease Section, Veterans Administration Medical Center, Pittsburgh, Pennsylvania 15240. Manuscript accepted February 8, 1982.

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LEGIONELLACEAE IN THE HOSPITAL WATER-SUPPLY

Epidemiological Link with Disease and Evaluation of a Method for Control of Nosocomial Legionnaires' Disease and Pittsburgh Pneumonia

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Summary An epidemiological link was found between contamination of a hospital water-supply by *Legionella pneumophila* and by Pittsburgh pneumonia agent (PPA) and subsequent cases of nosocomial legionnaires' disease and Pittsburgh pneumonia. The extent of *L pneumophila* isolation from the water-supply paralleled the occurrence of disease. Whenever *L pneumophila* was isolated from more than 30% of ten selected water sites, nosocomial legionellosis occurred. The temperature of the hot water tanks was raised to 60–77°C for 72 h, and water outlets were flushed for 30 min with hot water. A decline in numbers of *L pneumophila* and PPA in the water-supply was followed by a fall in the incidence of legionnaires' disease and Pittsburgh pneumonia. In addition, intermittent raising of the temperature in the hot water system decreased both the number of months in which disease occurred and the proportion of nosocomial pneumonias caused by these organisms.

Introduction

WE have established that *Legionella pneumophila* is ubiquitous in the potable water distribution system in a hospital with nosocomial legionnaires' disease.[1] Pittsburgh pneumonia agent (PPA), was also widely distributed within the hospital's water-supply.[2] Other workers[3–5] have likewise reported isolation of *L pneumophila* from potable water supplies but no epidemiological link has been established between organisms from this source and hospital-acquired legionnaires' disease and Pittsburgh pneumonia.

Several eradication measures have been instituted in an effort to eliminate *L pneumophila* from the water-supply,[3,4,6] but there has been no long-term study of effectiveness in

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Legionella pneumophila in residential water supplies: environmental surveillance with clinical assessment for Legionnaires' disease

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(*Accepted 29 March 1992*)

SUMMARY

Although cases of community-acquired Legionnaires' disease have been epidemiologically linked to residential water supplies, the risk of acquiring Legionnaires' disease from exposure to *Legionella pneumophila* in residential water systems is uncertain. The residential water supplies of 218 members of the American Legion in six different geographical areas in Pittsburgh were cultured for *L. pneumophila*. Residents of the homes provided a recent medical history and a blood sample for detection of antibodies to legionella. A urine sample for legionella urinary antigen testing was also requested from individuals residing in legionella-positive homes and individuals with a positive antibody test. Six percent (14/218) of the homes yielded *L. pneumophila* (range within six areas 0–22%). Lower hot water tank temperature was significantly associated with legionella positivity ($P < 0{\cdot}01$). Analysis of water samples for mineral content showed no association between legionella positivity and concentrations of calcium and magnesium. Water samples from the area where 22% of the homes surveyed were positive for legionella had a higher iron content than water samples from the other areas tested. None of the individuals residing in legionella-positive homes showed elevated antibody titres to legionella or the presence of legionella antigen in urine. For the immunocompetent hosts, the risk of contracting Legionnaires' disease from exposure to contaminated household water supplies in the Pittsburgh area appears to be low.

INTRODUCTION

Legionnaires' disease has been linked to exposure to water sources that harbour *Legionella pneumophila*. The strongest epidemiological studies have linked exposure to contaminated hospital water distribution systems to acquisition of nosocomial Legionnaires' disease [1–3]. Community-acquired cases of Legionnaires' disease have also been linked to exposure to the contaminated water systems of hotels, office buildings, and industrial plants [4, 5]. Finally, at least seven cases of community-acquired Legionnaires' disease have been attributed to exposure to contaminated residential water distribution systems [6–9].

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Review Articles

Current Concepts

LEGIONELLOSIS

JANET E. STOUT, PH.D., AND VICTOR L. YU, M.D.

LEGIONNAIRES' disease was first recognized during an outbreak of pneumonia involving delegates to the 1976 American Legion convention at a Philadelphia hotel. Full appreciation of its role other than as an exotic pathogen has only come in the past several years. As diagnostic methods have improved and epidemiologic understanding of its reservoir has been exploited, legionella has been found to be a common cause of community-acquired and nosocomial pneumonia. Many excellent reviews have been published,[1-4] so this review will focus on newer findings.

EPIDEMIOLOGY

Community-Acquired Pneumonia

Outbreaks of legionnaires' disease in hotels, cruise ships, and office buildings continue to garner media attention. The incidence of legionella as a cause of sporadic community-acquired pneumonia varies, but in studies from Europe and North America, it ranged from 2 to 15 percent of all community-acquired pneumonias that require hospitalization.[5] Studies in which diagnostic tests for legionella, especially culture, were consistently used showed *Legionella pneumophila* to be among the top three or four microbial causes of community-acquired pneumonia. One large-scale study of community-acquired pneumonia in Ohio suggested that only 3 percent of sporadic cases of legionnaires' disease were correctly diagnosed.[6] We have noted the cyclic nature of legionella as a cause of community-acquired pneumonia in Pittsburgh, with an incidence ranging from 2 to 9 percent over the past 10 years. Patients with community-acquired legionnaires' disease are more likely to have severe community-acquired pneumonia, as defined by more severely abnormal vital signs, more extensive infiltrate on chest radiography, and the need for admission to an intensive care unit.[7-11]

From the Veterans Affairs Medical Center and the University of Pittsburgh, Pittsburgh. Address reprint requests to Dr. Yu at the Infectious Diseases Section, VA Medical Center, University Dr. C., Pittsburgh, PA 15240.
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Nosocomial Pneumonia

The epidemiology of nosocomial legionellosis has gradually shifted. In the 1980s most cases reported to us were associated with outbreaks at tertiary care centers. In the past few years, sporadic nosocomial cases from community hospitals have predominated. The reported incidence of nosocomial pneumonia is directly correlated with two factors: the ready availability of specialized diagnostic tests in-house (especially sputum culture and urinary antigen assay) and the presence of legionella in the hospital water supply.

Risk Factors

Cigarette smoking, chronic lung disease, and immunosuppression (especially that caused by corticosteroid therapy) have been consistently implicated as risk factors.[12,13] Surgery is a major predisposing factor in nosocomial infection, with transplant recipients at the highest risk.[14-18] The incidence of legionnaires' disease in patients with the acquired immunodeficiency syndrome is low.[19] However, the clinical manifestations are more severe; lung abscesses, extrapulmonary infections, and bacteremia have been observed.[20-22] Regional differences in the rates of reported cases in the United States may be due to ecologic factors or to intensified surveillance in some states. For example, in 1994 the number of cases of legionnaires' disease in Allegheny County, Pennsylvania, exceeded that in 36 states.[23] Allegheny County has issued guidelines for legionella surveillance in all hospitals in the county.[24]

Pediatric Legionellosis

Both community-acquired and nosocomial cases of legionellosis are now being seen in children.[25-27] Most children with legionnaires' disease are immunosuppressed. A number of immunocompetent children have acquired legionnaires' disease postoperatively[28] or neonatally.[29] Most cases of legionellosis in neonates occurred in association with hospital-acquired ventilator-associated pneumonias.[30,31] Molecular subtyping of environmental and patient isolates has established that the water-distribution system is generally the source.

Mode of Transmission

Legionnaires' disease can be acquired by the inhalation of aerosols containing legionella or by microaspiration of water contaminated with legionella.[3] Aerosol-generating systems that have been linked to disease transmission include cooling towers, respiratory-therapy equipment, and whirlpool baths.[32,33] One of the more fascinating outbreaks originated from an

Unexpected Similarity of Pulsed-Field Gel Electrophoresis Patterns of Unrelated Clinical Isolates of *Legionella pneumophila*, Serogroup 1

Stephanie D. Drenning,[1,2] Janet E. Stout,[1,2] Jean R. Joly,[3] and Victor L. Yu[1,2]

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Phenotypic and genotypic methods identify subtypes of *Legionella pneumophila*, serogroup 1, and match patient and environmental isolates from suspected sources. The strength of this association is limited by the lack of information regarding the frequency and distribution of isolates belonging to various subtypes. In this study, 62 clinical isolates of *L. pneumophila*, serogroup 1, were subtyped by using pulsed-field gel electrophoresis (PFGE), to determine the distribution and degree of diversity of PFGE patterns among monoclonal antibody (MAb) subtypes. Unexpectedly, 8 of 21 MAb Philadelphia 1 isolates had a common PFGE pattern, and, among 12 MAb OLDA isolates, only 2 PFGE patterns were seen. Our hypothesis was that PFGE patterns were distributed randomly; however, statistical analysis showed that the distribution of subtypes was not random (Fisher's exact test 0.13; $P > .05$). In light of these results, researchers who do epidemiological investigations should use caution when interpreting the significance of matching PFGE patterns of *L. pneumophila*, serogroup 1.

Making the epidemiological link between cases of legionnaires disease and a suspected environmental source can be difficult, because of the sporadic nature of the disease and the variety of sources from which the organism can be isolated [1]. In epidemiological investigations, both phenotypic and genotypic methods have been used to demonstrate identity among strains of *Legionella pneumophila*. These methods include serotyping, monoclonal antibody (MAb) subtyping, isoenzyme analysis, protein and carbohydrate profiling, plasmid analysis, restriction endonuclease analysis, restriction fragment length polymorphism (RFLP) analysis of rRNA (ribotyping) or chromosomal DNA, amplified fragment length polymorphism analysis, restriction endonuclease analysis of whole-cell DNA with or without pulsed-field gel electrophoresis (PFGE), arbitrarily primed (AP) polymerase chain reaction (PCR), repetitive element (RE) PCR, and infrequent-restriction-site PCR [1–10].

MAb subtyping is a useful phenotypic method for subdividing strains of *L. pneumophila*, serogroup 1. Genotypic methods, such as PFGE, have become increasingly valuable for epidemiological investigation, because of their high discriminatory power, broad application, and speed of results [11]. One limitation of PFGE and other subtyping methods, however, is the lack of information regarding the frequency and distribution of the isolates belonging to the various subtypes or patterns [12]. In this study, we sought to determine the relatedness of PFGE patterns among clinical isolates of *L. pneumophila*, serogroup 1. A second objective was to determine the degree of relatedness of PFGE patterns among isolates of the same MAb subtype.

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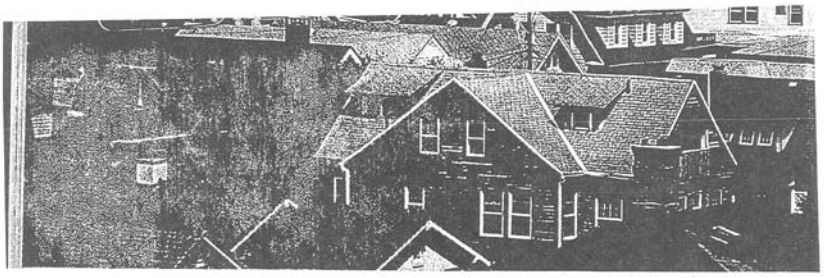
0022-1899/2001/18304-0014$02.00

Materials and Methods

Organisms. Sixty-two clinical isolates of *L. pneumophila*, serogroup 1, representing 8 MAb subtypes from 30 institutions in 9 states, were subjected to PFGE. Forty-seven of 62 isolates were from patients admitted to western Pennsylvania hospitals. These isolates were either recovered by or submitted to the special pathogens laboratory of the VA Medical Center (Pittsburgh, Pennsylvania) from 1983 to 1996 (table 1). For 24 of 62 isolates, it was not known whether the cases were nosocomial or community acquired; 27 of 62 were community-acquired infections, and 11 of 62 were nosocomial. *L. pneumophila* Philadelphia 1 (ATCC 33152) served as an internal control for run conditions and was included on each PFGE gel.

MAb subtyping. MAb subtyping of all *L. pneumophila*, serogroup 1, isolates was performed in the laboratory of one of the investigators (J.R.J., Montreal, Quebec, Canada). MAb pattern designations were done according to the standardized subtyping scheme [13].

PFGE of bacterial DNA. Bacteria were grown on buffered charcoal yeast extract agar plates for 24–48 h at 37°C. Bacterial suspensions were matched turbidometrically to a 0.5 McFarland standard, and genomic DNA was prepared as described elsewhere [14]. Agarose plugs of DNA were digested overnight with 30 units of *Sfi*I or *Sal*I (New England Biolabs), according to the recommended conditions. PFGE was performed by using a CHEF-DRII system (Bio-Rad). The DNA was electrophoresed for 30 h at 14°C in a 1% agarose gel at 6 V/cm with a linear gradient pulse time of



Legionella in residential water systems

By Janet E. Stout, Ph.D., and Robert R. Muder, M.D.

Recent studies[1,2] indicate that sporadic cases of Legionnaires' disease are acquired from a previously underappreciated source—residential water systems. This article gives an overview of research findings and what can be done to eradicate *Legionella* in home systems.

Legionnaires' in Hospitals

Shortly after the discovery of Legionnaires' disease in the community setting, outbreaks of Legionnaires' disease were reported in hospitals . Although cooling towers were first implicated as the source of exposure in early investigations, it soon became clear that potable water distribution systems (warm water systems) represented the primary source of exposure for hospital-acquired Legionnaires' disease.[3]

Subsequent investigations showed that 12% to 70% of hospital water systems were colonized with *Legionella*.[4] Prospective clinical studies have demonstrated the relationship between the presence of the bacterium in the water supply and the occurrence of disease.[5]

If hospital water distribution systems were colonized with *Legionella pneumophila* and were the source of infection for hospitalized patients, investigators hypothesized that the same must be true for residential water systems. In 1987, we published the first report of community-acquired Legionnaires' disease acquired from exposure within the home.[6] Subsequent reports showed that 6% to 32% of homes could be colonized with *Legionella* (*Table 1*).[1] Investigation of cases of community-acquired ognition that the disease can be contracted from the water in a patients' home.

We are involved in a large-scale study of community-acquired Legionnaires' disease sponsored by the U.S. Environmental Protection Agency. The study's objective is to determine, in a systematic fashion, how often residential water systems are the source of exposure for community-acquired Legionnaires' disease.

Legionella in Home Systems

The preliminary results of this study were reported in October 2003.[2] Our study is ongoing. However, the results are consistent with the message that the overall risk of acquiring this disease from exposure within the home is likely to be low. However, certain individuals are at greater risk of acquiring Legionnaires' disease from exposure to the bacterium in residential water systems.

About the Authors

Janet E. Stout, Ph.D., is director of the Special Pathogens Laboratory and **Robert R. Muder, M.D.**

Hospitals are often required to perform a supplemental disinfection of their water systems to protect individuals from hospital-acquired Legionnaires' disease. The authors of this article recently studied one hospital where three cases of hospital-acquired Legionnaires' disease were detected in less than two years. These cases were linked to *Legionella* colonization of the hospital's water system. Chlorine dioxide (ClO_2) was considered a cost-effective approach to disinfection given that ClO_2 generators could treat the 23 buildings comprising the hospital complex from one central location. The authors evaluated the efficacy of maintaining a residual of 0.5 to 0.8 mg/L of ClO_2 for *Legionella* control in the secondary distribution system of this 437-bed hospital over a two-year period. Monthly monitoring showed mean *Legionella* positivity at hot water outlets and cold building source water areas decreased from 23 to 12% and 9 to 0%, respectively ($p < 0.05$). ClO_2 residuals decreased with increasing distance from the application point and temperature. Mean ClO_2 concentrations were lowest in hot water outlets (0.08 mg/L) followed by cold water outlets (0.33 mg/L) and reservoirs (0.68 mg/L). Complete eradication (0% positivity) of *Legionella* was achieved after 1.75 years, and no cases of Legionnaires' disease were reported during this time.

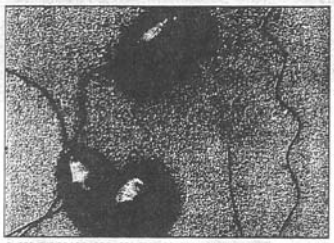


PHOTO: EYE OF SCIENCE/PHOTO RESEARCHERS INC

keeping *Legionella* out of water systems

BY FRANK P. SIDARI III, JANET E. STOUT, JEANNE M. VANBRIESEN, ANN MARIE BOWMAN, DOUGLAS GRUBB, ALAN NEUNER, MARILYN M. WAGENER, AND VICTOR L. YU

The source of hospital-acquired Legionnaires' disease is the hospital's potable water distribution system (Stout & Yu, 1997). Controlling *Legionella* in hospital water systems and preventing Legionnaires' disease has become a focus for hospitals because they serve a population of particularly susceptible people. Guidelines presented by the Allegheny County Health Department and the State of Maryland recommend that acute care facilities perform active environmental surveillance for *Legionella* in potable water (MDHMH, 2000; ACHD, 1997). The Joint Commission on Accreditation of Health Care Organizations recommends that hospitals have a plan to deal with waterborne pathogens, including *Legionella* (JCAHO, 2001).

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AJIC practice forum

A proactive approach to prevention of health care–acquired Legionnaires' disease: The Allegheny County (Pittsburgh) experience

Cheryl L. Squier, RN, CIC,[b,c] Janet E. Stout, PhD,[c,d] Sharon Krsytofiak, MS, MT(ASCP), CIC,[b] Joan McMahon, RN, MPH,[a] Marilyn M. Wagener, MS,[d] Bruce Dixon, MD,[a] and Victor L. Yu, MD[c,d]
Pittsburgh, Pennsylvania

Background: The Allegheny County Health Department (ACHD) in Pennsylvania distributed the first guidelines for prevention and control of health care–acquired Legionnaires' disease (LD) by 1995. The proactive approach advocated in the guidelines differed notably from that of the Centers for Disease Control and Prevention (CDC) by recommending routine environmental testing of the hospital water distribution system even when cases of health care–acquired Legionnaires' disease had never been identified.
Objectives: Our purpose was to (1) evaluate the impact of the ACHD guidelines on the *Legionella* diagnostic and preventive practices of health care facilities in Allegheny and surrounding counties and (2) compare the incidence of health care–acquired LD before and after issuance of the ACHD guidelines.
Methods: CDC case reports of LD from 1991 to 2001 were tabulated and compiled by the ACHD Infectious Disease Unit and the Association for Professionals in Infection Control and Epidemiology, Inc, Three Rivers Chapter. A survey was distributed to 110 hospitals and long-term care facilities in the region. The results were analyzed as occurring either in the preguideline period (1991-1994) or postguideline period (1995-2001).
Results: A significant decrease in the number of health care–acquired cases was demonstrated between the preguideline (33%) and postguideline (9%) periods ($P = .0001$). In contrast, community-acquired cases increased from 67% pre guideline to 91% post guideline. A total of 71% of the facilities were colonized with *Legionella*. Disinfection of the water distribution system was initiated by 44% of facilities. Use of urinary antigen testing significantly increased from 40% pre guideline to 79% post guideline ($P = .0001$).
Conclusions: Health care–acquired LD declined significantly after the issuance of guidelines for prevention and control of health care–acquired LD. The decline was associated with health care facilities performing routine environmental monitoring of their water distribution systems followed by the initiation of disinfection methods if indicated. Two unanticipated benefits were (1) cases of LD in the community and long-term care facilities were uncovered as a result of increased availability of *Legionella* tests and (2) litigation and unfavorable publicity involving ACHD hospitals ceased. (Am J Infect Control 2005;33:360-7.)

"If you don't look for it, you won't find it. If you don't find it, you don't think you have a problem. If you don't think you have a problem, you don't do anything about it."

Bruce Dixon MD, Director
Allegheny County Health Department
CNN & Time television program, November 1999

From the Allegheny County Health Department,[a] the Association for Professionals in Infection Control and Epidemiology, Three Rivers Chapter,[b] the Veterans Administration Pittsburgh Healthcare System,[c] and the University of Pittsburgh,[d] Pittsburgh, Pennsylvania.

Reprint requests: Victor L. Yu, MD, VA Medical Center, Infectious Disease Section, University Drive C, Pittsburgh, PA 15240. E-mail: vly+@pitt.edu.

doi:10.1016/j.ajic.2005.01.012

Since the early 1980s, it has been known that health care–acquired Legionnaires' disease occurs from exposure to *Legionella* in hospital water distribution systems.[1-3] As early as 1983, Pittsburgh investigators began advocating a proactive approach to prevention of health care–acquired Legionnaires' disease through active case detection and disinfection of the hospital water system.[4,5] This approach differed notably from that of the Centers for Disease Control and Prevention (CDC) by recommending routine environmental testing of the hospital water distribution system even if cases of health care–acquired Legionnaires' disease had never been discovered. In time, others would adopt this approach. Seven prospective studies have been performed in 52 hospitals in which cases of health care–acquired Legionnaires' disease had never been diagnosed. Environmental cultures for *Legionella* were performed on the water distribution systems of each of

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY JULY 2007, VOL. 28, NO. 7

ORIGINAL ARTICLE

Role of Environmental Surveillance in Determining the Risk of Hospital-Acquired Legionellosis: A National Surveillance Study With Clinical Correlations

Janet E. Stout, PhD; Robert R. Muder, MD; Sue Mietzner, MS; Marilyn M. Wagener, MS; Mary Beth Perri, BS; Kathleen DeRoos, MSN; Dona Goodrich, BS; William Arnold, MS; Theresa Williamson, MS; Ola Ruark, MSN; Christine Treadway, MSN; Elizabeth C. Eckstein, MSN; Debra Marshall, RN; Mary Ellen Rafferty, MS; Kathleen Sarro, RN; Joann Page, MS; Robert Jenkins, BA; Gina Oda, MS; Kathleen J. Shimoda, RN, BS; Marcus J. Zervos, MD; Marvin Bittner, MD; Sharon L. Camhi, MD; Anand P. Panwalker, MD; Curtis J. Donskey, MD; Minh-Hong Nguyen, MD; Mark Holodniy, MD; Victor L. Yu, MD; and the Legionella Study Group

OBJECTIVE. Hospital-acquired *Legionella* pneumonia has a fatality rate of 28%, and the source is the water distribution system. Two prevention strategies have been advocated. One approach to prevention is clinical surveillance for disease without routine environmental monitoring. Another approach recommends environmental monitoring even in the absence of known cases of *Legionella* pneumonia. We determined the *Legionella* colonization status of water systems in hospitals to establish whether the results of environmental surveillance correlated with discovery of disease. None of these hospitals had previously experienced endemic hospital-acquired *Legionella* pneumonia.

DESIGN. Cohort study.

SETTING. Twenty US hospitals in 13 states.

INTERVENTIONS. Hospitals performed clinical and environmental surveillance for *Legionella* from 2000 through 2002. All specimens were shipped to the Special Pathogens Laboratory at the Veterans Affairs Pittsburgh Medical Center.

RESULTS. *Legionella pneumophila* and *Legionella anisa* were isolated from 14 (70%) of 20 hospital water systems. Of 676 environmental samples, 198 (29%) were positive for *Legionella* species. High-level colonization of the water system (30% or more of the distal outlets were positive for *L. pneumophila*) was demonstrated for 6 (43%) of the 14 hospitals with positive findings. *L. pneumophila* serogroup 1 was detected in 5 of these 6 hospitals, whereas 1 hospital was colonized with *L. pneumophila* serogroup 5. A total of 633 patients were evaluated for *Legionella* pneumonia from 12 (60%) of the 20 hospitals: 377 by urinary antigen testing and 577 by sputum culture. Hospital-acquired *Legionella* pneumonia was identified in 4 hospitals, all of which were hospitals with *L. pneumophila* serogroup 1 found in 30% or more of the distal outlets. No cases of disease due to other serogroups or species (*L. anisa*) were identified.

CONCLUSION. Environmental monitoring followed by clinical surveillance was successful in uncovering previously unrecognized cases of hospital-acquired *Legionella* pneumonia.

Infect Control Hosp Epidemiol 2007; 28:818-824

Among cases of *Legionella* pneumonia that were reported to the Centers for Disease Control and Prevention (CDC) from 1980 to 1998, the percentage of cases identified as hospital-acquired ranged from 25% to 45%.[1] The hospital water system was identified as the source of these cases of *Legionella* pneumonia, most of which were caused by *Legionella pneumophila*.[2,3] Mortality associated with hospital-acquired *Legionella* pneumonia (28%) is approximately double the mortality for community-acquired cases (14%).[1]

The diagnosis of *Legionella* pneumonia cannot be made by

From the VA Pittsburgh Healthcare System (J.E.S., R.R.M., S.M., M.M.W.) and the University of Pittsburgh (J.E.S., R.R.M., S.M., M.M.W., V.L.Y.), Pittsburgh, and the Veterans Affairs Medical Center, Butler (K.S.), Pennsylvania; the William Beaumont Hospital, Royal Oak, Michigan (M.B.P., M.J.Z.); the Veterans Affairs Medical Center, Omaha, Nebraska (K.D., D.G., W.A., M.B.); the Southern Arizona Healthcare System, Tucson (T.W., S.L.C.); the Veterans Affairs Medical Center, Wilmington, Delaware (O.R., A.P.P.); the Louis Stokes Veterans Affairs Medical Center, Cleveland (C.T., E.C.E., C.J.D.), and the Veterans Affairs Medical Center, Dayton (D.M.), Ohio; the Stratton Veterans Affairs Medical Center, Albany, New York (M.E.R.); the Veterans Affairs Medical Center, Iowa City, Iowa (J.P.); the Veterans Affairs Medical Center, Gainesville, Florida (R.J., M.-H.N.); and the Veterans Affairs Palo Alto Health Care System, Palo Alto (G.O., M.H.), and the Veterans Affairs Medical Center, Long Beach (K.J.S), California. Members of the Legionella Study Group are listed at the end of the text.

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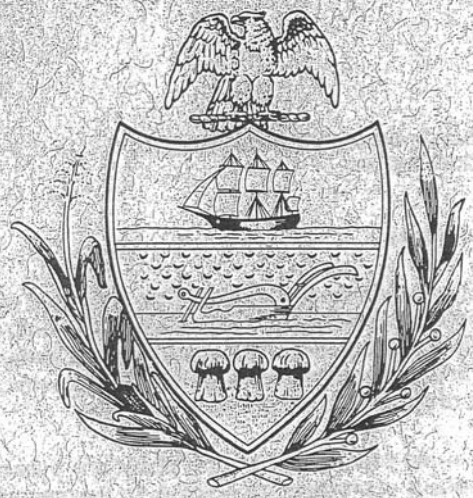
APPROACHES TO PREVENTION AND CONTROL OF LEGIONELLA INFECTION IN ALLEGHENY COUNTY HEALTH CARE FACILITIES



ALLEGHENY COUNTY HEALTH DEPARTMENT

APRIL, 1993

Central office

Stout, Janet E

From: Stout, Janet E
Sent: Thursday, May 19, 2005 9:02 AM
To: Herbers, Jerome (OIG)
Cc: 'Victor L. Yu'
Subject: RE: Pro-active LD prevention

Dear Dr. Herbers;

I am encouraged to have you and your office actively exploring the options available for preventing hospital-acquired Legionnaires' in our VA patient population. The "status quo" is woefully inadequate, as we have witnessed most recently in New York.

I will provide you with copies of two of our most recent manuscripts (one "in press" at the American Journal of Infection Control and one "in preparation"). Please note that we are sending these to you in confidence and the information contained in them should not be released until after their publication.

In addition, I will provide you with citations that will demonstrate the role of potable warm water distribution systems as the primary reservoir for transmission of hospital-acquired Legionnaires' disease (not cooling towers).

Do not hesitate to contact us again as you proceed in developing a more pro-active approach to this problem for the VA Healthcare System.

Sincerely,

Janet E. Stout, Ph.D.

-----Original Message-----
From: Herbers, Jerome (OIG) [mailto:Jerome.Herbers@va.gov]
Sent: Thursday, May 19, 2005 8:32 AM
To: Victor L Yu
Cc: janet stout
Subject: RE: 1:30 pm Wed May 16

Thank you very much for your time and counsel. You described well the challenges faced by a very large healthcare system in implementing preventive measures. All good intentions must compete for limited resources, and there are always numerous competing proposals. In that regard, as you say, the CDC recommendations may be an impediment in the case of prevention of Legionella infection.

I would very much appreciate your letting us know about any publications with strong evidence and/or a consensus of professional opinion. In the meantime, we will be looking at current VA cases and plan to keep the issue active at our end.

Jerry Herbers

Jerome E. Herbers, Jr., M.D.
Associate Director, Medical Consultation and Review
Office of the Inspector General (54)
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington DC 20420

From: "Herbers, Jerome (OIG)" <Jerome.Herbers@va.gov>
Subject: VA Legionnaire's Disease survey
Date: Tue, May 8, 2007 10:31 am
To: jes20@pitt.edu

Dr. Stout -

Thanks for your phone message. I pick up e-mail messages quickly, but sometimes miss voice messages for a while. I look forward to speaking with you and Dr. Yu about our survey results. I acknowledge that our efforts at moving VA healthcare facilities forward in LD prevention would not be possible without the advice you've generously given and, of course, without your pioneering work over the years.

Our report is now with VHA, which has another 2-3 weeks to develop a formal response and action plan. The report and response will subsequently be published for public access via the internet. Aside from this Friday, I have plenty of times available to speak by phone. Perhaps you could offer a time or two.

Yours,

Jerry Herbers

Download this as a file

Janet Stout

From: Herbers, Jerome (OIG) [Jerome.Herbers@va.gov]
Sent: Thursday, May 08, 2008 4:26 PM
To: Janet Stout
Subject: RE: VHA Legionella manuscript

Janet -
Thank you for the list of criteria for selecting labs for Legionella cultures. May I share it with Shantini Gamage in Cincinnati? She's the VA ID epidemiologist who worked on the new LD directive. I can anticipate a few questions and wonder how you would answer:
1. Is there an established external proficiency program?
2. Given that 2 years of experience might be an obstacle, could there be some mentoring or oversight mechanism during a probationary period?
3. Is it reasonable to have labs culture for Legionella, then refer positives elsewhere for speciation (or serogrouping)?
4. I assume that only a few labs could handle molecular analysis. What do you think of arranging for a single lab to be available for that eventuality?
- Jerry

-----Original Message-----
From: Janet Stout [mailto:jstout@specialpathogenslab.com]
Sent: Thursday, May 08, 2008 3:45 PM
To: Herbers, Jerome (OIG)
Subject: RE: VHA Legionella manuscript

Dr. Herbers;
I consider it a privilege to make a contribution. I look forward to working with you on the next draft.

On another subject, I'd like to address the objective criteria for selecting a laboratory for Legionella culture. We have had numerous discussions with VHA facilities trying to select a lab. I fear that the instruction in the Directive, although well intended, has given the wrong impression and may do some harm.

The Directive sets a minimum standard for an environmental microbiology lab that has no bearing on proficiency for Legionella testing. Competency in microbial testing of potable water does not ensure the ability of a laboratory to culture Legionella. Legionella testing requires a higher level of experience and skill. A clinical microbiology laboratory should not approach Legionella environmental cultures as if they were clinical Legionella cultures.

Listed below are objective minimum requirements for selecting a laboratory for Legionella testing:

1. Participation in an external proficiency program for Legionella environmental culture.

2. Internal quality control to validate the laboratory methods (positive and negative control water samples tested periodically)

3. A minimum of 2 years experience with performing Legionella environmental cultures.

4. The laboratory must be able to serogroup L. pneumophila and speciate Legionella.

5. A representative isolate from a positive hospital should be saved (frozen) for future molecular analysis if necessary.

Sincerely,

Janet

-----Original Message-----

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 2008-010

February 11, 2008

PREVENTION OF *LEGIONELLA* DISEASE

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes guidelines for the annual evaluation of *Legionella* risk at VHA inpatient facilities.

2. BACKGROUND

a. The Gram-negative bacterium, *Legionella*, causes respiratory diseases including *Legionella* pneumonia (traditionally known as Legionnaires' disease), hereafter abbreviated as "LD" for "*Legionella* disease." Disease is primarily caused by *Legionella pneumophila*; however other species of *Legionella* can be pathogenic, particularly in transplant and other immunocompromised patients. The bacteria, found naturally in water, have been associated with man-made reservoirs, such as building water distribution systems and cooling towers. Disease occurs after inhalation or aspiration of contaminated water, followed by an average incubation period of 2 to 10 days. The disease is not transmitted from person-to-person.

b. Health care facilities have been connected with the transmission of *Legionella* to patients. Such cases, often termed health care-associated (HCA) LD, frequently arise due to the presence of *Legionella* bacteria in hospital hot water distribution systems. However, HCA LD has also been associated with respiratory care equipment, ice machines, decorative fountains, hot tubs, and cooling towers. The Centers for Disease Control and Prevention (CDC) considers laboratory-confirmed cases to be "definite" HCA LD if continuous inpatient stay is equal to or greater than 10 days prior to onset of LD, or "possible" HCA LD if inpatient stay is 2 to 9 days prior to onset of LD.

c. Bone marrow and solid organ transplant patients are at increased risk for contracting HCA LD. Other at-risk patients include the immunocompromised (due to, for example, malignancy, renal disease, or diabetes), those over 65 years of age, those with chronic lung disease, and smokers.

d. Prevention of HCA LD depends on minimizing the exposure of patients to *Legionella* in facility water systems. A number of preventive measures are available including maintenance of appropriate hospital hot water temperatures to limit the growth of *Legionella*. Current evidence indicates that treatment of water with monochloramine or the addition of a copper-silver ionization system can reduce the amount of *Legionella* in facility water systems. Monitoring hospital water systems for *Legionella* and implementation of mitigation efforts, if necessary, can be an important component of a prevention plan to reduce HCA LD.

e. A multidisciplinary VHA Expert Working Group has developed guidance for the prevention of HCA LD at VHA inpatient facilities in response to the recommendations of the Department of Veterans Affairs Office of Inspector General in the 2007 Report, "Assessment of Legionnaire's Disease Risk in Veterans Health Administration Inpatient Facilities." The VHA

e. Heffelfinger JD, Kool JL, Fridkin S, Fraser VJ, Hageman J, Carpenter J, Whitney CG, Society for Healthcare Epidemiology of America. Risk of Hospital-acquired Legionnaires' Disease in Cities Using Monochloramine Versus Other Water Disinfectants. Infection Control and Hospital Epidemiology 24(8):569-574; 2003.

f. American Thoracic Society and Infectious Diseases Society of America. Guidelines for the management of adults with hospital-acquired, ventilator-associated, and health care-associated pneumonia. American Journal of Respiratory and Critical Care Medicine 171(4): 388-416; 2005.

g. Kelly AA, Danko LH, Kralovic SM, Simbartl LA, Roselle GA. *Legionella* in the Veterans Healthcare System: Report of an Eight-year Survey. Epidemiology and Infection 131(2):835-839; 2003.

h. Muder, RR. "Other *Legionella* Species" In: Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases, 6th ed. Vol. 2, Chapter 230, pgs. 2725-2730. Elsevier Churchill Livingstone, Philadelphia, PA; 2005

i. Stout JE, Muder RR, Mietzner S, Wagener MM, Perri MB, et al. Role of Environmental Surveillance in Determining the Risk of Hospital-acquired Legionellosis: A National Surveillance Study with Clinical Correlations. Infection Control and Hospital Epidemiology 28(7): 818-824; 2007.

j. Stout JE, Yu VL. Experiences of the First 16 Hospitals Using Copper-Silver Ionization for *Legionella* Control: Implications for the Evaluation of Other Disinfection Modalities. Infection Control and Hospital Epidemiology 24(8): 563-568; 2003.

k. Ta AC, Stout JE, Yu VL, and Wagener MM. Comparison of Culture Methods for Monitoring *Legionella* Species in Hospital Potable Water Systems and Recommendations for Standardization of Such Methods. Journal of Clinical Microbiology 33(8): 2118-2123; 1995.

l. World Health Organization (WHO). *Legionella* and the Prevention of Legionellosis. WHO Press; 2007 http://www.who.int/water_sanitation_health/emerging/legionella.pdf

6. FOLLOW-UP RESPONSIBILITY: The Chief Officer, Patient Care Services (11) is responsible for the contents of this Directive. Questions relating to the technical aspects of this Directive and to LD may be referred to the Infectious Diseases Program Office at (513) 475-6398. Questions relating to the Laboratory aspects of this Directive may be referred to the Pathology and Laboratory Medicine Service Line Director at (202) 273-8332. Questions regarding Engineering aspects of this Directive may be referred to the Director, Healthcare Engineering (10NB) at (202) 266-4604.

BIOGRAPHY FOR JANET E. STOUT

Dr. Stout received her BS in Biology from Clarion State College, Clarion, Pennsylvania; and her Master's and Ph.D. degrees in Microbiology from the University of Pittsburgh.

Dr. Stout is the Director of the Special Pathogens Laboratory in Pittsburgh, PA and concurrently a Research Associate Professor in the Department of Civil and Environmental Engineering University of Pittsburgh.

Dr. Stout discovered the link between the presence of *Legionella* bacteria in hospital water systems and the occurrence of hospital-acquired Legionnaires' disease while working at the Pittsburgh VA Medical Center. She was instrumental in the development of the prevention strategy that serves as the foundation for the VHA *Legionella* Directive. Dr. Stout gave the Professional Development Course on *Legionella* at the American Industrial Hygiene Association (AIHA) Conference in 2007.

She has authored approximately 80 peer review papers in the area of Legionnaires' disease, which include papers in the *New England Journal of Medicine, Journal of the American Medical Association,* the *Journal of Clinical Microbiology,* and the *Journal of the American Water Works Association.* Dr. Stout has also authored book chapters on Legionnaires' disease, including the *Legionella* chapter in the *Manual of Clinical Microbiology.*

Recent research projects include: Eradication of *Legionella* from hospital water systems by copper-silver ionization and chlorine dioxide and development of microbiological criteria for assessing risk of Legionnaires' disease.

Dr. Stout is a member of the American Society for Microbiology, the Association for Professionals in Infection Control, and the American Society of Heating, Refrigeration and Air-conditioning Engineers (ASHRAE).

Chairman MILLER. Thank you, Dr. Stout.

Dr. Yu.

STATEMENT OF DR. VICTOR L. YU, PROFESSOR OF MEDICINE, UNIVERSITY OF PITTSBURGH

Dr. YU. Thank you so much, Mr. Chairman, Congressman Rohrabacher and Congressman Broun for allowing us to tell you this terrible tragedy.

As you mentioned, I am Professor of Medicine at the University of Pittsburgh. I have been there since 1978, and during most of those years I was also Chief of the Infectious Disease Section at the Pittsburgh VA Medical Center. My CV is 51 pages long but I have published 600 papers and abstracts and written six textbooks of medicine. I have gotten many honors in my CV but I think I will only mention one. I received the Distinguished Research Award from the American Legion for our achievements and Janet's achievements in unraveling the mystery of how the disease was contracted and how the disease might be prevented and cured. That plaque honoring that achievement was in the lobby of the Pittsburgh VA Medical Center for many years, although I am told that it is no longer there.

The Special Pathogens Lab was established in 1980 and you gave sort of a good overview, and Dr. Stout listed its achievements, but it also made important discoveries in MRSA, methicillin-resistant *Staph aureus,* antibiotic-resistant bacteria, pneumonia, and urinary tract infections. We ultimately established collections of fungi and virtually all human pathogens of man that are commonplace. We established international collaborative studies with investigators in Africa, Australia, New Zealand, China, Hong Kong, Argentina, Brazil, Canada, Norway, Sweden, every inhabitable continent. Investigators interested in antibiotic-resistant bacteria contributed pathogens to our laboratory and in huge international collaborative attempts actually collected data from these patients and then sent

the isolates to one standard reference laboratory. Over 200 publications from these talented and prestigious investigative groups from France to Taiwan to Australia participated in this massive effort, which was a true international community effort.

When we first started in the early 1980s, we had one microbiologist and one graduate student named Janet E. Stout, and then over time the VA asked us to come under a mandate called the Special Clinical Resource Center. We became the Special Pathogens Lab of the entire Pittsburgh VA Center, and over the next 10 to 12 years we have evolved into five laboratory scientists headed by Dr. Stout. And then in 2006, inexplicably, Mr. Moreland, the director of the VA, terminated the laboratory. On Wednesday he came in, handed us a directive, the laboratory is closed. There was no forewarning of any sort. All five individuals, university employees who are scientists, were all terminated immediately. They lost their livelihood. No explanation was given. On July 12, one week later, I asked for a written explanation of why this happened. The effect was so stunning that we couldn't understand why it was done and I said it is morally imperative for you to place in writing why you terminated this laboratory of 20-plus years with all of its accomplishments and give us the reasons why so that we could respond. We couldn't even appeal because 48 hours later, all the personnel had to evacuate. They were told that if they left their personal belongings behind, they would never be able to retrieve them. And 48 hours later, the laboratory was padlocked. However, Mr. Moreland forgot one thing. We were processing specimens for patients in the ICU in addition to patients from medical centers all over the country. So if he terminated immediately, what about the patients at the VA Highland Drive, a few miles away? What about patients in the ICU a few floors away? So they reluctantly gave us 14 days but they gave me an order: no more specimens from anyplace else can be processed and tell everybody that you cannot have any more specimens processed. But we had 600 clients and they don't send us specimens every day. As outbreaks occur across the United States, public health departments who wonder if it is Legionnaires' disease send their specimens by Federal Express, and you can see the UPS and Federal Express trucks coming every day dropping off specimens, and now we have 10 to 14 days to process all these specimens. We couldn't contact 600 clients by fax. So now I had to make a decision. Should I not process these specimens, and since they gave us no reason for the closure, I sent an e-mail to Mr. Moreland and I said I have a difficult decision to make, Mr. Moreland you have told me I cannot process any of these specimens, and specimens from Bayside Hospital, Johns Hopkins-affiliated hospitals, Phoenix VA were coming in and they were thinking that maybe they had outbreaks of Legionnaires' disease. So I as a physician researcher placed an e-mail and said I have a conscience as a physician researcher. I can decide to disobey the order and know that I will be terminated as my laboratory colleagues were terminated or I can do my duty.

I did my duty. We processed those specimens. But we needed supplies and the supplies were kept by the security police from entering into the laboratory. Microscopes were taken from our laboratory, and there is documentation of all the disruptions. They held

a hearing, and the laboratory technicians had to leave their job and go to a witch hunt-type hearing, and they were told that if you don't come, maybe there is going to be problems, so they went to these hearings and then we had to process all these specimens that were coming in including patients in our own intensive care unit. So there was tremendous pressure on all of us. Janet Stout even ended up having to go to cardiac clinic because she was developing chest pains. But we worked hard on it. They rose to the occasion. When we ran out of supplies, the laboratory researchers pooled their own funds to buy supplies and bring them into the lab. If they had to go to the bathroom and they walked outside the door, the laboratory door fell shut. The security guard refused to let them in. They had to use their cell phones to call the lab people inside to let them in.

The work continued. And we had 15 specimens left from a government building, 14 hospitals and from a wife of a patient who died of Legionnaires' disease who was trying to find out if the source of her husband's *Legionella* came from their water supply, and in the appendix is the discussion of what she went through. She was in California and couldn't find a laboratory to do the processing, and then through a contact at one of the hospitals she ended up calling Janet Stout, who advised her what to do. She estimated that the cost from the other laboratories that she contacted would be over $2,000. Janet Stout said that she would do it for free, send us the specimens as soon as possible, but the timing was so bad. By the time she got to the specimens and Federal Expressed them to us, we planted the cultures. She wanted to know what the results were; so did we. Mr. Moreland said you cannot look at the culture results. We had processed all the specimens. All Janet had to do was look at the culture plate, and using dyes that were formulated by this Pittsburgh VA, we could tell if there was *Legionella,* and then using a microscope we could identify if it was *Legionella.* Fifteen specimens lined up on the counter. We asked for permission to go back into the hospital on day 11 after day 10 to give the results to these hospitals and to the wife. It was refused.

Over the next two weeks the specimens dried up. We don't know what the results were and we thought we lost it for the hospitals, but the Phoenix VA got lucky. Why? Because their specimens were the last specimens processed. They were interpreted and read and faxed. Sixty-five percent of the Phoenix VA water samples were positive for *Legionella.* They sent the specimens to us because they suspected an outbreak of Legionnaires' disease but there was controversy within the center that were these really *Legionella.* Well, maybe—we have a VA reference lab. If it is, we will look in the water. They found it. That was the last duty of the Pittsburgh VA Special Pathogens Laboratory.

Chairman MILLER. Dr. Yu, this is compelling testimony but could you summarize?

Dr. YU. Yes.

Chairman MILLER. Thank you.

Dr. YU. Okay. So the one question is, and I had to listen to it for all these years, the last two years, this is not approved research. It is not approved research, all these papers? And then two weeks ago I got from your committee a document that I had never

seen before and it says VA Pittsburgh Healthcare System Publication Audit. This was the document that Mr. Moreland used to say that we did unapproved research. All these Merit Review publications, that wasn't approved? So I looked at it, and this is one of the cleverest documents that man has ever contrived. A full description is in the Appendix, but I will give you the highlights. Six articles that had no documentation and this document is the documentation in Appendix B. Ten out of these 39 studies, all 39 studies, there is no documentation. Ten were observational studies, and under federal code do not have to be mandated by human rights review so they included these 10 studies that we had published. Seven studies that were not—that were published and not approved by the VA were studies from other hospitals. One of them was in Russia, and if a study is done in Russia, it doesn't need Pittsburgh VA IRB approval. Three studies had no patients in them, and if you do a study with no patients, you don't have to have human IRB approval. Every one of the 39 articles was legitimate.

So why are these microbes so important? Well, here is one example. One study came from published in *Chest.* It said there was no documentation, and in the Appendix, the documentation is there. Two other studies by Janet Stout said no documentation, and they were there. And what were those studies? We received a compound from Daiichi, Japan. We were looking for antibiotics that would cure Legionnaires' disease because the mortality was still high using existing antibiotics. Dr. Stout devised an intracellular model that you wouldn't have to use animals, so using that model, she found that this compound was highly active, more active than any compound we had ever seen. Then we recommended that it go into clinical trials. OrthoMcNeil developed a compound for clinical trials and it was given to several thousand patients in the United States with community pneumonia and hospitals all over the United States started sending their culture specimens to Janet Stout to see if they had Legionnaires' disease, and we found all these cases of Legionnaires' disease that no one would have suspected if they had not been sent to Dr. Stout.

And then we broke the code. What antibiotic did these patients receive? They received levofloxacin, the new name that OrthoMcNeil gave this compound. The mortality for Legionnaires' disease in this study was zero percent. Well no antibiotic is 100 percent effective. Four years later, in the largest outbreak ever to hit Europe, over 200 patients contracted Legionnaires' disease. The decision was made to give every single patient levofloxacin. Not a single patient died. Think about all the patients who died in the American Legion outbreak in 1976. Organisms that we had, Mr. Moreland destroyed all of these organisms. We now receive compounds from all over the world and we can't do the studies anymore and we can't devise a diagnostic test because of what Mr. Moreland did.

Thank you.

[The prepared statement of Dr. Yu follows:]

PREPARED STATEMENT OF VICTOR L. YU

Introduction

Academic credentials
Legionnaires' disease (LD)
Pneumonia
Bloodborne pathogens
MRSA
Antibiotic resistance

Encounter with Legionnaires' disease

Pittsburgh VA outbreak of hospital-acquired cases
High mortality
Unknown source
Outbreaks in VAs

Breakthrough discoveries

Culture media development and other tests
LD commonplace, but undiagnosed unless special tests done
Source discovered—drinking water of hospital

Establishment of Special Pathogens Lab (SPL)

Veterans Research Foundation (VRF) of Pittsburgh
Antibiotic studies
Diagnostic lab studies
Water disinfection studies
Development of experience and expertise
Lab space with intention of bringing in research funds to support VRF
Hiring of University employees
Special Clinical Resource Center with ability to bring in funding
Development of expertise—Five FTEs
University funds and equipment
Research M.D. fellows and graduate students

Advances in treatment and prevention of *Legionella*

Disinfection of hospital drinking water
Antibiotic cure

Expansion into other infectious diseases

Bloodborne pathogens—*Klebsiella*
Antibiotic-resistance microbes—MRSA
Pneumonia, Endocarditis, Urinary Tract Infections

SPL as mecca for infectious disease research

Visiting researchers
Grants
Large-scale collaborative studies
Breakthroughs in antibiotic resistance, bloodborne pathogens

Abrupt closure of SPL with two-days notice

No apparent reason for this drastic action
Refusal to process incoming specimens including Phoenix VA
Confiscation of university funds and equipment

Destruction of scientific collection

No warning
No explanation
VA response to Congressmen, lay media—

No research performed
Unlabeled specimens
Unapproved studies

Response to VA audit of unapproved studies

Discussion of specific studies showing value of collection
Levofloxacin
Klebsiella
MRSA

Introduction

My name is Dr. Victor Yu. I am a Professor of Medicine in the Division of Infectious Diseases at the University of Pittsburgh. I have been a University Professor since 1978 and most of that time was also Chief of the Infectious Disease section at the VA Medical Center, an affiliated teaching hospital of the University of Pittsburgh.

I have published widely on Legionnaires' disease, pneumonia, bloodborne pathogens, MRSA (Methicillin resistant *Staph. aureus*), antibiotic resistance, anal medical informatics. I have a background in mathematics and computer science so I have devised an idea of accumulating clinical information about patients, their laboratory values, their underlying diseases, the antibiotics that they received, and their outcome. I realized that having a computer database for thousands of patients would enable us to make statistical correlations about epidemiology and therapy In the era of antibiotic resistance and new emerging pathogens, such a database has been invaluable.

Using this approach, over .100 articles in different areas of infectious diseases have been published and led to therapeutic advances. I organized large international collaborative groups of physicians and scientists who have contributed patient information into the computer database as well as microbial pathogens that caused these infections. This treasure trove of computerized data plus a collection of human pathogens has led to many advances in management and diagnosis of very difficult infectious diseases.

Encounter with Legionnaires' Disease

After the American Legion outbreak in Philadelphia in 1976, it was soon discovered that other cases of Legionnaires' disease were occurring. As a junior assistant professor in 1979, I came across the first cases of hospital-acquired or nosocomial Legionnaires' disease. It had caused a serious problem at three VA Medical Centers: Wadsworth VA Medical Center in Los Angeles, the Pittsburgh VA Medical Center, and the Togus, Maine VA Medical Center: It was a shock to find out that it was being contracted by patients in the hospital.

Dr. Janet E. Stout, Ph.D., would soon make the startling discovery that the *Legionella* bacteria; the causative agent of Legionnaires' disease was in the driving water supply of the hospital. The prevailing theory at that time was that it was in cooling towers and air conditioners. Even today, many physicians are not aware that drinking water is the major source.

Because of this occurrence, we were given funding by VA Central Office to add a special microbiologist to the Infectious Disease staff to assist us. *Legionella* is a fastidious organism that requires expertise and special techniques to isolate. Dr. Susan Mather in VA Central Office (enclosed letter) oversaw the investigation into Legionnaires' disease.

One of the reasons we were given extra funding and assistance is that outbreaks were being described all over the world besides the VA Hospital, and we had formulated a culture media that microbiologists could identify *Legionella* by the coloration on the culture plates. This technical advance accelerated the ability to diagnose *Legionella* from patients and from the environment. Over the next many years, we would accomplish a number of things with respect to *Legionella,* microbiology and public health.

Dr. Stout has listed the advances made by the VA Special Pathogens Lab in her testimony which includes evaluating all the commercially available tests for Legionnaires' disease, evaluating all commercially available antibiotics for therapy of Legionnaires' disease, describing the clinical manifestations of Legionnaires' disease, and formulating the disinfection method of eradicating *Legionella* from drinking water.

HISTORY OF THE SPECIAL PATHOGENS LABORATORY

The Special Pathogens Lab was established in about 1980. Because of the large number of outbreaks that were occurring in Veterans Affairs Medical Centers, VA Central Office awarded two full-time employee slots to Pittsburgh to respond. During those early years, we pioneered the use of various tests and most importantly, formulated the culture media in which *Legionella* could be identified by color, thus

allowing the microbiologists to get preliminary identification of the *Legionella* by looking at a culture plate; a microscope was not needed. In the next several years, we became quite prolific in advances in Legionnaires' disease.

About 1984, we received our first VA Merit Review Grant dealing with Legionnaires' disease. About three years later, Martin Sax, then Chief of the Research and Development Committee, approached us and suggested that we become active members of the Veterans Research Foundation. Given our reputation, we could solicit funds from industry and other sources to supplement the funds coming into the Veterans Research Foundation. He offered us lab space as cuts in the VA budget were forcing many VA researchers to discontinue their studies. We agreed. We subsequently were able to bring in funds from foundations and industry for work on disinfection modalities, and antibiotic studies of a whole host of pathogens, including *Staphylococcus aureus* (MRSA), *Streptococcus pneumoniae, Enterococcus, Pseudomonas aeruginosa, Enterobacter, Stenotrophomonas maltophilia, Bacteroides,* and fungi (*Candida, Cryptococcus, Aspergillus*).

However, in subsequent years we branched out into pathogens of community-acquired pneumonia, urinary tract infections, abdominal abscesses, and endocarditis. We acquired expertise in antimicrobial resistance and published about 100 articles in this area. We were able to bring in hundreds of thousands of dollars into the Veterans Research Foundation which allowed them to gain critical mass and justify laboratory space.

In 1994, as the VA budget was being cut, VA Central Office sent out a solicitation to academic researchers about the possibility of using their capabilities to initiate laboratories for profit. This was based on a 1994 Special Clinical Resource Center memorandum. In 1996, the Director of the VA and Chief of Pathology agreed that designating the Special Pathogens Laboratory as Special Clinical Resource Center was feasible. And, in 1996, the Special Pathogens Lab went national.

Over the next many years our laboratory and clinical work continued. Funds were brought into the Veterans Research Foundation under grants I wrote as Professor of Medicine at the University of Pittsburgh. Five University employees including a CDC-trained microbiologist were brought in to handle the growing amount of research activity. New instrumentation, equipment and supplies awarded to the University of Pittsburgh was brought into the Special Pathogens Lab. All this equipment was tagged as University of Pittsburgh equipment.

In those early years, the VA budget was very thin and most VA laboratories were not only understaffed but their equipment was outdated. Since we were using microbiology equipment for research which also could be used to handle the clinical load, we outfitted the VA Clinical Microbiology Laboratory with modern equipment and furniture. This made our laboratory one of the best equipped laboratories in Pennsylvania, and both the research and patient care benefited.

Graduate students, infectious disease fellows, and visiting professors, came to the Special Pathogens Lab to our laboratory to learn new techniques and assist with clinical studies. Their participation led to many breakthroughs in infectious diseases over the next 12 years.

In 2006, inexplicably, the Special Pathogens Lab was shut down by Mr. Moreland, Director of the Pittsburgh VA. The specific reasons were never given to us as noted in my letter of July 12, 2006 (Appendix). We were given only 48 hours notice and the entire tab was to be shut down. All the Lab personnel were fixed, and the Lab was to be padlocked. Mr. Moreland had been in his position as Director of the Hospital for only a few years and some of the laboratory personnel had been there for more than 10 years and their livelihood and occupation was shattered with one 48-hour notice. It should be noted that this violated the provisions of the Special Clinical Resource Center memorandum which had guidelines to insure that patient care and other aspects would not suffer from abrupt lab closure.

However, Mr. Moreland overlooked the fact that we were processing specimens for the Pittsburgh VA Medical Center patients as well and reluctantly agreed to a two-week moratorium. During that time specimens from all over the country continued to come into the Special Pathogens Laboratory as usual.

We were ordered to notify all of our clients that the lab was being closed, but since we had 600 different clients including health departments and hospitals, faxing to 600 clients was impossible. Moreover we had two weeks to complete a huge workload. During this time, the laboratory personnel were harassed by security guards and administrators. Microscopes were removed. When the laboratory technician left the laboratory for breaks or lunch, the security guards refused to unlock the doors such that the personnel in the lab had to come out an open the doors for them. It was a Gestapo-like atmosphere and caused tremendous stress among the laboratory personnel. Yet, they accelerated their efforts in trying to process all the samples that were coming in.

Because the results were so important to the hospitals and health departments, we no longer had the time necessary to enter them into the computer, send out invoices, and so forth. Moreover, Mr. Moreland stopped the supplies from entering into our laboratory so that supplies which had been purchased were not allowed to be used and delivered to the personnel. Moreover, he refused to allow us to purchase materials for the specimens which included Pittsburgh VA patients to lie processed. The laboratory personnel pooled their own funds to buy these supplies.

They were true heroes working for the VA patients and the U.S. community. In the last two weeks, Mr. Moreland ordered me to stop accepting specimens from outside the University of Pittsburgh. I wrote to him that this was a Hobson's choice: Obey an administrative order from the Director or follow my conscience as a physician researcher and process specimens from patients, hospitals, and public health agencies. I decided to process these specimens and informed Mr. Moreland the reasons for doing so. One set of samples came from the Phoenix VA Medical Center. Sixty-five percent of the hospital drinking water specimens yielded *Legionella* and uncovered an endemic outbreak of Legionnaires' disease. This outbreak and the source would not have been identified if I had not continued to process the incoming water specimens.

During this time, the Lab personnel were not only harassed, but each was asked to give sworn testimony at an investigative hearing. This was done during their work hours and added to their stress.

The saga of what happened to the last 15 clients' specimens that were processed is a matter of record (See *www.legionella.org/vaspl.asp*). On the day of closure where the lab was to be padlocked, culture specimens from 15 clients remained to be read. They included hospitals, a government building, and samples from a patient's home. The lab successfully processed all these samples, but since they required 48 to 72 hours of incubation, they could not be read. The security guards would not allow staff into the laboratory. We made a plea to Mr. Moreland to allow the culture plates to be read. He refused. We made a plea to VA Central Office; they never replied. However, Senator Arlen Specter wrote a letter to Mr. Moreland on our behalf requesting that the final 15 culture samples be processed. He ignored that request. We offered to transport the VA cultures to another laboratory. Mr. Moreland refused. Those culture specimens dried out in the laboratory, were left unread, and ultimately trashed. The only thing that was needed to be done was to interpret the culture plates.

Ironically, in the 10 days after the closure, the *Pittsburgh Tribune Review* ran a front-page story of accomplishments of the Pittsburgh VA with the discovery of Legionnaires' disease. Because of the National Legion Convention was held in Pittsburgh that week, Congressmen from Pennsylvania attended. The American Legion knowing of our contacted Congressman Mike Doyle and Senator Arlen Specter; both of whom wrote letters of support. These letters were ignored by Mr. Moreland and VA Central Office.

The reasons they gave to the Congressmen and to the lay media are a matter of record. For example, Mr. Cowgill alleged we were not processing VA specimens but instead processing specimens from other countries. In letters from VA Central Office, William Feeley, Under Secretary, claimed we were not doing any research and that commercial labs could do the same work. These were outrageous exaggerations and untruths.

We have already furnished documentation showing errors and the difficulty of doing *Legionella* laboratory work. Experience, training and special equipment is necessary. We had become the premier reference laboratory for *Legionella* for the United States. Not only were visiting professors and scientists coming to the lab, but commercial laboratories sent their technicians to our laboratory to learn the correct technique as mandated by the American Society of Microbiology *Manual of Clinical Microbiology* written by Janet Stout and John D. Rihs. We did not charge for this teaching.

Response to VA Audit

In response to the outcry generated by the destruction of the scientific collection, the VA claimed that I had conducted non-approved research studies. The conducted an audit which was never shown or discussed with me. I obtained a copy of this audit from congressional investigators. In this biased audit of 39 articles and 11 projects, not a single study was found to be non-approved. The audit by the Pittsburgh VA administrators showed numerous errors that were obvious and blatant. Some examples:

Seven articles were cited as having no documentation for VA approval involved no VA patients and were not performed at the VA (one of these studies involved no patients whatsoever and would not be covered by human subject review).

Six articles were cited as having no documentation. Yet Appendix B contained the documentation for all of these articles.

Ten articles were cited as having no documentation were observational studies that did not fall under human subject research as defined by federal code. So no approvals were required.

Two articles were cited as having no documentation. However, the articles did not involve any patient contact or physician intervention, and therefore would not require human rights approval.

Three articles involved clinical trials and intervention which would require IRB and R&D approval. The audit showed that all three were approved.

Articles by Dr. Yu that were funded via VA Merit Review and would, of course, be approved by the VA R&D committee were not included in the audit.

In Appendix B, 11 Projects were reviewed. All 11 Projects were approved by R&D and/or IRB. Missing forms were cited, although it was clear that the studies were approved by R&D and IRB. Since approval was given, these forms were either lost by the R&D Committee or overlooked by the auditor.

For full details, see Appendix. Response to VA Publication Audit by Victor L. Yu.

The sheer number and the blatancy of these errors are consistent with a witch hunt conducted by a biased VA administration.

Klebsiella and Levofloxacin studies were cited inaccurately as unapproved. Details of the studies are summarized below.

Klebsiella—a virulent *Klebsiella* discovered by us in an international antibiotic resistance study was found in Taiwan but not elsewhere. In the past five years, patients who are Asian have been found to have a similar disease in the U.S. Two critically-ill patients were referred to us who were non-Asians and had not traveled outside of the U.S. Examination of the molecular type of these *Klebsiella* showed that were identical to the Taiwan *Klebsiella.* This *Klebsiella* is now in the U.S. Our entire collection of *Klebsiella* collected in two large-scale studies in the U.S. and all six inhabitable continents was destroyed. We lost the ability to compare the molecular characteristics of the *Klebsiella* in our collection with those of newly-infected patients. Study of our original collection and new *Klebsiella* would allow us to develop antibiotics and vaccines. (See Appendix—Approval from Request to Review Research Proposal for "Pathogenicity of *Klebsiella*")

Levofloxacin: Janet Stout found a new compound from OrthoMcNeil to be highly effective in the lab against *Legionella.* This compound was brought to clinical use and in the first trial of pneumonia, the compound cured an amazing 100 percent of patients with LD. This experience was reported and the compound was released as levofloxacin. Four years later, levofloxacin was used in a huge outbreak of LD in Spain. One hundred percent cure. All of our *Legionella* isolates were destroyed. (See Appendix—Response to publication audit. Project 9. Documentation of approval of "Levaquin Community-Acquired Pneumonia")

In summary, this massive collection of more than 8,000 microbes (5,000 *Legionella,* 300 species of other bacteria and fungi), 3,000 patient sera, and 202 patient specimens (urine, respiratory tract) was destroyed without warning. The VA administration never even confirmed that this collection had been destroyed despite repeated requests. The collection was unique in that the microbes and specimens were linked to the clinical histories of the patients who were infected by, these microbes.

VA Pittsburgh Healthcare System
Human Research Protection Program

PUBLICATION AUDIT

Project: For-Cause Publication Audit

Objective: The primary objective of this QA project was to determine whether Dr. Victor Yu was conducting research at the VA Pittsburgh Healthcare System (VAPHS) without appropriate Research & Development Committee (R&D) and Institutional Review Board (IRB) approval. Secondary objectives were to review all IRB and R&D records for which Dr. Yu was listed as a Principal Investigator and to identify the contents of six boxes of records from the Special Pathogens Laboratory.

Report Date: September 5, 2006
Barbara Strelec, Research Education and Compliance Coordinator

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I. METHODS

A. A PubMed search on the authors' name, Yu VL, was performed. Results were limited to manuscripts published in the last ten years.

Abstracts were reviewed to determine publication type. Letters, comments, editorials, case studies, and review articles were eliminated from consideration. For all other publications, the full-text article was obtained online where possible. Hard copies of articles that were not available online via the VAPHS library system were ordered from the library.

B. IRB and R&D records were reviewed to determine if appropriate committee approvals were obtained for the research protocols documented in the audited publications.

C. The contents of six boxes of records from the Special Pathogens Laboratory were examined to determine if research data was collected in compliance with the federal regulations and institutional policies.

II. RESULTS

There were 104 articles published in the last 10 years with Victor Yu listed as an author. Sixty-five were eliminated because they were review articles or published comments, editorials, case studies, or letters. Abstracts from the remaining 39 articles are given in Appendix A.

The following list of the 39 articles includes a statement regarding the institutional acknowledgement made by author Victor L. Yu, the dates during which the data was collected[1], whether or not the research appears to meet the federal definition of human subject research at 45 CFR 46.101 (f)[2], relevant quotes from the publication and a statement regarding the existence of VAPHS IRB or R&D documentation for the study.

1. **Endocarditis and pericarditis complicating pneumococcal bacteraemia, with special reference to the adhesive abilities of pneumococci: results from a prospective study.**
   Kan B, Ries J, Normark BH, Chang FY, Feldman C, Ko WC, Rello J, Snydman DR, **Yu VL,** Ortqvist A.
   Clin Microbiol Infect. 2006 Apr;12(4):338-44

   - Author Victor L. Yu acknowledged the Division of Infectious Disease, University of Pittsburgh.
   - Data collected between December 1998 and January 2001
   - Appears to meet the federal definition of human subject research
   - Data appears to be a sub-study of the research published in article #15
   - Article states "The local ethics committees at the participating hospitals approved the study." No mention of VAPHS lab or patients in methodology
   - VAPHS IRB records contain no documentation for this study

[1] Dates are provided to assist with any issues arising under the Health Insurance Portability and Accountability Act of 1996. This act became effective on April 14, 2003.
[2] Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposed. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects.

2. **Isolation of Staphylococcus aureus from the urinary tract: association of isolation with symptomatic urinary tract infection and subsequent staphylococcal bacteremia.**
   Muder RR, Brennen C, Rihs JD, Wagener MM, Obman A, Stout JE, **Yu VL**.
   Clin Infect Dis. 2006 May 15;42(10):1504-5.

   - Authors Robert R. Muder and Victor L. Yu acknowledged the Veterans Affairs Healthcare System and the University of Pittsburgh School of Medicine
   - Data collection dates not stated
   - Appears to meet the federal definition of human subject research
   - Article states "We performed a cohort study of 102 patients at a long-term care Veterans Affairs facility …"
   - VAPHS IRB records may contain documentation to support this research under an approved protocol for Dr. Robert Muder

3. **A proactive approach to prevention of health care-acquired Legionnaires'**
   disease: the Allegheny County (Pittsburgh) experience.
   Squier CL, Stout JE, Krsytofiak S, McMahon J, Wagener MM, Dixon B, **Yu VL**
   Am J Infect Control. 2005 Aug;33(6):360-7.

   - Author Victor L. Yu acknowledged the "Veterans Administration Pittsburgh Healthcare System" and the University of Pittsburgh
   - Data collected between 1999 and 2001
   - Does not appear to meet the federal definition of human subject research
   - VAPHS IRB and R&D records contain no documentation for this study

4. **Fluconazole MIC and the fluconazole dose/MIC ratio correlate with**
   therapeutic response among patients with candidemia.
   Clancy CJ, **Yu VL,** Morris AJ, Snydman DR, Nguyen MH.
   Antimicrob Agents Chemother. 2005 Aug;49(8):3171-7.

   - Author Victor L. Yu acknowledged the "Pittsburgh University Medical Center" and the VA Medical Center, Pittsburgh, Pennsylvania
   - Data collected in the early 1990's
   - Appears to meet the federal definition of human subject research
   - Article states "isolates were obtained from the blood streams of unique patients enrolled in a prospective multicenter study of candidemia."
   - VAPHS IRB and R&D records contain no documentation for this study

5. **Management of nonsevere pneumonia in military trainees with the urinary antigen test for Streptococcus pneumoniae: an innovative approach to targeted therapy.**
Guchev IA, **Yu VL**, Sinopalnikov A, Klochkov OI, Kozlov RS, Stratchounski LS
Clin Infect Dis. 2005 Jun 1;40(11):1608-16. Epub 2005 May 2.

- Author Victor L. Yu acknowledged the Infectious Disease Section, Veterans Affairs Medical Center and the University of Pittsburgh
- Data collection dates not stated
- Appears to meet the federal definition of human subject research
- Article states "This was a prospective, open label, controlled study. Urine samples were collected at visit 0 for detection of pneumococcal antigen by immunochromatography (BinaxNOW test:Binax)."
- Shirley Brinker (VA employee) acknowledged for secretarial assistance
- VAPHS IRB and R&D records contain no documentation for this study

6. **Comparative activity of quinolones, macrolides and ketolides against**
Legionella species using in vitro broth dilution and intracellular susceptibility testing.
Stout JE, Sens K, Mietzner S, Obman A, **Yu VL.**
Int J Antimicrob Agents. 2005 Apr;25(4):302-7.

- Author Victor L. Yu acknowledged the VA Pittsburgh Healthcare System, VA Medical Center, Infectious Disease Section
- Data collection dates not stated
- Does not appear to meet the federal definition of human subject research
- VAPHS R&D records contain no documentation for this study

7. **Antibiotic therapy for Klebsiella pneumoniae bacteremia: implications of production of extended-spectrum beta-lactamases.**
Paterson DL. Ko WC, Von Gottberg A, Mohapatra S, Casellas JM, Goossens H, Mulazimoglu L, Trenholme G, Klugman KP, Bonomo RA, Rice LB, Wagener MM, McCormack JG, **Yu VL.**
Clin Infect Dis. 2004 Jul 1;39(1):31-7. Epub 2004 Jun 8.

- Author Victor L. Yu acknowledged the Infectious Disease Section, VA Medical Center, Pittsburgh, Pennsylvania
- Data collected between January 1996 and December 1997
- Appears to meet the federal definition of human subject research
- Article states "The study was approved by institutional review boards, as required by the policies of participating hospitals at the time of the

study," and "We thank the staff and patients of the following hospitals for their participation in this study: Pittsburgh Veterans Affairs Medical Center (Pittsburgh)."
- VAPHS IRB and R&D records contain no documentation for this study

8. Levofloxacin efficacy in the treatment of community-acquired legionellosis.*
Yu VL, Greenberg RN, Zadeikis N, Stout JE, Khashab MM, Olson WH, Tennenberg AM.
Chest. 2004 Jun;125(6):2135-9

- * in title refers to the following acknowledgement: "From the VAMC and University of Pittsburgh (Drs. Yu and Stout), Pittsburgh, Pa"
- Data collection dates not stated
- This study does not appear to meet the federal definition of human subject research. The authors analyzed data from six previously published clinical trails.
- Article states "The Special Pathogens Laboratory at the VA Pittsburgh Healthcare System, Pittsburgh, PA, performed Legionella culture, urinary antigen, and serologic testing."
- VAPHS IRB and R&D records contain no documentation for this study

9. Combination antibiotic therapy lowers mortality among severely ill patients with pneumococcal bacteremia.
Baddour LM, **Yu VL,** Klugman KP, Feldman C, Ortqvist A, Rello J, Morris AJ, Luna CM, Snydman DR, Ko WC, Chedid MB, Hui DS, Andremont A, Chiou CC; International Pneumococcal Study Group.
Am J Respir Crit Care Med. 2004 Aug 15;170(4):440-4. Epub 2004 Jun 7.

- Author Victor L. Yu acknowledged the Division of Infectious Disease, University of Pittsburgh, Pittsburgh, Pennsylvania. Victor L. Yu also listed as a member of the Interantional Pneumococcal Study group: University of Pittsburgh and Veterans Affairs Medical Center, Pittsburgh, PA
- Data collected between December 1998 and December 2000
- Appears to meet the federal definition of human subject research
- Appears to be a sub-study of the research presented in Article #15
- VAPHS IRB and R&D records contain some documentation for this study (Appendix B1)

10. Similar hematologic effects of long-term linezolid and vancomycin therapy in a prospective observational study of patients with orthopedic infections.
Rao N, Ziran BH, Wagener MM, Santa ER, **Yu VL**.
Clin Infect Dis. 2004 Apr 15;38(8):1058-64. Epub 2004 Mar

- Author Victor L. Yu acknowledged the Division of Infectious Disease, Department of Medicine, University of Pittsburgh School of Medicine
- Data collected between November 1999 and December 2001
- Appears to meet the federal definition of human subject research
- VAPHS not mentioned in research methodology
- Article states "Written informed consent and institutional review board approval were not obtained because patients were treated according to local standards of care; no clinical interventions were made based on data collected."
- VAPHS IRB and R&D records contain no documentation for this study

11. International prospective study of Klebsiella pneumoniae bacteremia: implications of extended-spectrum beta-lactamase production in nosocomial Infections.
Paterson DL, Ko WC, Von Gottberg A, Mohapatra S, Casellas JM, Goossens H, Mulazimoglu L, Trenholme G, Klugman KP, Bonomo RA, Rice LB, Wagener MM, McCormack JG, Yu VL.
Ann Intern Med. 2004 Jan 6;140(1):I43.

- Victor L. Yu acknowledged as the corresponding author, Infectious Disease Section, Veterans Affairs Medical Center, Pittsburgh, PA
- Data collected between January 1996 and December 1997
- Appears to meet the federal definition of human subject research
- Article states "The study was approved by the institutional review boards as required by local hospital policy at the time of the study" and "The authors thank the staff and patients of the following hospitals for their participation: Pittsburgh Veterans Affairs Medical Center, Pittsburgh…".
- VAPHS IRB and R&D records contain no documentation for this study

12. Staphylococcus aureus bacteremia: recurrence and the impact of antibiotic treatment in a prospective mul ticenter study.
Chang FY, Peacock JE Jr, Musher DM, Triplett P, MacDonald BB, Mylotte JM, O'Donnell A, Wagener MM, **Yu VL.**
Medicine (Baltimore). 2003 Sep;82(5):333-9.

- Victor L. Yu acknowledged as the corresponding author, Infectious Disease Section, Veterans Affairs Medical Center, Pittsburgh, PA
- Data collected between August 1994 and March 1996
- Appears to meet the federal definition of human subject research
- Article states "Institutional review board review was performed at all hospitals as per local IRB requirements," and "From University of Pittsburgh and Veterans Affairs Medical Center, Pittsburgh Pennsylvania (FYC, MMW, VLY)"

- VAPHS IRB and R&D records contain no documentation for this study

13. A prospective multicenter study of Staphylococcus aureus bacteremia: incidence of endocarditis, risk factors for mortality, and clinical impact of methicillin resistance.
Chang FY, MacDonald BB, Peacock JE Jr, Musher DM, Triplett P, Mylotte JM, O'Donnell A, Wagener MM, **Yu VL**.
Medicine (Baltimore). 2003 Sep;82(5):322-32.

- Victor L. Yu acknowledged the VA Medical Center, Infectious Disease Section; he is also listed as the corresponding author
- Data collected between August 1994 and March 1996
- Appears to meet the federal definition of human subject research
- Article states "From March 1994 to March 1996, 505 consecutive patients in 6 hospitals (Presbyterian University Hospital; Montefiore University Hospital; Veterans Affairs Medical Center; Pittsburgh, PA…" and "Institutional review board review was performed at all hospitals as per local IRB requirements," and "From University of Pittsburgh and Veterans Affairs Medical Center, Pittsburgh Pennsylvania (FYC, MMW, **VLY**)"
- Research reported in Article #12 also cites this study
- VAPHS IRB and R&D records contain no documentation for this study

14. Experiences of the first 16 hospitals using copper-silver ionization for Legionella control: implications for the evaluation of other disinfection modalities.
Stout JE, **Yu VL**.
Infect Control Hosp Epidemiol. 2003 Aug;24(8):560-2

- Victor L. Yu acknowledged the Special Pathogens Laboratory, Veterans Affairs Medical Center; he is also listed as the corresponding author
- Data collected between 1995 and 2000
- Does not appear to meet the federal definition of human subject research
- VAPHS R&D files contain documentation for this study (Appendix B7)

15. An international prospective study of pneumococcal bacteremia: correlation with in vitro resistance, antibiotics administered, and clinical outcome.
Yu VL, Chiou CC, Feldman C, Ortqvist A, Rello J, Morris AJ, Baddour LM, Luna CM, Snydman DR, Ip M, Ko WC, Chedid MB, Andremont A, Klugman KP; International Pneumococcal Study Group.
Division of Infectious Disease, University of Pittsburgh, PA, USA.
vly+@pitt.edu
Clin Infect Dis. 2003 Jul 15;37(2):230-7. Epub 2003 Jul

- Author Victor L. Yu acknowledged the Division of Infectious Disease, University of Pittsburgh; he is also listed as the corresponding author
- Data collected between December 1998 and January 2001
- Appears to meet the federal definition of human subject research
- Article states "Institutional review board approval was obtained in accordance with local requirements" and "All isolates were frozen at -70 degrees C and then sent to the Veterans Affairs Pittsburgh Special Pathogens Laboratory…"
- The research reported in this article appears to be the parent study for the data reported in Articles #1 and #9
- VAPHS IRB and R&D files contain some documentation for this study (Appendix B1)

16. Community-acquired Klebsiella pneumoniae bacteremia: global differences in clinical patterns.
Ko WC, Paterson DL, Sagnimeni AJ, Hansen DS, Von Gottberg A, Mohapatra S, Casellas JM, Goossens H, Mulazimoglu L, Trenholme G, Klugman KP, McCormack JG, **Yu VL**
Emerg Infect Dis. 2002 Feb;8(2):160-6.

- Author Victor L. Yu acknowledged the Veterans Administration Medical Center and University of Pittsburgh; he is also listed as the corresponding author
- Data collected between January 1996 and December 1997
- Appears to meet the federal definition of human subject research
- Article states "A prospective study of consecutive patients with community-acquired K pneumoniae bacteremia was perfomed in 12 hospitals-Pittsburgh Veterans Affairs Medical Center…" and "The protocol was reviewed and approved by the Institutional Review Boards according to local requirements".
- VAPHS IRB and R&D files contain no documentation for this study

17. The role of topical antibiotic prophylaxis in patients undergoing contaminated head and neck surgery wi th flap reconstruction.
Simons JP, Johnson JT, **Yu VL**, Vickers RM, Gooding WE, Myers EN, Pou AM, Wagner RL, Grandis JR.
Department of Otolaryngology, University of Pittsburgh School of Medicine, University of Pittsburgh Cancer Institute, Pennsylvania 15213, USA.
Laryngoscope. 2001 Feb;111(2):329-35

- No acknowledgement of VAPHS in this article
- Data collection dates unknown
- Appears to meet the federal definition of human subject research
- Appears to be a "university only" study

- VAPHS IRB and R&D records contain no documentation for this study

18. Topical antibiotic prophylaxis for bacteremia after dental extractions.
Vergis EN, Demas PN, Vaccarello SJ, **Yu VL.**
Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 2001 Feb;91(2):162-5.

- Author Victor L. Yu acknowledged the Division of Infectious Diseases, Department of Oral and Maxillofacial Surgery, Veterans Affairs Medical Center, University of Pittsburgh; he is also listed as the corresponding author
- Data collection dates not stated
- Appears to meet the federal definition of human subject research
- Article states "The study included 36 patients ….. reflecting the Veterans Affairs Medical Center population."
- VAPHS IRB records contain some documentation for this study (Appendix B5)

19. Unexpected similarity of pulsed-field gel electrophoresis patterns of unrelated clinical isolates of Legionella pneumophila, serogroup 1.
Drenning SD, Stout JE, Joly JR, **Yu VL.**
J Infect Dis. 2001 Feb 15;183(4):628-32. Epub 2001 Jan 11.

- Author Victor L. Yu acknowledged the Department of Medicine, University of Pittsburgh School of Medicine, and Veterans Administration Pittsburgh Healthcare System
- Data collected from 1983 through 1996
- It is unclear if this study meets the federal definition of human subject research. There is no evidence in the article to suggest that individually identifiable private information was collected, however, it is not explicitly stated that the data was de-identified.
- Article states "..isolates were either recovered by or submitted to the Special Pathogens Laboratory of the VA Medical Center (Pittsburgh, Pennsylvania)
- VAPHS IRB and R&D records contain no documentation for this study

20. Staphylococcus aureus and other bacteremias in hemodialysis patients: antibiotic therapy and surgical removal of access site.
Lentino JR, Baddour LM, Wray M, Wong ES, **Yu VL.**
Infection. 2000 Nov-Dec;28(6):355-60

- Author Victor L. Yu acknowledged the VA Medical Center, Pittsburgh, PA; he is also listed as the corresponding author
- Data collection dates not stated

- Appears to meet the federal definition of human subject research
- Article states "This study was conducted at six university affiliated teaching hospitals in the United States: Pittsburgh VA Medical Center…"
- VAPHS IRB and R&D records contain no documentation for this study

21. Short-course empiric antibiotic therapy for patients with pulmonary infiltrates in the intensive care unit. A proposed solution for indiscriminate antibiotic prescription.
Singh N, Rogers P, Atwood CW, Wagener MM, **Yu VL.**
Am J Respir Crit Care Med. 2000 Aug;162(2 Pt 1):505-11

- Author Victor L. Yu acknowledged the Veterans Affairs Medical Center and University of Pittsburgh; he is also listed as the corresponding author
- Data collection dates not stated
- Appears to meet the federal definition of human subject research
- Article states "study was conducted in the surgical and medical ICUs of a tertiary care university-affiliated Veteran Affairs Medical Center" and "the study was approved by the institutional review board, and all patients or next of kin gave written informed consent".
- VAPHS IRB and R&D records contain no documentation for this study listing Victor Yu, MD as a Principal Investigator. This appears to be part of a protocol that was conducted under Dr. N. Singh and there are associated IRB and R&D records containing documentation related to this study.

22. Antimicrobial resistance and clinical outcome of Bacteroides bacteremia: findings of a multicenter prospective observational trial.
Nguyen MH, **Yu VL,** Morris AJ, McDermott L, Wagener MW, Harrell L, Snydman DR.
Clin Infect Dis. 2000 Jun;30(6):870-6. Epub 2000 Jun 13

- Author Victor L. Yu acknowledged the Department of Medicine, Veterans Administration Hospital and University of Pittsburgh School of Medicine
- Data collected between January 1991 and May 1995
- Appears to meet the federal definition of human subject research
- Article states "We performed a prospective observational multicenter study of bacteremia due to Bacteroides species at 3 university tertiary care centers: …and University of Pittsburgh Medical Center (Presbyterian University Hospital, Montefiore University Hospital, and Veterans Affairs Medical Center, Pittsburgh)
- VAPHS IRB and R&D records contain no documentation for this study

23. Azithromycin vs cefuroxime plus erythromycin for empirical treatment of community-acquired pneumonia in hospitalized patients: a prospective, randomized, multicenter trial.
Vergis EN, Indorf A, File TM Jr, Philli ps J, Bates J, Tan J, Sarosi GA, Grayston JT, Summersgill J, YU VL.
Arch Intern Med. 2000 May 8;160(9):1294-300

- Author Victor L. Yu acknowledged the Infectious Disease Sections, Veterans Affairs Medical Center and University of Pittsburgh; he is also listed as the corresponding author
- Dated collected between 1994 and 1996
- Appears to meet the federal definition of human subject research
- Article states "The study was approved by each center's institutional review board, and written informed consent was obtained from all patients" and "This prospective randomized, comparative, multicenter study was conducted from 1994 to 1996 at 4 medical centers: the Veterans Affairs Healthcare Systems in Little Rock, Ark., and Pittsburgh, Pa...."
- VAPHS IRB and R&D records contain some documentation for this study (Appendix B4)

24. Epidemiology of ciprofloxacin resistance and its relationship to extended-spectrum beta-lactamase production in Klebsiella pneumoniae isolates causing bacteremia.
Paterson DL, Mulazimoglu L, Casellas JM, Ko WC, Goossens H, Von Gottberg A, Mohapatra S, Trenholme GM, Klugman KP, McCormack JG, **Yu VL.**
Clin Infect Dis. 2000 Mar;30(3):473-8

- Author Victor L. Yu acknowledged the Infectious Disease Section, Veterans Affairs Medical Center; he is also listed as the corresponding author
- Data collected between January 1996 and December 1997; data from this study was also reported in Articles #7, #11 and #16
- It is unclear if this study meets the federal definition of human subject research. There is no evidence in the article to suggest that individually identifiable private information was collected, however, it is not explicitly stated that the data was de-identified.
- Article states "Isolates were then sent to a central study laboratory in Pittsburgh"
- VAPHS IRB and R&D records contain no documentation for this study

25. Nasal carriage of and infection with Staphylococcus aureus in HIV-infected patients.

Nguyen MH, Kauffman CA, Goodman RP, Squier C, Arbeit RD, Singh N, Wagener MM, **Yu VL**.
Ann Intern Med. 1999 Feb 2;130(3):221-5

- Author Victor L. Yu acknowledged the University of Pittsburgh Medical Center; he is also listed as the corresponding author
- Data collection dates not stated
- Appears to meet the federal definition of human subject research
- Article states "We enrolled all HIV-infected patients seen in the outpatient clinics of three acute care Veterans Affairs Medical Centers (….and Pittsburgh, Pennsylvania)
- VAPHS IRB and R&D records contain no documentation for this study

26. Pulmonary infiltrates in the surgical ICU*: prospective assessment of predictors of etiology and mortality.
Singh N, Falestiny MN, Rogers P, Reed MJ, Pularski J, Norris R, **Yu VL.**
Chest. 1998 Oct;114(4):1129-36

- Author Victor L. Yu acknowledged the Veterans Affairs Medical Center
- Data collection dates not stated
- Appears to meet the federal definition of human subject research
- Article states "Data were collected by critical care and infectious disease collaborators at the Pittsburgh VA Medical Center…."
- VAPHS IRB and R&D records contain no documentation for this study with Victor Yu, MD as the PI. However, the study may have received approval under a protocol submitted by Dr. Singh.

27. Activity of azithromycin, clarithromycin, roxithromycin, dirithromycin, quinupristin/dalfopristin and erythromycin against Legionella species by intracellular susceptibility testing in HL-60 cells.
Stout JE, Arnold B, **Yu VL.**
J Antimicrob Chemother. 1998 Feb;41(2):289-91

- Author Victor L. Yu acknowledged the Special Pathogens Laboratory, Veterans Affairs Medical Center, and The University of Pittsburgh School of Medicine; he is also listed as the corresponding author
- Data collection dates not stated
- Does not appear to meet the federal definition of human subject research
- Appears to be lab work on a commercial cell line
- VAPHS R&D records contain no documentation for this study

28. Nosocomial legionnaires' disease discovered in community hospitals following cultures of the water system: seek and ye shall

find.
Goetz AM, Stout JE, Jacobs SL, Fisher MA, Ponzer RE, Drenning S, **Yu VL.**
Veterans Administration Medical Center and Legionella Study Group, Pittsburgh, PA 15240, USA.
Am J Infect Control. 1998 Feb;26(1):8-11

- Full text article not available online, ordered from the PITT Health Sciences Library; receipt pending
- Data collection dates unknown
- It is not clear from the abstract if this study meets the federal definition of human subject research
- VAPHS R&D records contain some documentation for this study (Appendix B7)

29. Comparative activity of ciprofloxacin, ofloxacin, levofloxacin, and erythromycin against Legionella species by broth microdilution and intracellular susceptibility testing in HL-60 cells.
Stout JE, Arnold B, **Yu VL.**
Special Pathogens Laboratory, Veterans Affairs Medical Center, Pittsburgh, Pennsylvania, USA
Diagn Microbiol Infect Dis. 1998 Jan;30(1):37-43

- Full text article not available online, ordered from the PITT Health Sciences Library; receipt pending
- Data collection dates unknown
- According to the abstract this study does not meet the federal definition of human subject research
- VAPHS R&D records contain no documentation for this study

30. Do in vitro susceptibility data predict the microbiologic response to amphotericin B? Results of a prospective study of patients with Candida fungemia.
Nguyen MH, Clancy CJ, **Yu VL**, Yu YC, Morris AJ, Snydman DR, Sutton DA, Rinaldi MG
J Infect Dis. 1998 Feb;177(2):425-30

- Full text article not available online, ordered from the VAPHS library holdings; receipt pending
- Data collection dates unknown
- According to the abstract, this study does appear to meet the federal definition of human subject research
- VAPHS R&D records contain no documentation for this study

31. Intermittent use of copper-silver ionization for Legionella control in water distribution systems: a potential option in buildings housing individuals at low risk of infection.

Liu Z, Stout JE, Boldin M, Rugh J, Diven WF, **Yu VL.**
University of Pittsburgh, Pennsylvania, USA
Clin Infect Dis. 1998 Jan;26(1):138-40

- Full text article not available online, ordered from the VAPHS library holdings; receipt pending
- Data collection dates unknown
- According to the abstract, this study does not appear to meet the federal definition of human subject research
- VAPHS R&D records contain some documentation for this study (Appendix B7)

32. Invasive aspergillosis in liver transplant recipients in the 1990s.
Singh N, Arnow PM, Bonham A, Dominguez E, Paterson DL, Pankey GA, Wagener MM, **Yu VL.**
Veterans Affairs Medical Center and University of Pittsburgh, Pennsylvania 15240, USA
Transplantation. 1997 Sep 15;64(5):716-20

- Full text article not available online, ordered from the VAPHS library holdings; receipt pending
- Data collection dates unknown
- According to the abstract, this study does appear to meet the federal definition of human subject research
- VAPHS IRB and R&D records contain no documentation for this study with Victor Yu, MD as the PI. However, the study may have received approval under a protocol submitted by Dr. Singh.

33. Cirrhotic fever in the 1990s: a prospective study with clinical implications.
Singh N, **Yu VL**, Wagener MM, Gayowski T.
Veterans Affairs Medical Center, Pittsburgh, Pennsylvania 15240, USA.
Clin Infect Dis. 1997 Jun; 24(6):1135-8

- Full text article not available online, ordered from the VAPHS library holdings; receipt pending
- Data collection dates unknown
- According to the abstract, this study does appear to meet the federal definition of human subject research

- VAPHS IRB and R&D records contain no documentation for this study with Victor Yu, MD as the PI. However, the study may have received approval under a protocol submitted by Dr. Singh.

34. Lack of serologic evidence for Helicobacter pylori infection in head and neck cancer.
Grandis JR, Perez-Perez GI, **Yu VL**, Johnson JT, Blaser MJ.
Department of Otolaryngology, University of Pittsburgh School of Medicine, Pennsylvania 15213, USA
Head Neck. 1997 May;19(3):216-8

- Full text article not available online; will order from the PITT Health Sciences Library
- Author Victor L. Yu acknowledged the Department of Medicine, University of Pittsburgh School of Medicine; it appears that this is a "university only" study
- Data collection dates unknown
- According to the abstract, this study appears to meet the federal definition of human subject research
- VAPHS IRB and R&D records contain no documentation for this study

35. Psychological stress and depression in older patients with intravenous drug use and human immunodeficiency virus infection: implications for intervention.
Singh N, Squier C, Sivek C, Wagener MM, **Yu VL.**
VA Medical Center, Infectious Disease Section, Pittsburgh, PA 15240, USA.
Int J STD AIDS. 1997 Apr;8(4):251-5

- Author Victor L. Yu listed as the corresponding author
- Data collected between December 1990 and July 1994
- Appears to meet the federal definition of human subject research
- Article states "All patients with HIV followed at the Pittsburgh VA Medical Center were eligible for entry.... All patients signed an informed consent prior to study entry"
- VAPHS IRB and R&D records contain no documentation for this study with Victor Yu, MD as the PI. However, the study may have received approval under a protocol submitted by Dr. Singh.

36. Analysis of trends in antimicrobial resistance patterns among clinical isolates of Bacteroides fragilis group species from 1990 to 1994.
Snydman DR, McDermott L, Cuchural GJ Jr, Hecht DW, Iannini PB, Harrell LJ, Jenkins SG, O'Keefe JP, Pierson CL, Rihs JD, **Yu VL**,

Finegold SM, Gorbach SL.
Department of Medicine, New England Medical Center, Tufts University School of Medicine, Boston, Massachusetts 02111, USA
Clin Infect Dis. 1996 Dec;23 Suppl 1:S54-65

- Full text article not available online; ordered from the VAPHS library holdings; receipt pending
- Data collected between 1990 and 1994
- According to the abstract, study does not appear to meet the federal definition of human subject research
- VAPHS IRB and R&D records contain no documentation for this study

37. Low-dose fluconazole as primary prophylaxis for cryptococcal infection in AIDS patients with CD4 cell counts of < or = 100/mm3: demonstration of efficacy in a positive, multicenter trial.
Singh N, Barnish MJ, Berman S, Bender B, Wagener MM, Rinaldi MG, **Yu VL.**
Veterans Affairs Medical Center, Pittsburgh, Pennsylvania, USA
Clin Infect Dis. 1996 Dec;23(6):1282-6

- Full text article not available online; ordered from the VAPHS library holdings, receipt pending
- Data collection dates unknown
- According to the abstract, study does appear to meet the federal definition of human subject research
- VAPHS IRB and R&D records contain no documentation for this study with Victor Yu, MD as the PI. However, the study may have received approval under a protocol submitted by Dr. Singh.

38. Nosocomial Legionnaires' disease caused by Legionella pneumophila serogroup 5: laboratory and epidemiologic implications.
Chang FY, Jacobs SL, Colodny SM, Stout JE, **Yu VL.**
Special Pathogen Laboratory, YA Medical Center, Pittsburgh, PA 15240, USA.
J Infect Dis. 1996 Nov;174(5):1116-9

- Full text article not available online; ordered from the VAPHS library holdings, receipt pending
- Data collection dates unknown
- According to the abstract, study does appear to meet the federal definition of human subject research
- VAPHS R&D records contain some documentation for this study (Appendix B7)

39. In vitro activities of two novel oxazolidinones (U100592 and U100766), a new fluoroquinolone (trovafloxacin), and dalfopristin-quinupristin against Staphylococcus aureus and Staphylococcus epidermidis.

Mulazimoglu L, Drenning SD, **Yu VL**.
Section of Infectious Diseases, Marmara University School of Medicine, Istanbul, Turkey
Antimicrob Agents Chemother. 1996 Oct;40(10):2428-30

- Author Victor L. Yu acknowledged the Veterans Affairs Medical Center and the University of Pittsburgh; he is also listed as the corresponding author
- Data collected from 1991 through 1994
- Appears to meet the federal definition of human subject research
- Article states "A total of 283 staphylococci, isolated between 1991 and 1994 from patients of the Veterans Affairs Medical Center, Pittsburgh, Pa."
- VAPHS IRB and R&D records contain no documentation for this study

III. CONCLUSIONS

A. Publication Audit

Twenty eight[3] of the thirty nine audited articles document research that appears to meet the definition of human subject research according to the federal code.

> Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects. **45 CFR 46.102(f).**

Of the twenty eight articles that reported data from human subject research, only four[4] have **some** IRB/R&D documentation with Dr. Yu listed as the principal investigator.

[3] Articles 1, 2, 4, 5, 7, 9, 10, 11, 12, 13, 15, 16, 17, 18, 20, 21, 22, 23, 25, 26, 30, 32, 33, 34, 35, 37, 38, 39
[4] Articles 15, 18, 23, 38

However, an additional seven articles in this category may report research conducted under an approved protocol of one of the co-authors. Giving the benefit of doubt to Dr. Yu, it appears that no IRB/R&D documentation exists for research reported in at least 17 manuscripts.

Eleven articles reported research that did not or may not meet the federal definition of human subject research[5]. Of these eleven, only three[6] have some R&D documentation with Dr. Yu listed as the principal investigator.

> The Office of Human Research Protections (OHRP) guidance states that private information or specimens are individually identifiable when they can be linked to specific individuals by the investigator either directly or indirectly through coding systems. Research involving only coded private information or specimens does not constitute human subject research if both of the following conditions are met:
> - The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals, and
> - The investigator cannot readily ascertain the identity of the individual to whom the coded private information or specimens pertain.

Additional details regarding the studies in this category are required to state with certainty whether or not the investigator was engaged in human subject research.

section deleted

The Federal Policy for the Protection of Human Subjects (Common Rule) codified by the Department of Health and Human Services at 45 CFR 46 and by the Veterans Administration at 38 CFR 16 in January 1991 governed the research studies reported in the audited publications. Based on these regulations, this publication audit suggests a strong likelihood that Dr. Yu was engaged in human subject research at the VAPHS without the appropriate committee approvals.

B. IRB/R&D Record Review

Please see Appendix B. This information was complied by the IRB coordinator and is self-explanatory. Where applicable, this appendix was referenced in the individual article review above. It is uncertain if the VAPHS Office of Research is in possession of all pertinent research records due to the move from the University Drive facility in July 2005.

C. Special Pathogens Laboratory Record Review

A review of the records (Appendix C) contained in the six boxes from the Special Pathogens Laboratory suggest that research data was not collected in compliance with the federal guidelines. It appears that some data was collected and some specimens were stored with either identifiers or a linkage code. Informed consent documents were found

[5] Articles 3, 6 ,8, 14, 19, 24, 27, 28, 29, 31 36
[6] Articles 14, 28, 31

for only one study. It is possible that consent forms were placed in the subject's medical record or elsewhere. The data collection forms in these boxes do not all indicate the study for which the data was collected, therefore, it is difficult to link the data to the studies mentioned in the audited publications.

IV. SUMMARY:

In summary, the publication audit has shown the following findings:

1. There is evidence showing that Dr. Yu has conducted human subjects research activities without prior IRB and R&D Committee approvals. It does not appear that any human subjects were subject to harm or injury as most studies involved in vitro testing of human subject specimens or observation of disease processes.
2. The protocols found under Dr. Yu's name with some evidence of IRB and/or R&D Committee review all had missing documentation of required reviews, including lack of continuing review, lack of study closure, and lack of final R&D Committee approvals.
3. Due to Dr. Yu's termination, all active studies under his name are administratively closed as of 9/5/2006.

Appendix A
Publication Abstracts

Items 1 - 39 of 39

☐ **1:** Clin Microbiol Infect. 2006 Apr;12(4):338-44. Related Articles, Books, LinkOut

Full text
blackwell-synergy.com

Endocarditis and pericarditis complicating pneumococcal bacteraemia, with special reference to the adhesive abilities of pneumococci: results from a prospective study.

Kan B, **Ries J**, **Normark BH**, **Chang FY**, **Feldman C**, **Ko WC**, **Rello J**, **Snydman DR**, **Yu VL**, **Ortqvist A**.
Unit of Infectious Diseases, Department of Medicine, Karolinska Institutet, Karolinska University Hospital, Solna, Sweden.

The incidence of pneumococcal cardiac infections is unknown and the pathogenicity of such complications is poorly understood. In a prospective, international, observational study, eight of 844 patients hospitalised with Streptococcus pneumoniae bacteraemia developed endocarditis (n = 5) or pericarditis (n = 3). The clinical and microbiological characteristics of these patients were compared with those of control patients. The corresponding incidence of pneumococcal endocarditis was c. 1-3/1 million inhabitants/year. There was no common pattern in the medical history of patients with an infectious cardiac complication. The severity of illness upon admission was comparable with that for patients without infectious cardiac complications, as was the 14-day mortality rate (25% and 17%, respectively). For encapsulated S. pneumoniae, no significant differences were found between patients with infectious cardiac complications and controls in adherence assays. However, non-encapsulated S. pneumoniae showed higher hydrophobicity and increased adherence to human epithelial cells.

Publication Types:

- Multicenter Study
  PMID: 16524410 [PubMed - indexed for MEDLINE]

2: Clin Infect Dis. 2006 Jan 1;42(1):46-50. Epub 2005 Nov 23.

Related Articles, Books, LinkOut

The University of Chicago Press Pittsburgh Print Collection

Comment in: Clin Infect Dis. 2006 May 15;42(10):1504-5.

Isolation of Staphylococcus aureus from the urinary tract: association of isolation with symptomatic urinary tract infection and subsequent staphylococcal bacteremia.

Muder RR, **Brennen C**, **Rihs JD**, **Wagener MM**, **Obman A**, **Stout JE**, **Yu VL**.
Veterans Affairs Pittsburgh Healthcare System, Pittsburgh, PA 15240, USA.
Robert.Muder@med.va.gov

BACKGROUND: Staphylococcus aureus is frequently isolated from urine samples obtained from long-term care patients. The significance of staphylococcal bacteriuria is uncertain. We hypothesized that S. aureus is a urinary pathogen and that colonized urine could be a source of future staphylococcal infection. METHODS: We performed a cohort study of 102 patients at a long-term care Veterans Affairs facility for whom S. aureus had been isolated from clinical urine culture. Patients were observed via urine and nasal cultures that were performed every 2 months. We determined the occurrence of (1) symptomatic urinary tract infection concurrent with isolation of S. aureus (by predetermined criteria), (2) staphylococcal bacteremia concomitant with isolation of S. aureus from urine, and (3) subsequent episodes of staphylococcal infection. RESULTS: Of 102 patients, 82% had undergone recent urinary catheterization. Thirty-three percent of patients had symptomatic urinary tract infection at the time of initial isolation of S. aureus, and 13% were bacteremic. Eight-six percent of the initial urine isolates were methicillin-resistant S. aureus. Seventy-one patients had follow-up culture data; 58% of cultures were positive for S. aureus at > or =2 months (median duration of staphylococcal bacteriuria, 4.3 months). Sixteen patients had subsequent staphylococcal infections, occurring up to 12 months after initial isolation of S. aureus; 8 late-onset infections were bacteremic. In 5 of 8 patients, the late blood isolate was found to have matched the initial urine isolate by pulsed-field gel electrophoresis typing. CONCLUSIONS: S. aureus is a cause of urinary tract infection among patients with urinary tract catheterization. The majority of isolates are methicillin-resistant S. aureus. S. aureus bacteriuria can lead to subsequent invasive infection. The efficacy of antistaphylococcal therapy in preventing late-onset staphylococcal infection in patients with persistent staphylococcal bacteriuria should be tested in controlled trials.

PMID: 16323090 [PubMed - indexed for MEDLINE]

3: Am J Infect Control. 2005 Aug;33(6):360-7. Related Articles, Books, LinkOut
ELSEVIER FULL-TEXT ARTICLE

A proactive approach to prevention of health care-acquired Legionnaires' disease: the Allegheny County (Pittsburgh) experience.

Squier CL, **Stout JE**, **Krsytofiak S**, **McMahon J**, **Wagener MM**, **Dixon B**, **Yu VL**.

Association for Professionals in Infection Control and Epidemiology, Three Rivers Chapter, and Veterans Administration Pittsburgh Healthcare System, Pennsylvania, USA.

BACKGROUND: The Allegheny County Health Department (ACHD) in Pennsylvania distributed the first guidelines for prevention and control of health care-acquired Legionnaires ' disease (LD) by 1995. The proactive approach advocated in the guidelines differed notably from that of the Centers for Disease Control and Prevention (CDC) by recommending routine environmental testing of the hospital water distribution system even when cases of health care-acquired Legionnaires' disease had never been identified. OBJECTIVES: Our purpose was to (1) evaluate the impact of the ACHD guidelines on the Legionella diagnostic and preventive practices of health care facilities in Allegheny and surrounding counties and (2) compare the incidence of health care-acquired LD before and after issuance of the ACHD guidelines. METHODS: CDC case reports of LD from 1991 to 2001 were tabulated and compiled by the ACHD Infectious Disease Unit and the Association for Professionals in Infection Control and Epidemiology, Inc, Three Rivers Chapter. A survey was distributed to 110 hospitals and long-term care facilities in the region. The results were analyzed as occurring either in the preguideline period (1991-1994) or postguideline period (1995-2001). RESULTS: A significant decrease in the number of health care-acquired cases was demonstrated between the preguideline (33%) and postguideline (9%) periods (P=.0001). In contrast, community-acquired cases increased from 67% pre guideline to 91% post guideline. A total of 71% of the facilities were colonized with Legionella. Disinfection of the water distribution system was initiated by 44% of facilities. Use of urinary antigen testing significantly increased from 40% pre guideline to 79% post guideline (P=.0001). CONCLUSIONS: Health care-acquired LD declined significantly after the issuance of guidelines for prevention and control of health care-acquired LD. The decline was associated with health care facilities performing routine environmental monitoring of their water distribution systems followed by the initiation of disinfection methods if indicated. Two unanticipated benefits were (1) cases of LD in the community and long-term care facilities were uncovered as a result of increased availability of Legionella tests and (2) litigation and unfavorable publicity involving ACHD

hospitals ceased.

PMID: 16061143 [PubMed - indexed for MEDLINE]

☐ **4:** Antimicrob Agents Chemother. 2005 Aug;49(8):3171-7.

Related Articles, Compound via MeSH, Substance via MeSH, Cited Articles, Free in PMC, Cited in PMC, Books, LinkOut

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Fluconazole MIC and the fluconazole dose/MIC ratio correlate with therapeutic response among patients with candidemia.

Clancy CJ, Yu VL, Morris AJ, Snydman DR, Nguyen MH.
University of Florida College of Medicine, P.O. Box 100277, JHMHC, Gainesville, FL 32610, USA. nguyemt@medicine.ufl.edu

We tested 32 Candida isolates recovered in the early 1990s from the bloodstreams of patients with candidemia for in vitro susceptibility to fluconazole and determined if MIC and/or the daily dose of fluconazole/MIC ratio correlated with the response to therapy. This is a unique data set since 87.5% (28/32) of patients were treated with fluconazole doses now considered to be inadequate (</=200 mg), which contributed to high therapeutic failure rates (53% [17/32]). The geometric mean MIC and dose/MIC ratio for isolates associated with therapeutic failure (11.55 mug/ml and 14.3, respectively) differed significantly from values associated with therapeutic success (0.95 mug/ml and 219.36 [P = 0.0009 and 0.0004, respectively]). The therapeutic success rates among patients infected with susceptible (MIC </= 8 mug/ml), susceptible-dose dependent (S-DD) (MIC = 16 or 32 mug/ml), and resistant (MIC >/= 64 mug/ml) isolates were 67% (14/21), 20% (1/5), and 0% (0/6), respectively. A dose/MIC ratio >50 was associated with a success rate of 74% (14/19), compared to 8% (1/13) for a dose/MIC ratio </=50 (P = 0.0003). Our data suggest that both fluconazole MIC and dose/MIC ratio correlate with the therapeutic response to fluconazole among patients with candidemia. In clinical practice, dose/MIC ratio might prove easier to interpret than breakpoint MICs, since it quantitates the effects of increasing fluconazole doses that are alluded to in the S-DD designation.

Publication Types:

- Clinical Trial
- Multicenter Study

PMID: 16048920 [PubMed - indexed for MEDLINE]

5: Clin Infect Dis. 2005 Jun 1;40(11):1608-16. Epub 2005 May 2. Related Articles, Cited in PMC, Books, LinkOut

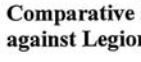
Management of nonsevere pneumonia in military trainees with the urinary antigen test for Streptococcus pneumoniae: an innovative approach to targeted therapy.

Guchev IA, Yu VL, Sinopalnikov A, Klochkov OI, Kozlov RS, Stratchounski LS.
Pulmonary Medicine Department, Smolensk Military Hospital, Smolensk, Russia.

BACKGROUND: The drug of choice for treatment of Streptococcus pneumoniae infection is generally a penicillin (including amoxicillin). Targeted therapy is, however, rarely used, because results of definitive diagnostic tests for pneumonia are not available for several days. Thus, broad-spectrum antibiotics are used for empirical treatment of pneumonia to cover both typical and atypical pathogens. Our purpose was to assess the usefulness of a strategy of targeted antimicrobial therapy based on the results of a rapid urinary antigen test for S. pneumoniae. METHODS: Military trainees with pneumonia were prospectively assigned to 2 groups: patients with positive urinary antigen test results who were treated with amoxicillin (1000 mg 3 times per day), and patients with negative urinary antigen test results who were treated with clarithromycin (500 mg 2 times per day). The duration of therapy was 5-10 days for both groups. RESULTS: A total of 219 evaluable patients were enrolled in the study. The most common causes of pneumonia were S. pneumoniae, Chlamydia pneumoniae, and Mycoplasma pneumoniae. Patients with positive urinary antigen test results had illness of greater severity at the time of study entry. Twenty-two percent of patients had positive urinary antigen test results (i.e., the amoxicillin group), and 78% had negative urinary antigen test results (i.e., the clarithromycin group). The clinical success rates were 94% for the clarithromycin group and 90% for the amoxicillin group (P = not significant). None of the patients who were classified as having treatment failure died. Resolution of clinical manifestations was slower for patients with pneumococcal pneumonia defined by a positive urinary antigen test result. CONCLUSIONS: The urine antigen test allowed targeted use of a penicillin (amoxicillin) for young immunocompetent individuals with nonsevere, community-acquired pneumonia. Clarithromycin was highly effective against both S. pneumoniae pneumonia and pneumonia due to atypical pathogens.

PMID: 15889358 [PubMed - in process]

6: Int J Antimicrob Agents. 2005 Apr;25(4):302-7. Related Articles, Books, LinkOut



Comparative activity of quinolones, macrolides and ketolides against Legionella species using in vitro broth dilution and

intracellular susceptibility testing.

Stout JE, Sens K, Mietzner S, Obman A, Yu VL.
VA Pittsburgh Healthcare System, VA Medical Center, Infectious Disease Section, University Drive C, Pittsburgh, PA 15240, USA.

The comparative in vitro activity of quinolones (trovafloxacin, gemifloxacin, levofloxacin, ciprofloxacin, moxifloxacin and grepafloxacin), ketolides (ABT-773 and telithromycin) and macrolides (clarithromycin, azithromycin and erythromycin) were evaluated against Legionella pneumophila by broth dilution and an HL-60 intracellular model. The MIC90 of the quinolones, clarithromycin and ABT-773 were more than eight times lower than for erythromycin. Telithromycin, ABT-773 and azithromycin had significantly greater intracellular activity against L. pneumophila than erythromycin at 1xMIC and 8xMIC. The rank order of intracellular activity against L. pneumophila serogroup 1 was quinolones>ketolides>macrolides. Clinical trials to determine the clinical efficacy of ketolides for the treatment of Legionnaires' disease are warranted.

PMID: 15784309 [PubMed - indexed for MEDLINE]

7: Clin Infect Dis. 2004 Jul 1;39(1):31-7. Epub 2004 Jun 8.

Related Articles, Compound via MeSH, Substance via MeSH, Cited in PMC, Books, LinkOut

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Antibiotic therapy for Klebsiella pneumoniae bacteremia: implications of production of extended-spectrum beta-lactamases.

Paterson DL, Ko WC, Von Gottberg A, Mohapatra S, Casellas JM, Goossens H, Mulazimoglu L, Trenholme G, Klugman KP, Bonomo RA, Rice LB, Wagener MM, McCormack JG, Yu VL.
Infectious Disease Section, VA Medical Center, Pittsburgh, Pennsylvania 15240, USA.

The prevalence of extended-spectrum beta -lactamase (ESBL) production by Klebsiella pneumonia approaches 50% in some countries, with particularly high rates in eastern Europe and Latin America. No randomized trials have ever been performed on treatment of bacteremia due to ESBL-producing organisms; existing data comes only from retrospective, single-institution studies. In a prospective study of 455 consecutive episodes of Klebsiella pneumoniae bacteremia in 12 hospitals in 7 countries, 85 episodes were due to an ESBL-producing organism. Failure to use an antibiotic active against ESBL-producing K. pneumoniae was associated with extremely high mortality. Use of a carbapenem (primarily imipenem) was associated with a significantly lower 14-day mortality than was use of other antibiotics active in vitro. Multivariate analysis including other predictors of mortality showed that use of a carbapenem during the 5-day period after onset of bacteremia due to an ESBL-producing organism was independently associated with lower mortality. Antibiotic choice is particularly important in seriously ill patients with infections due to ESBL-

producing K. pneumoniae.

PMID: 15206050 [PubMed - indexed for MEDLINE]

☐ **8:** Chest. 2004 Jun;125(6):2135-9.

Related Articles, Compound via MeSH, Substance via MeSH, Cited in PMC, Books, LinkOut

Comment in:

- Chest. 2004 Jun;125(6):1979-80.

Levofloxacin efficacy in the treatment of community-acquired legionellosis.

Yu VL, Greenberg RN, Zadeikis N, Stout JE, Khashab MM, Olson WH, Tennenberg AM.
VAMC and University of Pittsburgh, Pittsburgh, PA, USA.

BACKGROUND: Although fluoroquinolones possess excellent in vitro activity against Legionella, few large-scale clinical trials have examined their efficacy in the treatment of Legionnaires disease. Even fewer studies have applied rigorous criteria for diagnosis of community-acquired Legionnaires disease, including culture of respiratory secretions on selective media. METHODS: Data from six clinical trials encompassing 1,997 total patients have been analyzed to determine the efficacy of levofloxacin (500 mg qd or 750 mg qd) in treating patients with community-acquired pneumonia (CAP) due to Legionella. RESULTS: Of the 1,997 total patients with CAP from the clinical trials, 75 patients had infection with a Legionella species. Demographics showed a large portion of these patients were < 55 years of age and nonsmokers. More than 90% of mild-to-moderate and severe cases of Legionella infection resolved clinically at the posttherapy visit, 2 to 14 days after treatment termination. No deaths were reported for any patient with Legionnaires disease treated with levofloxacin during the studies. CONCLUSIONS: Levofloxacin was efficacious at both 500 mg for 7 to 14 days and 750 mg for 5 days. Legionnaires disease is not associated only with smokers, the elderly, and the immunosuppressed, but also has the potential to affect a broader demographic range of the general population than previously thought.

Publication Types:

- Multicenter Study

PMID: 15189933 [PubMed - indexed for MEDLINE]

☐ **9:** Am J Respir Crit Care Med. 2004 Aug 15;170(4):440-4. Epub 2004 Jun 7.

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Comment in:

- Am J Respir Crit Care Med. 2005 Dec 1;172(11):1472-3; author reply 1474.
- Am J Respir Crit Care Med. 2005 Dec 1;172(11):1472; author reply 1474.
- Am J Respir Crit Care Med. 2005 Dec 1;172(11):1473-4; author reply 1474.

Combination antibiotic therapy lowers mortality among severely ill patients with pneumococcal bacteremia.

Baddour LM, **Yu VL**, **Klugman KP**, **Feldman C**, **Ortqvist A**, **Rello J**, **Morris AJ**, **Luna CM**, **Snydman DR**, **Ko WC**, **Chedid MB**, **Hui DS**, **Andremont A**, **Chiou CC**; **International Pneumococcal Study Group**.
Mayo Clinic, Rochester, NY, USA.

Retrospective studies have suggested that combination antibiotic therapy for severe bacteremic pneumococcal pneumonia may reduce mortality. We assessed this issue in a prospective, multicenter, international observational study of 844 adult patients with bacteremia due to Streptococcus pneumoniae. The effect of combination antibiotic therapy versus monotherapy on mortality was examined by univariate analyses and by logistic regression models. The 14-day mortality was not significantly different for the two groups. However, among critically ill patients, combination antibiotic therapy was associated with lower 14-day mortality (23.4 versus 55.3%, $p = 0.0015$). This improvement in survival was independent of country of origin, intensive care unit support, class of antibiotics, or in vitro activity of the antibiotics prescribed. Combination antibiotic therapy improved survival among critically ill patients with bacteremic pneumococcal illness.

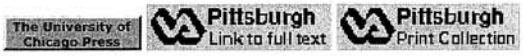
Publication Types:

- Clinical Trial
- Multicenter Study

PMID: 15184200 [PubMed - indexed for MEDLINE]

☐ **10:** Clin Infect Dis. 2004 Apr 15;38(8):1058-64. Epub 2004 Mar 26.

Related Articles, Compound via MeSH, Substance via MeSH, Cited in PMC, Books, LinkOut



Comment in:

- Clin Infect Dis. 2004 Apr 15;38(8):1065-6.

Similar hematologic effects of long-term linezolid and vancomycin therapy in a prospective observational study of patients with orthopedic infections.

Rao N, Ziran BH, Wagener MM, Santa ER, Yu VL.
Division of Infectious Disease, Departm ent of Medicine, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania 15232, USA. raon@msx.upmc.edu

Linezolid is an alternative to vancomycin for the long-term treatment of gram-positive bacterial orthopedic infections because of its antibacterial spectrum and oral bioavailability, but duration-related myelosuppression could offset its advantages. To evaluate the hematologic effects of these agents, we prospectively studied 65 consecutive adults with gram-positive bacterial orthopedic infections requiring > or =2 weeks of vancomycin therapy (n=52) or linezolid therapy (n=20). Trends suggesting higher incidence of hematologic effects among the patients receiving vancomycin were not significant, regardless of whether the end point was lowest cell count during therapy or change from baseline. The only difference was a higher incidence of thrombocytopenia (<150x10(9) platelets/L) in the subset of the linezolid recipients who had received vancomycin within 2 weeks before starting linezolid therapy than in the linezolid recipients who had not received vancomycin (5 [71%] of 7 patients vs. 2 [15%] of 13; P=.02). All hematologic effects were reversible. In conclusion, hematologic effects were detectable through weekly monitoring and were reversible; therefore, concern about myelosuppression need not preclude linezolid use for orthopedic infections requiring long-term therapy.

PMID: 15095207 [PubMed - indexed for MEDLINE]

☐ **11:** Ann Intern Med. 2004 Jan 6;140(1):26-32. Related Articles, Substance via MeSH, Cited in PMC, Books, LinkOut

Summary for patients in:

- Ann Intern Med. 2004 Jan 6;140(1):I43.

International prospective study of Klebsiella pneumoniae bacteremia: implications of extended-spectrum beta-lactamase

production in nosocomial Infections.

Paterson DL, Ko WC, Von Gottberg A, Mohapatra S, Casellas JM, Goossens H, Mulazimoglu L, Trenholme G, Klugman KP, Bonomo RA, Rice LB, Wagener MM, McCormack JG, Yu VL.
Veterans Affairs Medical Center, Pittsburgh, Pennsylvania 15240, USA.

BACKGROUND: Commonly encountered nosocomially acquired gram-negative bacteria, especially Klebsiella pneumoniae, produce extended-spectrum beta-lactamases (ESBLs) as an antibiotic resistance mechanism. OBJECTIVE: To determine whether microbiology laboratories should report the presence of ESBLs and to establish the infection-control implications of ESBL-producing organisms. DESIGN: Prospective observational study. SETTING: 12 hospitals in South Africa, Taiwan, Australia, Argentina, the United States, Belgium, and Turkey. PATIENTS: 440 patients with 455 consecutive episodes of K. pneumoniae bacteremia between 1 January 1996 and 31 December 1997; of these, 253 episodes were nosocomially acquired. MEASUREMENTS: The K. pneumoniae isolates were examined for the presence of ESBLs. Pulsed-field gel electrophoresis was used to analyze the molecular epidemiology of nosocomial bacteremia with ESBL-producing K. pneumoniae. RESULTS: Overall, 30.8% (78 of 253) episodes of nosocomial bacteremia and 43.5% (30 of 69) episodes acquired in intensive care units were due to ESBL-producing organisms. After adjustment for potentially confounding variables, previous administration of beta-lactam antibiotics containing an oxyimino group (cefuroxime, cefotaxime, ceftriaxone, ceftazidime, or aztreonam) was associated with bacteremia due to ESBL-producing strains (risk ratio, 3.9 [95% CI, 1.1 to 13.8]). In 7 of 10 hospitals with more than 1 ESBL-producing isolate, multiple strains with the same genotypic pattern were observed, indicating patient-to-patient spread of the organism. CONCLUSIONS: Production of ESBLs by Klebsiella pneumoniae is a widespread nosocomial problem. Appropriate infection control and antibiotic management strategies are needed to stem the spread of this emerging form of resistance.

Publication Types:

- Multicenter Study

PMID: 14706969 [PubMed - indexed for MEDLINE]

☐ **12:** Medicine (Baltimore). 2003 Sep;82(5):333-9.

Related Articles, Cited in PMC, Books, LinkOut

Staphylococcus aureus bacteremia: recurrence and the impact of antibiotic treatment in a prospective mul ticenter study.

Chang FY, Peacock JE Jr, Musher DM, Triplett P, MacDonald BB, Mylotte

JM, **O'Donnell A**, **Wagener MM**, **Yu VL**.
VA Medical Center, Infectious Disease Section, University Drive C, Pittsburgh, PA 15240, USA.

Staphylococcus aureus bacteremia is associated with substantial morbidity. Recurrence is common, but incidence and risk factors for recurrence are uncertain. The emergence of methicillin resistance and the ease of administering vancomycin, especially in patients who have renal insufficiency, have led to reliance on this drug with the assumption that it is as effective as beta-lactam antibiotics, an assumption that remains open to debate.We initiated a multicenter, prospective observational study in 6 university hospitals and enrolled 505 consecutive patients with S. aureus bacteremia. All patients were monitored for 6 months and patients with endocarditis were followed for 3 years. Recurrence was defined as return of S. aureus bacteremia after documentation of negative blood cultures and/or clinical improvement after completing a course of antistaphylococcal antibiotic therapy. All blood isolates taken from patients with recurrent bacteremia underwent pulsed-field gel electrophoresis testing. Recurrence was subclassified as reinfection (different pulsed-field gel electrophoresis patterns) or relapse (same pulsed-field gel electrophoresis pattern).Forty-two patients experienced 56 episodes of recurrence (79% were relapses and 21% were reinfection). Relapse occurred earlier than reinfection (median, 36 versus 99 d, $p < 0.06$). Risk factors for relapse of S. aureus bacteremia included valvular heart disease, cirrhosis of the liver, and deep-seated infection (including endocarditis). Nafcillin was superior to vancomycin in preventing bacteriologic failure (persistent bacteremia or relapse) for methicillin-susceptible S. aureus (MSSA) bacteremia. Failure to remove infected intravascular devices/catheters and vancomycin therapy were common factors in patients experiencing multiple (greater than 2) relapses. However, by multivariate analysis, only endocarditis and therapy with vancomycin (versus nafcillin) were significantly associated with relapse.Recurrences occurred in 9.4% of S. aureus bacteremias following antistaphylococcal therapy, and most were relapses. Duration of antistaphylococcal therapy was not associated with relapse, but type of antibiotic therapy was. Nafcillin was superior to vancomycin in efficacy in patients with MSSA bacteremia.

Publication Types:

- Multicenter Study

PMID: 14530782 [PubMed - indexed for MEDLINE]

☐ **13:** Medicine (Baltimore). 2003 Sep;82(5):322-32.

Related Articles, Cited in PMC, Books, LinkOut

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A prospective multicenter study of Staphylococcus aureus bacteremia: incidence of endocarditis, risk fac tors for mortality, and clinical impact of methicillin resistance.

Chang FY, MacDonald BB, Peacock JE Jr, Musher DM, Triplett P, Mylotte JM, O'Donnell A, Wagener MM, Yu VL.
VA Medical Center, Infectious Disease Section, University Drive C, Pittsburgh, PA 15240, USA.

Our objectives were to determine the incidence of endocarditis in patients whose Staphylococcus aureus bacteremia was community-acquired, related to hemodialysis, or hospital-acquired; to assess clinical factors that would reliably distinguished between S. aureus bacteremia and S. aureus endocarditis; to assess the emergence of methicillin-resistant S. aureus (MRSA) as a cause of endocarditis; and to examine risk factors for mortality in patients with S. aureus endocarditis.We conducted a prospective observational study in 6 university teaching hospitals; we evaluated 505 consecutive patients with Staphylococcus aureus bacteremia. Thirteen percent of patients with S. aureus bacteremia were found to have endocarditis, including 21% with community-acquired S. aureus bacteremia, 5% with hospital-acquired bacteremia, and 12% on hemodialysis. Infection was due to MRSA in 31%.Factors predictive of endocarditis included underlying valvular heart disease, history of prior endocarditis, intravenous drug use, community acquisition of bacteremia, and an unrecognized source. Twelve patients with bacteremia had a prosthetic valve; 17% developed endocarditis. Unexpectedly, nonwhite race proved to be an independent risk factor for endocarditis by both univariate and multivariate analyses. Persistent bacteremia (positive blood cultures at day 3 of appropriate therapy) was identified as an independent risk factor for both endocarditis and mortality, a unique observation not reported in other prospective studies of S. aureus bacteremia.Patients with endocarditis due to MRSA were significantly more likely to have complicating renal insufficiency and to experience persistent bacteremia than those with endocarditis due to MSSA. The 30-day mortality was 31% among patients with endocarditis compared to 21% in patients who had bacteremia without endocarditis ($p = 0.055$). Risk factors for death due to endocarditis included severity of illness at onset of bacteremia (as measured by Apache III and Pitt bacteremia score), MRSA infection, and presence of atrioventricular block on electrocardiogram.Patients with S. aureus bacteremia who have community acquisition of infection, underlying valvular heart disease, intravenous drug use, unknown portal of entry, history of prior endocarditis, and possibly, nonwhite race should undergo echocardiography to screen for the presence of endocarditis. We recommend that blood cultures be repeated 3 days following initiation of antistaphylococcal antibiotic therapy in all patients with S. aureus bacteremia. Positive blood cultures at 3 days may prove to be a useful marker in promoting more aggressive management, including more potent antibiotic therapy and surgical resection of the valve in endocarditis cases. MRSA as the infecting

organism should be added to the list of risk factors for consideration of valvular resection in cases of endocarditis.

Publication Types:

- Multicenter Study

PMID: 14530781 [PubMed - indexed for MEDLINE]

☐ **14:** Infect Control Hosp Epidemiol. 2003 Aug;24(8):563-8.

Related Articles, Compound via MeSH, Substance via MeSH, Books, LinkOut

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Comment in:

- Infect Control Hosp Epidemiol. 2003 Aug;24(8):560-2.

Experiences of the first 16 hospitals using copper-silver ionization for Legionella control: implications for the evaluation of other disinfection modalities.

Stout JE, **Yu VL**.
Special Pathogens Laboratory, Veterans Affairs Medical Center, Pittsburg, Pennsylvania 15240, USA.

BACKGROUND AND OBJECTIVES: Hospital-acquired legionnaires' disease can be prevented by disinfection of hospital water systems. This study assessed the long-term efficacy of copper-silver ionization as a disinfection method in controlling Legionella in hospital water systems and reducing the incidence of hospital-acquired legionnaires' disease. A standardized, evidence-based approach to assist hospitals with decision making concerning the possible purchase of a disinfection system is presented. DESIGN: The first 16 hospitals to install copper-silver ionization systems for Legionella disinfection were surveyed. Surveys conducted in 1995 and 2000 documented the experiences of the hospitals with maintenance of the system, contamination of water with Legionella, and occurrence of hospital-acquired legionnaires' disease. All were acute care hospitals with a mean of 435 beds. RESULTS: All 16 hospitals reported cases of hospital-acquired legionnaires' disease prior to installing the copper-silver ionization system. Seventy-five percent had previously attempted other disinfection methods including superheat and flush, ultraviolet light, and hyperchlorination. By 2000, the ionization systems had been operational from 5 to 11 years. Prior to installation, 47% of the hospitals reported that more than 30% of distal water sites yielded Legionella. In 1995, after installation, 50% of the hospitals reported 0% positivity, and 43% still reported 0% in 2000. Moreover, no cases of hospital-acquired legionnaires' disease have occurred in any hospital

since 1995. CONCLUSIONS: This study represents the final step in a proposed 4-step evaluation process of disinfection systems that includes (1) demonstrated efficacy of Legionella eradication in vitro using laboratory assays, (2) anecdotal experiences in preventing legionnaires' disease in individual hospitals, (3) controlled studies in individual hospitals, and (4) validation in confirmatory reports from multiple hospitals during a prolonged time (5 to 11 years in this study). Copper-silver ionization is now the only disinfection modality to have fulfilled all four evaluation criteria.

PMID: 12940575 [PubMed - indexed for MEDLINE]

15: Clin Infect Dis. 2003 Jul 15;37(2):230-7. Epub 2003 Jul 7.

Related Articles, Compound via MeSH, Substance via MeSH, Cited in PMC, Books, LinkOut

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Comment in:

- Clin Infect Dis. 2004 Mar 1;38(5):763-4; author reply 765-6.
- Clin Infect Dis. 2004 Mar 1;38(5):763; author reply 765-6.
- Clin Infect Dis. 2004 Mar 1;38(5):764-5; author reply 765-6.

An international prospective study of pneumococcal bacteremia: correlation with in vitro resistance, antibiotics administered, and clinical outcome.

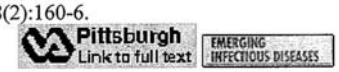
Yu VL, **Chiou CC**, **Feldman C**, **Ortqvist A**, **Rello J**, **Morris AJ**, **Baddour LM**, **Luna CM**, **Snydman DR**, **Ip M**, **Ko WC**, **Chedid MB**, **Andremont A**, **Klugman KP**; **International Pneumococcal Study Group**.
Division of Infectious Disease, University of Pittsburgh, PA, USA. vly+@pitt.edu

We performed a prospective, international, observational study of 844 hospitalized patients with blood cultures positive for Streptococcus pneumoniae. Fifteen percent of isolates had in vitro intermediate susceptibility to penicillin (minimum inhibitory concentration [MIC], 0.12-1 microg/mL), and 9.6% of isolates were resistant (MIC, >or=2 microg/mL). Age, severity of illness, and underlying disease with immunosuppression were significantly associated with mortality; penicillin resistance was not a risk factor for mortality. The impact of concordant antibiotic therapy (i.e., receipt of a single antibiotic with in vitro activity against S. pneumoniae) versus discordant therapy (inactive in vitro) on mortality was assessed at 14 days. Discordant therapy with penicillins, cefotaxime, and ceftriaxone (but not cefuroxime) did not result in a higher mortality rate. Similarly, time required for defervescence and frequency of suppurative complications were not associated with concordance of beta-lactam antibiotic therapy. beta-Lactam antibiotics should still be useful for treatment of pneumococcal infections that do not involve cerebrospinal fluid, regardless of in vitro susceptibility, as determined by current NCCLS breakpoints.

PMID: 12856216 [PubMed - indexed for MEDLINE]

☐ **16:** Emerg Infect Dis. 2002 Feb;8(2):160-6.

Related Articles, Cited in PMC, Books, LinkOut



Community-acquired Klebsiella pneumoniae bacteremia: global differences in clinical patterns.

Ko WC, **Paterson DL**, **Sagnimeni AJ**, **Hansen DS**, **Von Gottberg A**, **Mohapatra S**, **Casellas JM**, **Goossens H**, **Mulazimoglu L**, **Trenholme G**, **Klugman KP**, **McCormack JG**, **Yu VL**.
National Cheng Kung University Medical College, Taiwan.

We initiated a worldwide collaborative study, including 455 episodes of bacteremia, to elucidate the clinical patterns of Klebsiella pneumoniae. Historically, community-acquired pneumonia has been consistently associated with K. pneumoniae. Only four cases of community-acquired bacteremic K. pneumoniae pneumonia were seen in the 2-year study period in the United States, Argentina, Europe, or Australia; none were in alcoholics. In contrast, 53 cases of bacteremic K. pneumoniae pneumonia were observed in South Africa and Taiwan, where an association with alcoholism persisted (p=0.007). Twenty-five cases of a distinctive syndrome consisting of K. pneumoniae bacteremia in conjunction with community-acquired liver abscess, meningitis, or endophthalmitis were observed. A distinctive form of K. pneumoniae infection, often causing liver abscess, was identified, almost exclusively in Taiwan.

PMID: 11897067 [PubMed - indexed for MEDLINE]

☐ **17:** Laryngoscope. 2001 Feb;111(2):329-35.

Related Articles, Compound via MeSH, Substance via MeSH, Books, LinkOut

The role of topical antibiotic prophylaxis in patients undergoing contaminated head and neck surgery wi th flap reconstruction.

Simons JP, **Johnson JT**, **Yu VL**, **Vickers RM**, **Gooding WE**, **Myers EN**, **Pou AM**, **Wagner RL**, **Grandis JR**.
Department of Otolaryngology, University of Pittsburgh School of Medicine, University of Pittsburgh Cancer Institute, Pennsylvania 15213, USA.

OBJECTIVES/HYPOTHESIS: Patients undergoing contaminated head and neck surgery with flap reconstruction have wound infection rates of 20% to 25% with parenteral antibiotic prophylaxis. Studies suggest that perioperative antimicrobial mouthwash reduces oropharyngeal flora and may prevent wound infections. We hypothesized that the addition of topical antibiotics to a parenteral prophylactic

regimen would reduce the incidence of wound infection in these high-risk patients. STUDY DESIGN: We performed a randomized, prospective clinical trial. METHODS: Patients received either 1) parenteral piperacillin/tazobactam (3.375 g every 6 hours for 48 h) or 2) parenteral piperacillin/tazobactam plus topical piperacillin/tazobactam administered as a mouthwash immediately before surgery and once a day for 2 days postoperatively, with piperacillin/tazobactam added to the intraoperative irrigation solution. The wounds of all patients were evaluated daily using predefined objective criteria. RESULTS: Sixty-two patients met inclusion criteria and were enrolled in the study. The overall wound infection rate was 8.1% (95% confidence interval [CI], 2.7%-17.8%). Two of 31 patients (6.4%) who received parenteral antibiotics alone developed a wound infection compared with 3 of 31 patients (9.7%) randomly assigned to receive topical plus parenteral antibiotics. This difference was not statistically significant (P = >.05). Infection rate was not associated with flap type (rotational vs. free tissue transfer), mandibular reconstruction, age, gender, tumor site, stage, surgical duration, or blood loss. CONCLUSIONS: These results suggest that piperacillin/tazobactam is a highly effective antibiotic for prevention of wound infection in patients undergoing flap reconstruction following contaminated head and neck surgery. However, the addition of topical piperacillin/tazobactam does not appear to enhance the prophylactic benefit of parenteral antibiotics alone.

Publication Types:

- Clinical Trial
- Randomized Controlled Trial

PMID: 11210884 [PubMed - indexed for MEDLINE]

☐ **18:** Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 2001 Feb;91(2):162-5.

Related Articles, Compound via MeSH, Substance via MeSH, Books, LinkOut

ELSEVIER FULL-TEXT ARTICLE Pittsburgh Print Collection

Topical antibiotic prophylaxis for bacteremia after dental extractions.

Vergis EN, **Demas PN**, **Vaccarello SJ**, **Yu VL**.
Division of Infectious Diseases, School of Medicine, University of Pittsburgh, PA, USA.

OBJECTIVE: Current prophylaxis for endocarditis in patients undergoing dental procedures consists of oral administration of amoxicillin. There is concern that the risk of anaphylaxis from systemically administered antibiotics might approach the incidence of endocarditis. Emergence of resistance among bacteria is also favored by systemically administered antibiotics. The present study was designed to assess the efficacy of topical amoxicillin given prophylactically as a mouthwash in reducing the incidence of bacteremia after dental extraction. STUDY DESIGN:

Thirty-six outpatients in a dental clinic were randomized in a 3:2:2 ratio to experimental prophylaxis of topical amoxicillin (3 g per mouthwash rinse; 15 patients), standard prophylaxis of oral amoxicillin (3 g in a single dose; 11 patients), or no prophylaxis (10 patients), respectively. Patients were stratified by severity of periodontal disease and number of teeth extracted. Data were analyzed for differences in the incidence of bacteremia by means of the 2-tailed Fisher exact test. RESULTS: Breakthrough bacteremia after dental extraction was observed in 60% (6 of 10 patients) who received topical amoxicillin and in 89% (8 of 9 patients) who received no prophylaxis (P =.30). By comparison, breakthrough bacteremia after dental extraction was observed in 10% (1 of 10 patients) who received standard prophylaxis with oral amoxicillin (60% vs 10%; P =.05). CONCLUSIONS: Topical amoxicillin decreased the incidence of bacteremia in comparison with no prophylaxis, but statistical significance was not achieved (P =.30). Topical amoxicillin was significantly less effective than standard prophylaxis with oral amoxicillin in decreasing the incidence of bacteremia after dental extractions.

Publication Types:

- Clinical Trial
- Randomized Controlled Trial

PMID: 11174592 [PubMed - indexed for MEDLINE]

☐ **19:** J Infect Dis. 2001 Feb 15;183(4):628-32. Epub 2001 Jan 11.

Related Articles, Cited in PMC, Books, LinkOut

The University of Chicago Press | Pittsburgh Link to full text

Unexpected similarity of pulsed-field gel electrophoresis patterns of unrelated clinical isolates of Legionella pneumophila, serogroup 1.

Drenning SD, **Stout JE**, **Joly JR**, **Yu VL**.
Department of Medicine, University of Pittsburgh School of Medicine, and Veterans Administration Pittsburgh Healthcare System, University Drive C, PA 15240, USA.

Phenotypic and genotypic methods identify subtypes of Legionella pneumophila, serogroup 1, and match patient and environmental isolates from suspected sources. The strength of this association is limited by the lack of information regarding the frequency and distribution of isolates belonging to various subtypes. In this study, 62 clinical isolates of L. pneumophila, serogroup 1, were subtyped by using pulsed-field gel electrophoresis (PFGE), to determine the distribution and degree of diversity of PFGE patterns among monoclonal antibody (MAb) subtypes. Unexpectedly, 8 of 21 MAb Philadelphia 1 isolates had a common PFGE pattern, and, among 12 MAb OLDA isolates, only 2 PFGE patterns were seen. Our hypothesis was that PFGE patterns were distributed randomly;

however, statistical analysis showed that the distribution of subtypes was not random (Fisher's exact test 0.13; P>.05). In light of these results, researchers who do epidemiological investigations should use caution when interpreting the significance of matching PFGE patterns of L. pneumophila, serogroup 1.

PMID: 11170989 [PubMed - indexed for MEDLINE]

20: Infection. 2000 Nov-Dec;28(6):355-60. Related Articles, Books, LinkOut
SpringerLink FULL-TEXT ARTICLE

Staphylococcus aureus and other bacteremias in hemodialysis patients: antibiotic therapy and surgical removal of access site.

Lentino JR, **Baddour LM**, **Wray M**, **Wong ES**, **Yu VL**.
Loyola University Stritch School of Medicine, Hines VA Hospital, IL 60141-5000, USA.

BACKGROUND: Bacteremia is commonplace in patients undergoing hemodialysis since the vascular access site is a ready source of infection. Mortality is notably high. However, uncertainties exist with respect to therapy including indications for surgical removal of vascular access site and duration of therapy. We therefore conducted a large-scale collaborative study of bacteremia in hemodialysis patients in six US academic medical centers to define the epidemiology of such infections and to address issues of management. PATIENTS AND METHODS: We conducted a prospective observational study over 2 years. Severity of illness at onset of bacteremia was defined by objective criteria. Patients were followed for 90 days to assess late complications including endocarditis and mortality. Univariate and multivariate analyses were used to assess risk factors for mortality. RESULTS: Patients experiencing 127 consecutive episodes of bacteremia were enrolled. The most common cause of bacteremia was Staphylococcus aureus (31%), followed by aerobic gram-negative bacilli (28%) and coagulase-negative staphylococci (13%). Polymicrobial bacteremia occurred in 6% of patients. The most frequent focus of infection was the access site for hemodialysis, although urinary tract, gastrointestinal tract and lung were also implicated. Aerobic gram-negative bacilli and enterococci usually originated from the urinary tract. S. aureus was significantly more likely to cause infection of the access site than other bacteria ($p = 0.0001$). S. aureus endocarditis was diagnosed in two patients who were receiving antibiotic therapy for S. aureus bacteremia. Removal of the infected access site (shunt, fistula, catheter) was performed for 86% of the patients (95% of the intravenous catheters and 80% of the arteriovenous fistulas/shunts). Overall mortality was 33% at 90 days and was significantly associated with severity of illness at onset of antibiotic therapy and age >60 years. Mortality was not significantly different in patients undergoing surgical removal of infected access site versus those treated with antibiotics alone. CONCLUSION: When S. aureus was isolated from the blood, the access site was the most frequent source. Surgical removal of the access site did not have a notable impact on mortality. Until a randomized trial proves otherwise, it appears

that surgical removal of the access site can be individualized. Selected patients who are less severely ill (based on objective criteria) can maintain their hemodialysis access site and be treated with 2 weeks of antibiotic therapy.

Publication Types:

- Multicenter Study

PMID: 11139154 [PubMed - indexed for MEDLINE]

☐ **21:** Am J Respir Crit Care Med. 2000 Aug;162(2 Pt 1):505-11.

Related Articles, Compound via MeSH, Substance via MeSH, Cited in PMC, Books, LinkOut

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Comment in:

- ACP J Club. 2001 Mar-Apr;134(2):45.
- Am J Respir Crit Care Med. 2001 Jul 1;164(1):172-3.

Short-course empiric antibiotic therapy for patients with pulmonary infiltrates in the intensive care unit. A proposed solution for indiscriminate antibiotic prescription.

Singh N, **Rogers P**, **Atwood CW**, **Wagener MM**, **Yu VL**.
Veterans Affairs Medical Center and University of Pittsburgh, Pittsburgh, Pennsylvania, USA.

Inappropriate antibiotic use for pulmonary infiltrates is common in the intensive care unit (ICU). We sought to devise an approach that would minimize unnecessary antibiotic use, recognizing that a gold standard for the diagnosis of nosocomial pneumonia does not exist. In a randomized trial, clinical pulmonary infection score (CPIS) (Pugin, J., R. Auckenthaler, N. Mili, J. P. Janssens, R. D. Lew, and P. M. Suter. Diagnosis of ventilator-associated pneumonia by bacteriologic analysis of bronchoscopic and nonbronchoscopic "blind" bronchoalveolar lavage fluid. Am. Rev. Respir. Dis. 1991;143: 1121-1129) was used as operational criteria for decision-making regarding antibiotic therapy. Patients with CPIS </= 6 (implying low likelihood of pneumonia) were randomized to receive either standard therapy (choice and duration of antibiotics at the discretion of physicians) or ciprofloxacin monotherapy with reevaluation at 3 d; ciprofloxacin was discontinued if CPIS remained </= 6 at 3 d. Antibiotics were continued beyond 3 d in 90% (38 of 42) of the patients in the standard as therapy compared with 28% (11 of 39) in the experimental therapy group (p = 0.0001). In patients in whom CPIS remained </= 6 at the 3 d evaluation point, antibiotics were still continued in 96% (24 of 25) in the standard therapy group

but in 0% (0 of 25) of the patients in the experimental therapy group (p = 0.0001). Mortality and length of ICU stay did not differ despite a shorter duration (p = 0.0001) and lower cost (p = 0.003) of antimicrobial therapy in the experimental as compared with the standard therapy arm. Antimicrobial resistance, or superinfections, or both, developed in 15% (5 of 37) of the patients in the experimental versus 35% (14 of 37) of the patients in the standard therapy group (p = 0.017). Thus, overtreatment with antibiotics is widely prevalent, but unnecessary in most patients with pulmonary infiltrates in the ICU. The operational criteria used, regardless of the precise definition of pneumonia, accurately identified patients with pulmonary infiltrates for whom monotherapy with a short course of antibiotics was appropriate. Such an approach led to significantly lower antimicrobial therapy costs, antimicrobial resistance, and superinfections without adversely affecting the length of stay or mortality.

Publication Types:

- Clinical Trial
- Randomized Controlled Trial

PMID: 10934078 [PubMed - indexed for MEDLINE]

22: Clin Infect Dis. 2000 Jun;30(6):870-6. Epub 2000 Jun 13.

Related Articles, Cited in PMC, Books, LinkOut

The University of Chicago Press Pittsburgh Link to full text

Antimicrobial resistance and clinical outcome of Bacteroides bacteremia: findings of a multicenter prospective observational trial.

Nguyen MH, **Yu VL**, **Morris AJ**, **McDermott L**, **Wagener MW**, **Harrell L**, **Snydman DR**.
Department of Medicine, Veterans Administration Hospital and University of Pittsburgh School of Medicine, Pittsburgh, PA, USA.

There is debate regarding the correlation between in vitro susceptibility testing and clinical response to therapy for Bacteroides bacteremia. We conducted a prospective multicenter observational study of 128 patients with bacteroides bacteremia. Outcome was correlated with results of in vitro susceptibility testing of Bacteroides isolates recovered from blood and/or nonblood sites, determined with use of 3 end points: mortality at 30 days, clinical response (cure vs. failure), and microbiological response (eradication vs. persistence). The mortality rate among patients who received inactive therapy (45%) was higher than among patients who received active therapy (16%; P=.04). Clinical failure (82%) and microbiological persistence (42%) were higher for patients who received inactive therapy than for patients who received active therapy (22% and 12%, respectively; P=.0002 and.06, respectively). In vitro activity of agents directed at Bacteroides species reliably predicts outcome: the specificity was 97%, and

positive predictive value was 82%. Antimicrobial susceptibility testing may be indicated for patients whose blood specimens yield Bacteroides species.

Publication Types:

- Multicenter Study

PMID: 10852736 [PubMed - indexed for MEDLINE]

23: Arch Intern Med. 2000 May 8;160(9):1294-300.

Related Articles, Compound via MeSH, Substance via MeSH, Cited in PMC, Books, LinkOut

FULL TEXT AT ARCHIVES OF INTERNAL MEDICINE
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Azithromycin vs cefuroxime plus erythromycin for empirical treatment of community-acquired pneumonia in hospitalized patients: a prospective, randomized, multicenter trial.

Vergis EN, Indorf A, File TM Jr, Philli ps J, Bates J, Tan J, Sarosi GA, Grayston JT, Summersgill J, YU VL.
Infectious Disease Sections, Veterans Affairs Medica l Center and University of Pittsburgh, PA, USA.

OBJECTIVE: To compare the efficacy and safety of azithromycin dihydrate monotherapy with those of a combination of cefuroxime axetil plus erythromycin as empirical therapy for community-acquired pneumonia in hospitalized patients. METHODS: Patients were enrolled in a prospective, randomized, multicenter study. The standard therapy of cefuroxime plus erythromycin was consistent with the American Thoracic Society, Canadian Community-Acquired Pneumonia Consensus Group, and Infectious Disease Society of America consensus guidelines. The doses were intravenous azithromycin (500 mg once daily) followed by oral azithromycin (500 mg once daily), intravenous cefuroxime (750 mg every 8 hours), followed by oral cefuroxime axetil (500 mg twice daily), and erythromycin (500-1000 mg) intravenously or orally every 6 hours. Randomization was stratified by severity of illness and age. Patients who were immunosuppressed or residing in nursing homes were excluded. RESULTS: Data from 145 patients (67 received azithromycin and 78 received cefuroxime plus erythromycin) were evaluable. Streptococcus pneumoniae and Haemophilus influenzae were isolated in 19% (28/145) and 13% (19/145), respectively. The atypical pathogens accounted for 33% (48/145) of the etiologic diagnoses; Legionella pneumophila, Chlamydia pneumoniae, and Mycoplasma pneumoniae were identified in 14% (20/ 145), 10% (15/145), and 9% (13/145), respectively. Clinical cure was achieved in 91% (61/67) of the patients in the azithromycin group and 91% (71/78) in the cefuroxime plus erythromycin group. Adverse events (intravenous catheter site reactions, gastrointestinal tract disturbances) were significantly more common in patients who received cefuroxime plus

erythromycin (49% [30/78]) than in patients who received azithromycin (12% [8/67]) (P<.001). CONCLUSIONS: Treatment with azithromycin was as effective as cefuroxime plus erythromycin in the empirical management of community-acquired pneumonia in immunocompetent patients who were hospitalized. Azithromycin was well tolerated.

Publication Types:

- Clinical Trial
- Multicenter Study
- Randomized Controlled Trial

PMID: 10809032 [PubMed - indexed for MEDLINE]

☐ **24:** Clin Infect Dis. 2000 Mar;30(3):473-8.

Related Articles, Compound via MeSH, Substance via MeSH, Cited in PMC, Books, LinkOut

The University of Chicago Press | Pittsburgh Link to full text

Epidemiology of ciprofloxacin resistance and its relationship to extended-spectrum beta-lactamase production in Klebsiella pneumoniae isolates causing bacteremia.

Paterson DL, Mulazimoglu L, Casellas JM, Ko WC, Goossens H, Von Gottberg A, Mohapatra S, Trenholme GM, Klugman KP, McCormack JG, Yu VL.
Infectious Disease Section, Veterans Affairs Medical Center, Pittsburgh, PA 15240, USA.

A prospective study of Klebsiella pneumoniae bacteremia was performed in 12 hospitals in 7 countries. Of 452 episodes of bacteremia, 25 (5.5%) were caused by K. pneumoniae that was resistant in vitro to ciprofloxacin. Extended-spectrum beta-lactamase (ESBL) production was detected in 15 (60%) of 25 ciprofloxacin-resistant isolates, compared with 68 (16%) of 427 ciprofloxacin-susceptible strains (P=.0001). Multivariate analysis revealed that risk factors for ciprofloxacin resistance in K. pneumoniae included prior receipt of a quinolone (P=.0065) and an ESBL-producing strain (P=.012). In all, 18% of ESBL-producing isolates were also ciprofloxacin-resistant. Pulsed-field gel electrophoresis showed that 11 of the 15 ciprofloxacin-resistant ESBL-producing strains belonged to just 4 genotypes, suggesting that patient-to-patient transmission of such strains occurred. The close relationship between ESBL production and ciprofloxacin resistance is particularly worrisome because the first reported instance of plasmid-mediated ciprofloxacin resistance has been in an isolate of K. pneumoniae also possessing an ESBL.

PMID: 10722430 [PubMed - indexed for MEDLINE]

25: Ann Intern Med. 1999 Feb 2;130(3):221-5.

Related Articles, Cited in PMC, Books, LinkOut

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Nasal carriage of and infection with Staphylococcus aureus in HIV-infected patients.

Nguyen MH, Kauffman CA, Goodman RP, Squier C, Arbeit RD, Singh N, Wagener MM, Yu VL.
University of Pittsburgh Medical Center, Pennsylvania, USA.

BACKGROUND: Staphylococcus aureus is a common cause of serious infection in patients infected with HIV. OBJECTIVES: To evaluate risk factors for and quantitative effect of S. aureus infection in HIV-infected patients, with special attention to nasal carriage. DESIGN: Prospective, multihospital cohort study. SETTING: Three tertiary care Veterans Affairs Medical Centers. PARTICIPANTS: 231 ambulatory HIV-infected patients. RESULTS: Thirty-four percent of patients were nasal carriers of S. aureus. Of these patients, 38% were persistent carriers and 62% were intermittent carriers. Twenty-one episodes of infection occurred in 13 patients: Ten were bacteremias (including 2 cases of endocarditis), 1 was pneumonia, and 10 were cutaneous or subcutaneous infections. Seventeen (85%) of these episodes occurred in patients with CD4 counts less than 100 cells/mm3. Recurrent infections occurred in 3 of 7 patients who survived an initial S. aureus infection. The mortality rate was higher among patients with S. aureus infection than among those without infection (P = 0.03). Factors significantly associated with S. aureus infection were nasal carriage, presence of a vascular catheter, low CD4 count, and neutropenia. Molecular strain typing indicated that for 6 of 7 infected patients, the strain of S. aureus isolated from the infected sites was the same as that previously cultured from the nares. CONCLUSION: Nasal carriage is an important risk factor for S. aureus infection in HIV-infected patients. Controlled studies are indicated to determine whether eradication of nasal carriage in a selected subset of patients (for example, those with a low CD4 cell count) might prevent invasive S. aureus infection in patients with HIV infection.

PMID: 10049200 [PubMed - indexed for MEDLINE]

26: Chest. 1998 Oct;114(4):1129-36.

Related Articles, Books, LinkOut

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Pulmonary infiltrates in the surgical ICU: prospective assessment of predictors of etiology and mortality.

Singh N, Falestiny MN, Rogers P, Reed MJ, Pularski J, Norris R, Yu VL.
Veterans Affairs Medical Center, Pittsburgh, PA 15240, USA.

A prospective cohort study of 129 consecutive patients developing pulmonary

infiltrates in the surgical ICU was conducted to determine the predictors and outcome of pulmonary infiltrates. Most common etiologies of pulmonary infiltrates were pneumonia (30%), pulmonary edema (29%), acute lung injury (15%), and atelectasis (13%). Enteral nutrition was associated with a significantly lower incidence of acute lung injury as compared with pneumonia (22% vs 58%, p = 0.012). Patients with liver disease were significantly more likely to have pulmonary infiltrates due to acute lung injury as compared with other etiologies (p = 0.02). Clinical pulmonary infection score (Pugin score) > 6 virtually excluded acute lung injury, pulmonary edema, or atelectasis as etiologies of pulmonary infiltrates. Nosocomial Haemophilus/pneumococcal pneumonia occurred significantly earlier in the ICU as compared with Gram-negative (p = 0.05) or methicillin-resistant Staphylococcus aureus pneumonia (p = 0.01). Pneumonia in trauma patients was significantly more likely to be due to Haemophilus/pneumococcus as compared with all other ICU patients (54% vs 0%, p = 0.0004). These data have implications for treatment of patients with nosocomial pneumonia in the ICU.

Publication Types:

- Multicenter Study

PMID: 9792588 [PubMed - indexed for MEDLINE]

☐ **27:** J Antimicrob Chemother. 1998 Feb;41(2):289-91.

Related Articles, Compound via MeSH, Substance via MeSH, Books, LinkOut

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Activity of azithromycin, clarithromycin, roxithromycin, dirithromycin, quinupristin/dalfopristin and erythromycin against Legionella species by intracellular susceptibility testing in HL-60 cells.

Stout JE, Arnold B, Yu VL.
Special Pathogens Laboratory, Veterans Affairs Medical Center, and The University of Pittsburgh School of Medicine, PA 15240, USA.

We evaluated a human monocyte cell line (HL-60) as a model for testing the intracellular activity of anti-Legionella antibiotics; 1.5 x 10(6) HL-60 cells/well were differentiated into adherent cells and infected with 1.5 x 10(7) cfu of Legionella pneumophila. The most active agents against L. pneumophila as judged by broth dilution MICs were (in order of activity) azithromycin, clarithromycin, roxithromycin, quinupristin/dalfopristin, erythromycin and dirithromycin. The most active inhibitors of L. pneumophila intracellular multiplication were (in

order of activity) azithromycin, erythromycin, quinupristin/dalfopristin, roxithromycin, dirithromycin and clarithromycin. All the agents were highly active against Legionella micdadei and Legionella bozemanii when compared with L. pneumophila.

PMID: 9533475 [PubMed - indexed for MEDLINE]

28: Am J Infect Control. 1998 Feb;26(1):8-11.

Related Articles, Cited in PMC, Books, LinkOut

ELSEVIER FULL-TEXT ARTICLE

Nosocomial legionnaires' disease discovered in community hospitals following cultures of the water system: seek and ye shall find.

Goetz AM, **Stout JE**, < b>Jacobs SL, **Fisher MA**, **Ponzer RE**, **Drenning S**, **Yu VL**.
Veterans Administration Medical Center and Legionella Study Group, Pittsburgh, PA 15240, USA.

BACKGROUND: The reservoir for hospital-acquired legionnaires' disease is the water distribution system. The Allegheny County (Pa.) Health Department recommended environmental cultures for all health care facilities for the prevention of hospital-acquired Legionella infection including facilities with no known cases of legionnaires' disease. METHODS: Environmental cultures of hot water tanks, faucets, and showerheads were performed in six health care facilities according to health department guidelines. If hot water tanks, faucets, or showerheads yielded Legionella, monitoring with Legionella culture and urinary antigen was performed for all cases of nosocomial pneumonia. RESULTS: Legionella was isolated from the water distribution system in 83% (five of six) of facilities. Three facilities dropped out of the study; two decided to disinfect the water and one had no Legionella in the water system. The other three facilities all discovered cases of legionnaires' disease during the 1-year study period after introduction of Legionella testing. L. pneumophilia, serogroups 1, 3, and 5, caused 12 cases of hospital-acquired legionnaires' disease. Positive diagnostic tests included: 10 of 12 (83%) urinary antigen, 6 of 8 (75%) respiratory cultures, and 2 of 5 (40%) serology. Molecular typing confirmed that the source of infection was the water supply in two hospitals. CONCLUSION: Routine environmental cultures for Legionella in the water distribution system are recommended even if the hospital had not previously recognized cases of hospital acquired legionnaires' disease. The Allegheny County Health Department guidelines were inexpensive

to implement and resulted in the discovery of cases that would have otherwise been undiagnosed.

PMID: 9503106 [PubMed - indexed for MEDLINE]

29: Diagn Microbiol Infect Dis. 1998 Jan;30(1):37-43.

Related Articles, Compound via MeSH, Substance via MeSH, Books, LinkOut

ELSEVIER FULL-TEXT ARTICLE

Comparative activity of ciprofloxacin, ofloxacin, levofloxacin, and erythromycin against Legionella species by broth microdilution and intracellular susceptibility testing in HL-60 cells.

Stout JE, **Arnold B**, **Yu VL**.
Special Pathogens Laboratory, Veterans Affairs Medical Center, Pittsburgh, Pennsylvania, USA.

Animal lung macrophages or human peripheral blood mononuclear cells have been used for testing intracellular activity of anti-Legionella antibiotics; such studies are labor intensive such that comparative antibiotic studies for the many Legionella species are few. We evaluated a human monocyte cell line (HL-60) as an alternative model. HL-60 (1.5 x 10(6) cells/well) was differentiated into adherent cell and infected with 1.5 x 10(7) CFU of Legionella pneumophilia (L. pneumophilia). Erythromycin and quinolones, ciprofloxacin, ofloxacin, and levofloxacin were added to cells at 1 and 8 x MIC. Percent (%) inhibition ratios equal to total L. pneumophila with agent divided by L. pneumophila without agent x 100 were determined at 48 h; lower ratios implied greater potency. By broth dilution in buffered yeast extract broth, the most potent agents against L. pneumophila were (MIC): ciprofloxacin (0.015-0.03), ofloxacin (0.015-0.03), levofloxacin (0.015-0.03), erythromycin (0.125-1.0 microgram/mL). In the intracellular model, the most potent inhibitors of L. pneumophila multiplication at 8 x MIC were (in order of potency) levofloxacin (24.2%), ciprofloxacin (30.6%), ofloxacin (37.1%), and erythromycin (55.0%). All the quinolones were highly active and significantly more potent against L. micdadei and L. bozemanii when compared to L. pneumophila.

PMID: 9488830 [PubMed - indexed for MEDLINE]

30: J Infect Dis. 1998

Related Articles, Compound via MeSH, Substance via MeSH, Cited in PMC, Books, LinkOut

Feb;177(2):425-30.

Do in vitro susceptibility data predict the microbiologic response to amphotericin B? Results of a prospective study of patients with Candida fungemia.

Nguyen MH, Clancy CJ, Yu VL, Yu YC, Morris AJ, Snydman DR, Sutton DA, Rinaldi MG.
University of Florida College of Medicine, VA Medical Center, Gainesville 32610, USA. nguyen.med@shands.ufl.edu

Outcome for 105 patients with candidemia treated with amphotericin B was correlated with amphotericin B in vitro susceptibility results. Thirty-three patients had microbiologic failure, which was defined as persistence of Candida in the bloodstream despite > or = 3 days of amphotericin B. Amphotericin B minimum inhibitory concentrations (MICs) were determined by the National Committee for Clinical Laboratory Standards methodology. After determination of MICs, the minimal lethal concentrations (MLCs) were determined. The isolates tested yielded a narrow range of amphotericin B MICs (0.06-2 microg/mL); only 5% (5/105) exhibited MICs > or = 1 microg/mL. The MLC range, on the other hand, was significantly broader (0.125 to > 16 microg/mL); 24% (25/105) exhibited MLCs > or = 1 microg/mL. The strongest predictor for microbiologic failure was 48-h MLC (P < .001), followed by 24-h MLC (P = .03) and 48-h MIC (P = .11). A resistant break point for amphotericin B of > 1 microg/mL for MLC and > or = 1 microg/mL for MIC could be inferred from this study.

PMID: 9466531 [PubMed - indexed for MEDLINE]

☐ **31:** Clin Infect Dis. 1998 Jan;26(1):138-40.

Related Articles, Compound via MeSH, Substance via MeSH, Cited in PMC, Books, LinkOut

Intermittent use of copper-silver ionization for Legionella control in water distribution systems: a potential option in buildings housing individuals at low risk of infection.

Liu Z, Stout JE, Boldin M, Rugh J, Diven WF, Yu VL.
University of Pittsburgh, Pennsylvania, USA.

One copper-silver ionization system was sequentially installed onto the hot-water recirculation lines of two hospital buildings colonized with

Legionella pneumophila, serogroup 1. A third building with the same water supply and also colonized with Legionella served as a control. Four weeks after activation of the system, distal site positivity for Legionella in the first test building dropped to zero. After operating for 16 weeks, the system was disconnected and installed onto the second test building. Twelve weeks of disinfection reduced the distal site positivity for Legionella in the second test building to zero. Legionella recolonization did not occur in the first test building for 6-12 weeks and in the second test building for 8-12 weeks after inactivation of the system. The control building remained Legionella-positive throughout the experimental period. A significantly higher copper concentration was found in the biofilm taken from a sampling device than in that from water. This is likely to be the reason that the copper-silver ionization system had the residual effect of preventing early recolonization. Our study raises the possibility that one copper-silver unit could be rotated among several buildings to maintain a Legionella-free environment. Such an approach may be cost-effective for buildings housing individuals at low risk for contracting legionnaires' disease.

PMID: 9455522 [PubMed - indexed for MEDLINE]

☐ **32:** Transplantation. 1997 Sep 15;64(5):716-20. Related Articles, Compound via MeSH, Substance via MeSH, Cited in PMC, Books, LinkOut

LWWonline Pittsburgh Print Collection

Invasive aspergillosis in liver transplant recipients in the 1990s.

Singh N, **Arnow PM**, **Bonham A**, **Dominguez E**, **Paterson DL**, **Pankey GA**, **Wagener MM**, **Yu VL**.
Veterans Affairs Medical Center and University of Pittsburgh, Pennsylvania 15240, USA.

Invasive aspergillosis occurred in 26 liver transplant recipients since 1990 at five liver transplant centers. The median time to onset was 17 days after transplantation. Twenty-seven percent of the patients had undergone retransplantation. Invasive aspergillosis occurred significantly earlier after transplantation in smokers than in nonsmokers (P=0.017). Patients with late-onset aspergillosis (occurring after posttransplant day 90) were more likely to have had prior cytomegalovirus infection than those with early-onset aspergillosis (occurring within 90 days of transplantation) (67% vs. 10%, respectively, P=0.013). Only 8% of the patients had received additional corticosteroids or OKT3, which suggests

that augmented immunosuppression may not be a relevant risk factor for invasive aspergillosis in the 1990s due to less frequent use of these agents. The median serum bilirubin level of the patients was 21.8 mg/dl, 85% of the patients had renal insufficiency, and 54% were on dialysis before the onset of invasive aspergillosis, which suggest that overall severity of illness, including poorly functioning hepatic allograft and renal failure may be the major determinants of disease occurrence. Overall mortality was 92% (24/26). No difference in mortality could be shown for the patients who received amphotericin B versus liposomal amphotericin B preparations (100% vs. 89%); however, the mean time to death after the initiation of therapy was 20 days in patients who received amphotericin B and 43 days in those who received liposomal amphotericin B preparations.

PMID: 9311708 [PubMed - indexed for MEDLINE]

33: Clin Infect Dis. 1997 Jun;24(6):1135-8. Related Articles, Books, LinkOut

Pittsburgh Print Collection

Cirrhotic fever in the 1990s: a prospective study with clinical implications.

Singh N, **Yu VL**, **Wagener MM**, **Gayowski T**.
Veterans Affairs Medical Center, Pittsburgh, Pennsylvania 15240, USA.

Fifty consecutive patients with fever and cirrhosis were prospectively studied to assess if cirrhotic fever was a true clinical entity and to determine its characteristics and outcome. In 20% (10) of the 50 patients, an identifiable source of fever or infection, was not documented (these patients were defined as having cirrhotic fever). The patients with cirrhotic fever were significantly less toxic, as indicated by lower temperature (P = .0001), tachycardia (P = .0005), and tachypnea (P = .05), but had fever for a longer duration (P = .009) than did patients with infectious fever. Patients with cirrhotic fever were significantly less likely to have focal signs or symptoms (P < .0001) or a portal of infection confirmed by culture (P = .0001), as compared with patients with infectious fever. Outcome (at 30-days or long-term) was not different for patients with cirrhotic fever vs.-patients with infectious fever or matched controls who did not have fever. Eight (80%) of the 10 patients with cirrhotic fever underwent transplantation; fever did not recur after transplantation in any of these patients. Thus, fever in up to 20% of the febrile patients with cirrhosis may be attributable to cirrhosis

itself; such patients may be spared the ongoing diagnostic maneuvers and unnecessary trials of antibiotics.

PMID: 9195071 [PubMed - indexed for MEDLINE]

34: Head Neck. 1997 May;19(3):216-8. Related Articles, Substance via MeSH, Cited in Books, Books, LinkOut

FULL TEXT AVAILABLE ONLINE WILEY InterScience

Lack of serologic evidence for Helicobacter pylori infection in head and neck cancer.

Grandis JR, **Perez-Perez GI**, < b>Yu VL, **Johnson JT**, **Blaser MJ**.
Department of Otolaryngology, University of Pittsburgh School of Medicine, Pennsylvania 15213, USA.

BACKGROUND: Several epidemiologic investigations have established a link between Helicobacter pylori infection and gastric malignancies. Because the stomach is in continuity with the oral cavity and the bacterium has been isolated from dental plaque and saliva, we hypothesized that H. pylori infection of the upper aerodigestive tract might result in mucosal disruption, allowing for subsequent transformation by known carcinogens such as tobacco and alcohol. METHODS: To test this hypothesis, we assayed for the presence of IgG antibodies to H. pylori in the serum of 21 patients with squamous cell carcinoma of the head and neck (SCCHN) and 21 matched controls without a history of head and neck cancer. RESULTS: The incidence of seropositivity in the SCCHN patients was 57% and in the controls, 62% ($p > 0.05$). CONCLUSIONS: These data do not support an etiologic role for H. pylori infection in head and neck cancer.

PMID: 9142522 [PubMed - indexed for MEDLINE]

35: Int J STD AIDS. 1997 Apr;8(4):251-5. Related Articles, Books, LinkOut

ingentaconnect

Psychological stress and depression in older patients with intravenous drug use and human immunodeficiency virus infection: implications for intervention.

Singh N, **Squier C**, **Sivek C**, **Wagener MM**, **Yu VL**.
VA Medical Center, Infectious Disease Section, Pittsburgh, PA 15240,

USA.

We aim to assess the age-related differences in psychological stress and depression in patients with human immunodeficiency virus (HIV) infection. Prospective, longitudinal, observational study of patients with HIV followed at a university affiliated VA Medical Center. Fifty-six consecutive patients with HIV infection aged 19-68 were studied. Data on demographics, living arrangements, education, employment, income, social, religious, and community support, medical status, psychological stress, depression, and coping was assessed at baseline and every 6 months. Instruments for psychological testing included Beck Depression Inventory, Profile Mood Status (POMS) scale and ways of coping scale (inventory of coping with illness scale). Sixty-nine per cent (38/56) of the patients were older than 35 years of age. Older patients exhibited significantly greater emotional and psychological stress; the mean POMS score for older patients was 56.8 as compared to 21.5 for younger patients (P = 0.004). Older patients had significantly greater depression (P = 0.001), higher tension and anxiety (P = 0.005), greater anger and hostility (P = 0.03), greater confusion and bewilderment (P = 0.01), and more fatigue (P = 0.003) as compared with younger patients. Older patients were significantly more likely to have intravenous drug use as an HIV risk factor (P = 0.02), less likely to be employed (P = 0.005), and more likely to use non-traditional therapies (P = 0). Intravenous drug use was an independent predictor of psychological stress in older patients. Patients with HIV, older than 35 years of age, are significantly more likely to suffer from depression and psychological stress; intravenous drug use was an independent predictor of stress. Interventions for the treatment of depression should be especially sought in this subgroup of patients with HIV.

PMID: 9147158 [PubMed - indexed for MEDLINE]

☐ **36:** Clin Infect Dis. 1996 Dec;23 Suppl 1:S54-65.

Related Articles, Cited in PMC, Books, LinkOut

Analysis of trends in antimicrobial resistance patterns among clinical isolates of Bacteroides fragilis group species from 1990 to 1994.

Snydman DR, McDermott L, Cuchural GJ Jr, Hecht DW, Iannini PB, Harrell LJ, Jenkins SG, O'Keefe JP, Pierson CL, Rihs JD, Yu

VL, **Finegold SM**, **Gorbach SL**.
Department of Medicine, New England Medical Center, Tufts University School of Medicine, Boston, Massachusetts 02111, USA.

Antimicrobial resistance, including plasmid-mediated resistance, among Bacteroides fragilis group species is well documented. A 5-year (1990-1994) prospective, eight-center survey of 3,177 clinical isolates of Bacteroides species was undertaken to review trends in resistance, using the breakpoints for full and intermediate susceptibility established by the National Committee for Clinical Laboratory Standards. No documented resistance to either metronidazole or chloramphenicol was found in this survey. Among B. fragilis isolates virtually no resistance was seen to imipenem, meropenem, ampicillin/sulbactam, piperacillin/tazobactam, or ticarcillin/clavulanate. Significant increases in resistance among B. fragilis isolates to cefotetan, ceftizoxime, and clindamycin ($p < .01$) were noted. Resistance to cefoxitin remained unchanged. Among the non-fragilis species of the B. fragilis group, there was virtually no resistance to imipenem, meropenem, chloramphenicol, or metronidazole. The three beta-lactamase inhibitors had increasing levels of resistance, although 95%-98% of strains were susceptible ($p < .05$). There was a significant decline in cefoxitin, cefmetazole, and clindamycin activity over time against these strains ($p <.01$). There was a significant ($P < .001$) increase in geometric mean minimum inhibitory concentration for most drugs and species tested from 1990 to 1994. Clusters in the eight institutions could not account for this rise in resistance. This survey demonstrates that rates of resistance of B. fragilis and non-fragilis species of B. fragilis group are increasing.

Publication Types:

- Multicenter Study

PMID: 8953108 [PubMed - indexed for MEDLINE]

37: Clin Infect Dis. 1996 Dec;23(6):1282-6.

Related Articles, Compound via MeSH, Substance via MeSH, Cited in PMC, Books, LinkOut

Pittsburgh Print Collection

Low-dose fluconazole as primary prophylaxis for cryptococcal infection in AIDS patients with CD4 cell counts of < or = 100/mm3: demonstration of efficacy in a positive, multicenter trial.

Singh N, **Barnish MJ**, **Berman S**, **Bender B**, **Wagener MM**, **Rinaldi MG**, **Yu VL**.
Veterans Affairs Medical Center, Pittsburgh, Pennsylvania, USA.
The efficacy of low-dose fluconazole (200 mg orally administered thrice weekly) as primary prophylaxis for cryptococcal infection was prospectively assessed in a multicenter trial involving 218 patients who we re infected with human immunodeficiency virus (HIV) and who had CD4 cell counts of < or = 100/mm3. The median CD4 cell count at baseline was 39/mm3, 58% of the patients had an AIDS-defining illness or infection prior to enrollment. Cryptococcal meningitis occurred in 0.4% (1) of the 218 patients. The breakthrough isolate was susceptible to fluconazole, and the fluconazole kinetic study demonstrated adequate drug absorption and serum fluconazole levels; noncompliance could not be excluded in this case. Mucocutaneous and/or esophageal candidiasis developed in 18% (40) of the patients. Noncompliance with fluconazole therapy was the only variable independently associated with breakthrough candidiasis in the study patients (P = .00002). Thus, fluconazole (200 mg thrice weekly) given to HIV-infected patients with CD4 cell counts of < or = 100/mm3 was efficacious as primary prophylaxis for cryptococcosis, with notably lower costs and increased convenience for patients in comparison with daily administration of the drug.

Publication Types:

- Clinical Trial
- Multicenter Study

PMID: 8953072 [PubMed - indexed for MEDLINE]

38: J Infect Dis. 1996 Nov;174(5):1116-9.

Related Articles, Cited in PMC, Books, LinkOut

Pittsburgh Print Collection

Nosocomial Legionnaires' disease caused by Legionella pneumophila serogroup 5: laboratory and epidemiologic implications.

Chang FY, **Jacobs SL**, **Colodny SM**, **Stout JE**, **Yu VL**.
Special Pathogen Laboratory, YA Medical Center, Pittsburgh, PA 15240, USA.

Environmental monitoring and clinical surveillance for Legionella species were done for 12 months as recommended by the Allegheny County Health Department (Pittsburgh). The water system of a hospital was found to be colonized with Legionella pneumophila serogroup 5. Three patients with nosocomial L. pneumophila serogroup 5 disease were subsequently diagnosed after laboratory tests for legionellae were made available for all patients with nosocomial pneumonia. All serogroup 5 isolates from the hospital water matched the 3 patient isolates by pulsed-field gel electrophoresis (PFGE). Furthermore, isolates found in the water supply dating back 10 years showed the same PFGE pattern. In contrast, 12 L. pneumophila serogroup 5 isolates from eight other institutions had different PFGE patterns. Routine environmental cultures were important in stimulating the application of Legionella laboratory testing, which subsequently identified unsuspected patients with nosocomial legionnaires' disease.

PMID: 8896520 [PubMed - indexed for MEDLINE]

☐ **39:** Antimicrob Agents Chemother. 1996 Oct;40(10):2428-30.

Related Articles, Compound via MeSH, Substance via MeSH, Cited Articles, Free in PMC, Cited in PMC, Books, LinkOut

FREE full text article at aac.asm.org | Pittsburgh Link to full text | Pittsburgh Print Collection | FREE full text article in PubMed Central

In vitro activities of two novel oxazolidinones (U100592 and U100766), a new fluoroquinolone (trovafloxacin), and dalfopristin-quinupristin against Staphylococcus aureus and Staphylococcus epidermidis.

Mulazimoglu L, **Drenning SD**, **Yu VL**.
Section of Infectious Diseases, Marmara University School of Medicine, Istanbul, Turkey.

Two oxazolidinones (U100592 and U100766), trovafloxacin, and a streptogramin combination (dalfopristin-quinupristin) were highly active in vitro against Staphylococcus aureus and Staphylococcus epidermidis, including methicillin-resistant strains. Trovafloxacin was more active than ciprofloxacin. Time-kill synergy studies demonstrated indifference for the oxazolidinones combined with vancomycin and rifampin against methicillin-resistant staphylococci. Spontaneous resistance was observed with all agents.

PMID: 8891159 [PubMed - indexed for MEDLINE]

Appendix B
Record Review
Institutional Review Board and Research & Development

The following list represents a review of all IRB and R&D records for which Dr. Victor L. Yu was listed as the Principal Investigator.[7]

1. **Project Title**: Prospective Observational Study on Pneumococcal Bacteremia: Penicillin Resistant vs. Penicillin Sensitive Isolates
   Principal Investigator: Victor L. Yu, MD

   The IRB cover memo states "the objective is to perform in vitro antibiotic susceptibility on the pneumococci isolated from the patients, including minimum inhibitory concentration (MIC) and minimum bactericidal concentration (MBC) for beta-lactam agents, vancomycin, and macrolides by both e-tests and agar dilution method. Specific antibiotics including ceftriaxone (Roche Laboratories) that increased potency will also undergo in vitro susceptibility testing."

   The IRB file contains the following records for this study:
   - Contingent IRB approval-3/24/2000
   - Final IRB approval with waiver of informed consent-5/3/2000
   - Final R&D approval-3/7/2000.

   The IRB file does not contain the following **required** records:
   - Request for continuing review
   - Request for study closure

2. **Project Title**: Retrospective Surplus Sample Collection Protocol For BD Probetec ET Assay Development

[7] This review was conducted by the IRB coordinator, Kathy Parks.

Principal Investigator: Victor L. Yu, MD

According to the abstract the objective of this study was to provide surplus frozen sputum, brochoalveolar lavage or bronchial wash specimens that have tested positive for Legionella pneumophila to Becton Dickinson & Company for the development of a Legionella pneumophila assay to be performed on the BDProbeTec ET system.

The IRB file contains the following records for this study:

- IRB submission states "No Humans"-procedures at this time would not include IRB review
- Final R&D approval-2/21/2002
- R&D approval of study closure-3/5/2003

The IRB file does not contain the following **required** records:

- Request for continuing review 2/2003, this resulted in a lapse in approval from 2/2003 to 3/2003

3. **Project Title:** Prospective Observational Study on Pneumococcal Meningitis: Penicillin-resistant versus Penicillin-sensitive Isolates
Principal Investigator: Victor L. Yu, MD

The IRB cover memo states "the objective of the study is to perform in vitro antibiotic susceptibility on the pneumococci isolated from the patient, including minimum inhibitory concentration (MIC) and minimum bactericidal concentration (MBC) for beta-lactam agents, vancomycin, and macrolides by both e-tests and agar dilution method. Specific antibiotics including ceftriaxone (Roche Laboratories) that have increased potency against drug-resistant S.pneumoniae will also undergo in vitro susceptibility testing. Molecular subtyping and serotyping will also be performed.

The IRB file contains the following records for this study:

- Initial IRB review-Exemption granted 7/3/2002
- Final R&D approval-8/14/2002
- R&D approval of study closure-12/15/2003

The IRB file does not contain the following **required** records:

- R&D request for continuing review-8/2003, this resulted in a lapse in approval from 8/2003-12/2003

4. **Project Title:** Azithromycin vs. Erythromycin with or without Cefuroxime for Therapy of Community-Acquired Pneumonia
Principal Investigator: Victor L. Yu, MD

According to the abstract the purpose of the study "is to evaluate a new drug, azithromycin, for therapy on pneumonia as compared to the standard antibiotic, erythromycin with cefurozime".

The IRB file contains the following records for this study:

- IRB final approval-1/21/92
- Report of contact-study not initiated due to FDA approval-4/22/93
- Deferral of amended protocol/consent form-5/27/94
- IRB approval of amendment-6/30/94
- IRB approval of revised consent form-10/13/94
- Continuing review approval-5/16/95
- Continuing review approval-4/15/96
- SAEs and notification of closed enrollment-1996
- IRB approval of study closure-7/3/97
- R&D approval of continuing review-5/13/94

The IRB file does not contain the following **required** records:

- IRB continuing review-1/93
- R&D final approval-1/92

5. **Project Title**: Topical Antibiotic Prophylaxis in Patients Undergoing Dental Extractions: Assessment of Bacteriologic Efficacy
Principal Investigator: Victor L. Yu, MD

According to the protocol the objective of the study was to assess the bacteriologic efficacy of topical amoxicillin in reducing the incidence of bacteremia following dental extraction in a randomized study.

The IRB file contains the following records for this study:

- Contingent IRB approval-8/26/94
- IRB final approval-12/21/94
- IRB continuing review approval-7/18/95
- IRB approval of study closure-8/2/96
- Contingent R&D approval-8/2/94

The IRB file does not contain the following **required** records for this study:

- Final R&D approval

6. **Project Title:** The Efficacy of Topical Antibiotic Prophylaxis for Head and Neck Surgery
Principal Investigator: Victor L. Yu, MD

According to the protocol the objectives of the study were 1). To assess the bacteriology of parentaral perioperative clindamycin with topical clindamycin using two durations of therapy, 2). To assess the bacteriologic efficacy of another

antibiotic with an extended spectrum of activity against gram negative aerobes versus clindamycin mouthwash and 3). To determine if prolonged use of topical agents results in overgrowth of resistant bacteria in the oropharynx.

The IRB file contains the following records for this study:

- Excerpt from IRB minutes
- Final IRB approval-10/14/92
- R&D reviewer comments

The IRB file does not contain the following **required** records for this study:

- Requests for continuing review-study approval expired 9/25/93
- Request for study closure
- Final R&D approval

7. **Project Title:** Various Studies Examining Treatment, Prevalence and Eradication of Legionella
   Principal Investigator: Victor L. Yu, MD

According to the protocol the objectives of the study were: 1) to assess the efficacy of disinfection modalities in eradicating Legionella from water distribution systems, 2) to assess the epidemiology of community-acquired Legionnaires'disease and 3) to determine the source of the infecting Legionella.

The IRB file contains the following records for this study:

- R&D continuing review submission form-11/17/2005
- R&D approval of continuing review-12/162005
- Notice of administrative closure of study-8/28/06

The IRB file does not contain the following **required** records:

- Original submission to R&D
- Final R&D approval
- R&D continuing review request
- Request for study closure

8. **Project Title**: A Randomized Trial of Fluconazole vs. Amphotericin B in the Treatment of Candida Urinary Tract Infections
   Principal Investigator: Victor L Yu, MD

The IRB file contains the following records for this study:

- IRB continuing review-1/96-1/97
- IRB continuing review-1/97-1/98

9. **Project Title:** Levaquin Community-Acquired Pneumonia Study
   Principal Investigator: Victor L. Yu, MD

The IRB file contains the following record for this study:

- Project termination notice-4/29/98

Additional Records

IRB minutes dating from 1995-2000 were reviewed for any reference to research protocols submitted by Victor L. Yu, MD. The following excerpt from those minutes provides some documentation for one additional protocol.

10. "Preemptive Prophylaxis with Oral vs. Intravenous Ganciclovir for the Prevention of CMV Disease in Liver Transplant Recipients," submitted by Victor L. Yu, MD
6/28/96-Renewal
6/27/97-Renewal
2/25/00-Terminated

University of Pittsburgh IRB Records

11. Project Title: Prospective Assessment of Clinical and Microbiological Characteristics of Patients with Crptococcal Disease
Principal Investigator: Victor L. Yu, MD

The University of Pittsburgh IRB approved this study on 6/10/03 and terminated it on 7/12/04 due to non-renewal. University of Pittsburgh IRB files contain no additional records for Dr. Yu.

Testimony of Victor L. Yu, M.D.

Appendix

I. Response to Publication Audit by Pittsburgh VA

Conclusion: For the 39 articles reviewed, not a single example of human subject research without appropriate approval was found

II. Research and development Approval Form for Legionella Studies

III. Research Project Approval for Klebsiella Study

IV. Memo from Victor L. Yu to M. Moreland requesting written justification for closure –July 12, 2006

V. Letter to Drs Jain, Graham, DeRubertis protesting the destruction of the scientific collection – January 17, 2007

VI. Phoenix VA letter of support for assistance in Legionella cultures

Response to Publication Audit
VA Pittsburgh Healthcare System
September 5, 2006
Victor L. Yu, M.D.

The document from the Pittsburgh VA concluded that the audit "suggests a strong likelihood that Dr. Yu was engaged in human subject research at the VAPHS without the appropriate committee approvals."

A close reading of this audit shows numerous errors were made in the audit of the 39 articles published: some were minor, but many errors were so obvious as to bring in the issue of bias. Using the language of the audit, I conclude that this audit "suggests a strong likelihood" that numerous errors found in the VA Pittsburgh Healthcare audit were due to the bias of the Pittsburgh VA Medical Center administration. The Pittsburgh VA needed to rationalize the illegal and unjustified closure of the Pittsburgh Special Pathogens Laboratory and the willful destruction of a scientific collection. So, they produced a misleading and erroneous audit. The magnitude and obviousness of some of the errors is striking.

1. **Multiple Counting**
9 articles emanating from a single study were counted to inflate the total number of articles purported to be in question
Articles 1, 9, 15; Articles 7, 11, 16, 29; Articles 12, 13

Audit Error: Article 1. This article is derived from Article 9 and 15 which has IRB and R&D approval. None of the patients discussed were at the Pittsburgh VA.

2. **Audit Error:** NonVA studies.
7 studies covered in the audit involved no patients at the Pittsburgh VA; the studies were conducted elsewhere.
Articles 1, 5, 8, 10, 14, 17, 34

3. **Audit Error:** 6 studies in which it was claimed in *VAPHS IRB and R&D records contain no documentation for this study*" had documented IRB approval which were in the files of the VA Research and Development office. The projects containing the documentation are in Appendix B.
Articles 1 (Project 1), 8 (Project 9), 6, 19, 27, 29 (all 4 are under Project 7)

4. **Audit Error:** 10 studies did not meet the definition of human subject research according to the federal code. This code is cited explicitly on page 17 of the audit. Thus, IRB approval was not required.

These studies were "observational" in the "no intervention nor interaction with the individual patient "occurred" and "no identifiable private information" was involved. In each of the articles a statement in the Methods noted that "the study was observational in that administration of antimicrobial agents and other management was controlled by the patient's physician, not the investigator." This audit error is inexplicable since the title of some articles and the methods classified the study as observational was so obvious.

Moreover, HIPAA regulations known as the Privacy Rule was not mandated until 2003 prior to the approval of these proposals. So, at the time of these studies, formal approval was not mandated.
Articles 4, 7, 11, 12, 13, 16, 20, 22, 24, 30

5. Only three studies of the 39 articles reviewed involved interventional studies involving VA patients. These 3 studies clearly fulfilled the definition of human subject research. For these studies, both IRB and Human Subjects approval were obtained and approved by the R & D Committee. Informed consent was obtained on all patients and copies were given to patients and placed in the patient chart. In two studies, the audit states "VAPHS IRB records contain some documentation for the study". In one study (Article 21), approval was listed under the PI, who was not Dr. Yu.
Articles 18, 21, 23

Audit Error: Article 25. In this study, nasal swabs for *S. aureus* were obtained as part of Infection Control policy and patient care. Nasal swabs are routinely used in the Pittsburgh VA for surveillance. Moreover, the article was published in 1999 prior to HIPAA Guidelines.

6. **Audit error.** 2 studies reviewed did not involve any patient contact and intervention and involved isolates not specifically linked to individual patients.
Articles 36, 39

7. **Audit Error:** One article fulfills the OHRP Guidelines discussed on page 18, paragraph 3. In these studies, the specimens were saved and "not collected specifically for the proposed research project" and "the investigator cannot ascertain the identity of the individual to which specimens pertain".
Article 39

8. Seven articles reviewed had IRB approval by the PI (who was not Dr. Yu). This is discussed on page 18, paragraph 1.

9. Six articles were not cited and had full documentation.
Articles 15, 26, 28, 32, 33, 35

Note that several articles listed above as "Audit Error" fulfilled different criteria.

In summary, for all 39 studies reviewed, not a single example of human subject research without appropriate approval was found.

Appendix B – Record Review
IRB and R&D

11 projects were reviewed by the Pittsburgh VA auditor.

Many reviews by the auditor noted the following: Lack of "R*equest for continuing review*" and Lack of "*R&D approval of the study closure*"; or Lack of "*Request for study closure*". The implication is that these were unapproved studies.

In fact, all of the projects were approved. All of the citations noted by the auditor were technicalities noted after the projects were approved. The technicalities were not related to research merit or human rights issues. However, it is important to note that the validity of appropriateness of the projects from a research and human rights perspective can be confirmed in the audit document itself.

In the 20 plus years that I have performed over 100 studies, I have never been informed of any delinquency in this area by either the IRB or R&D Committee. I saw the results of this misleading and flawed audit only after the Congressional Investigational Oversight Subcommittee showed it to me.

The chairman of the VA Research Committee introduced a policy for all VA investigators that submission of an abstract or publication of the article would be sufficient as documentation for IRB continuing approval or study closure. Every year, our research group and other VA researchers submitted all abstracts and publications for the year to the Committee. The Research Foundation also used these documents to demonstrate the research productivity of the Pittsburgh VA Medical Center. Thus, the fact that this audit was based on a review of our published articles immediately validates that the "*R&D for study closure*" was fulfilled. This is pertinent to Projects 1 and 6.

Comments on each specific Project:

Project 1 Prospective Observational Study on Pneumococcal Bacteremia
Citation: Request for continuing review
Request for study closure

Note that this approved project was concluded and an article published. The article was awarded the Wolinsky Prize for the best clinical infectious disease article for 2003. The fact that the article was published fulfills the criteria for study closure.

Project 2 Retrospective surplus sample collection for B
Citation: Request for continuing review 02/2003

This project was never initiated. This is confirmed by R&D approval of study closure on 03/05/2003.

Project 3: Prospective observational study in pneumococcal meningitis

Citation: Request for continuing review

This approved project has been completed and an abstract presented. No VA patients participated in this study. We were the repository for the pneumococcal isolate collection.

Project 4: Azithromycin vs. erythromycin
Citation: IRB continuing review – 01/1993
R&D final approval – 01/1992

This approved study was completed and published.
Note that IRB approval of study closure was given on 07/03/1997 and R & D approval of continuing review was on 05/13/1994. So, the IRB continuing review in 01/1993 and R&D final approval on 01/1992 must have been lost by the R&D Committee or overlooked by the auditor.

Project 5: Topical antibiotic prophylaxis
Citation: Final R & D approval

Note that IRB approval of study closure was 08/02/1996. So, the study was formally closed on 08/02/1996. The R&D approval was either lost by the R&D Committee or the auditor overlooked it.

Project 6: Efficacy of topical antibiotics
Citation: Request continuing review
Request for study closure
Final R&D approval

This study was never initiated.

Project 7: Various studies examining treatment, prevalence, and eradication of Legionella
Citation: Original submission to R&D
Final R&D approval
R&D continuing review request
Request for study closure

This is an important document which confirms that all of the *Legionell*a studies conducted were approved by the R&D Committee.

The dates show that *R& D approval of continuing review* was performed. So, the original documents must have been lost by the R&D Committee or overlooked by the auditor. I have in my possession the form that documents that the initial R&D approval was performed on 10/01/1998 and that it did not expire until 12/11/2006. The Special Pathogens Laboratory was terminated in July, 2006.

This project was also cited for lack of "*Request for study closure*". It seems a gross injustice to cite Lack of *Request for study closure* after the Pittsburgh VA terminated the Pittsburgh VA Special Pathogens Laboratory. The VA closed the study when I was terminated.

Project 8: Randomized trial of fluconazole
No Citation

Project 9: Levaquin (levofloxacin) Community-Acquired pneumonia
No Citation
Note: It was the basis for Article 8 which the auditor claimed had no documentation.

Project 10: Preemptive prophylaxis
No Citation

Project 11: University of Pittsburgh
The study was concluded by 2004 so we did not request renewal.

One reasonable conclusion from review of Projects 1, 2, 3, 4, 5, 6, 7, 11 in Appendix B was that this was a targeted witch hunt attempting to cast aspersion on Dr. Yu's reputation as a clinical investigator. These minor technicalities were never pointed out to Dr. Yu during his 25 years as the most productive researcher in the Pittsburgh VA as judged by publication numbers. None of the technicalities dealt with project approval. It is ironic that that information provided in the audit itself confirmed that all the projects were approved. Documents lost by the Research Office or overlooked by the auditor were then used to impugn Dr. Yu and imply that improprieties occurred.

Victor L. Yu, M.D.
Professor of Medicine
University of Pittsburgh
Date: September 5, 2008

Animal Studies Subcommittee (IACUC)
VA Pittsburgh Healthcare System #646
University Drive • Pittsburgh, PA 15240

Mark
Approved!

CONTINUING REVIEW SUBMISSION FORM

Date: October 24, 2003
Investigator: **Victor L. Yu, M.D.**
Protocol: Pathogenicity of Klebsiella Pneumoniae Isolated from Different Geographical Locations and Disease Presentations
ID: 02096 Protocol#: N/A Protocol#: N/A

Initial AnSS Approval Date: 03/20/2003
Previous Continuing Reviews: N/A
Approval Expiration: 03/19/2004

Submission Form Due Date: 03/04/2004
Continuing Review Date: 03/18/2004

This form is used for the first and second renewal of an approved animal protocol. NOTE: Prior to the third anniversary, the IACUC must conduct a re-review of the entire protocol.

Request to Review Research Proposal/Project
646 Pittsburgh, (UD), PA

1. **Principal Investigator/Program Director:** Yu (Last) Victor (First) L. (MI) ____ (Degree)
2. **SSN:** 476 - 46-9721 3. **Telephone:** 412/688-6179 **Ext.:** ____ 4. **Mail Code:** ____
5. **VA Appointment:** [XX] Full-Time [ ] Part-Time [ ] WOC [ ] Consultant [ ] Contract (Check one)
6. **Status of PI in Proposal:** 01 (Enter Code) *(01 = Awardee or Initiator 02 = Not Awardee; i.e., Participant in VA Co-Op Study)*
7. **Type of Submission:** [x] New [ ] Renewal of Active Project (Check one)
   If Renewal, complete a and b: a) Enter 4-digit number of active project____ b) Has title changed? [ ] Yes [ ] No
8. **Project Title:** (142 characters maximum) Pathogenicity of Klebsiella Pneumoniae isolated from different geographical locations and disease presentations.
9. **Co-Principal Investigators:** *(Enter only if study is funded. Must have a VA appointment and must be designated a Co-PI in application.)*
   ____ (Last name, first name, mi, degree) ____ (Social Security Number) [ ] Check if at another VAMC
   ____ (Last name, first name, mi, degree) ____ (Social Security Number) [ ] Check if at another VAMC
10. **Anticipated Starting Date:** 04 / 01/ 99 (mm/dd/yy)
11. **Funding Source and Fund Administration:** *(Codes are on back of instruction sheet)*

Source Code (4-digits)	Name if Source Code ends in "99"	Admin Code (2-digits)	Name if Admin Code is "08"
0000		01	

If Source Code is 9007 9022, or 9024, enter VACO Project Number ____

12. **Project Uses:** *(Mark each item and submit completed forms. If Animal Subjects is Yes, Complete Item 15.)*
    Human Subjects [ ] Yes [x] No Invest Drugs [ ] Yes [x] No Radioisotopes [ ] Yes [x] No
    Animal Subjects [x] Yes [ ] No Invest Devices [ ] Yes [X] No Biohazards [ ] Yes [X] No
13. **Project Focus:** *(Mark each item.)*
    Agent Orange [ ] Yes [x] No Females [ ] Yes [x] No Prisoners of War [ ] Yes [x] No
14. **Keywords:** *(Minimum 3, maximum 6. Use MeSH terms only. Enter one term per line.)*
    1) Klebsiella 4) ____
    2) Pneumonia 5) ____
    3) Animal 6) ____
15. **Animal Subjects:** *(Species and, if applicable, strain. Enter one species per line.)*
    1) Mouse C57BL/6J 5) ____
    2) ____ 6) ____
    3) ____ 7) ____
    4) ____ 8) ____

(Continue on Page 4)

16. Abstract: *(Submit on separate sheet or on floppy disk; see instructions)*

17. Institutional Support: *(Mark each item. *If Yes, a letter of support/collaboration must be attached to this form.)*

Laboratory*	☐ Yes ☒ No	Medicine*	☐ Yes ☒ No	Pharmacy*	☐ Yes ☒ No
Radiology*	☐ Yes ☒ No	Nuclear Medicine*	☐ Yes ☒ No	Nursing*	☐ Yes ☒ No
Psychiatry*	☐ Yes ☒ No	Outpatient*	☐ Yes ☒ No	Surgery*	☐ Yes ☒ No

Other* ☐ Yes ☒ No > If Yes, Specify _____

Lab Space ☒ Yes ☐ No > If Yes, Bldg and Room Animal Facility, Building 6

Budget Page ☐ Yes ☒ No > Must be included with all submissions (except Funding Source Code 0000)

18. Institutional Approvals: *(Signatures as appropriate)*

Section Chief _____ 3/19/99
Date

Service Chief _____ 3/19/99
Date

19. Comments: _____

Principal Investigator See above (Dr Yu)
Signature Date

Note: If this is your First Research Proposal submitted at this Medical Center, please also submit an Investigator Data Sheet (Page 18) and a Personal Data Form. The same applies to co-principal investigators who have not submitted these forms.

Research Office use only:

Date Received: _____

Item check: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 VAF 10-5368

Date Returned: _____ *Reason:* _____

Date Entered: _____

Research & Development Committee
VA Pittsburgh Healthcare System #646
7180 Highland Drive • Pittsburgh, PA 15206

CONTINUING REVIEW SUBMISSION FORM

Date: July 10, 2006
Investigator: **Victor L. Yu, M.D.**
Protocol: Various Studies Examining Treatment, Prevalence and Eradication of Legionella
ID: 00137 Prom#: 0010 Protocol#: N/A

Initial R&D Approval Date: 10/01/1998
Previous Continuing Reviews: 01/25/2006
Approval Expiration: 12/11/2006

Submission Form Due Date: 10/04/2006
Continuing Review Date: 10/25/2006

Regulations specify that Continuing Review is required for all approved research studies. Failure to comply will result in suspension or termination.

Please provide the following:
1) An Abstract (Guidelines Attached)
2) Research Staff Form
3) A NEW VA Conflict of Interest Form for the PI and each Investigator, Co-investigator, or Collaborator devoting 5% or more effort to the project.
4) Any manuscripts that have been submitted for publication or peer reviewed abstracts of work that have been presented during the past year.

Have there been any changes, since the last report, with respect to:
1. Your role at the VA? ☐Yes ☐No
2. The programmatic relationship to VAPHS R&D activity? ☐Yes ☐No

If you answered yes to any of the above questions, attach documentation explaining the change.

3. Has the study terminated? ☐Yes ☐No If yes, provide a final report.

If you have any questions, please contact the Research Office at #412-688-6104.

Signature: _____ Date: _____
(ONLY THE PRINCIPAL INVESTIGATOR IS AUTHORIZED TO SIGN)

APPROVED/DISAPPROVED

Signature: _____ Date: _____
Chairperson, Research & Development Committee

Department of Veterans Affairs

REPORT OF SUBCOMMITTEE ON HUMAN STUDIES

MIRB# 00253

Project/Program Title: Exposure Assessment for Community Acquired Legionnaire's Disease

Principal Investigator: Janet E. Stout, PhD

VAMC: Pittsburgh, (UD), PA Review Date: 12/14/2001

COMMITTEE FINDINGS

1. The information given in the Informed Consent under the Description of Research by Investigator is complete, accurate, and understandable to a research subject or surrogate who possesses standard reading and comprehension skills. [X] YES [ ] NO

2. The informed consent is obtained by the principal investigator or a trained and supervised designate under suitable circumstances. [X] YES [ ] NO

3. Every effort has been made to decrease risk to subject(s)? [X] YES [ ] NO

4. The potential research benefits justify the risk to subject(s)? [X] YES [ ] NO

5. If subject is incompetent and surrogate consent is obtained, have all of the following conditions been met: a) the research can't be done on competent subjects; b) there is no risk to the subject, or if risk exists the direct benefit to subject is substantially greater; c) If an incompetent subject resist, he/she will not have to participate; d) If there exists any question about the subject's competency, the basis for decision on competency has been fully described. [X] YES [ ] NO

6. If the subject is paid, the payment is reasonable and commensurate with the subject's contribution. [ ] YES [ ] NO [X] NA

7. Members of minority groups and women have been included in the study population whenever possible and scientifically desirable. [X] YES [ ] NO

8. Comments: (Indicate if Expedited Review) This study is approved for the period of 1/17/02 to 12/13/02. Extension beyond 12/13/02 requires reapproval of the SHS. Any adverse effects must be reported to the SHS and the Research Office.

RECOMMENDATION: [X] APPROVED [ ] DISAPPROVE/REVISE

SIGNATURE OF CHAIRMAN: Ali E. Sonel, M.D. DATE: 1/17/02

VA FORM OCT 1985 10-1223 EXISTING STOCK OF VAF 10-1223 JAN 1990, WILL NOT BE USED

Department of Veterans Affairs

REPORT OF SUBCOMMITTEE ON HUMAN STUDIES

Project/Program Title Legionella Colonization of Health Facility Water Systems

Principal Investigator Robert R. Muder, MD and Janet E. Stout, PhD

VAMC Pittsburgh, (UD), PA Review Date: 9/25/98

COMMITTEE FINDINGS

1. The information given in the Informed Consent under the Description of Research by Investigator is complete, accurate, and understandable to a research subject or surrogate who possesses standard reading and comprehension skills. ☒ YES ☐ NO

2. The informed consent is obtained by the principal investigator or a trained and supervised designate under suitable circumstances. ☒ YES ☐ NO

3. Every effort has been made to decrease risk to subject(s)? ☒ YES ☐ NO

4. The potential research benefits justify the risk to subject(s)? ☒ YES ☐ NO

5. If subject is incompetent and surrogate consent is obtained, have all of the following conditions been met: a) the research can't be done on competent subjects; b) there is no risk to the subject, or if risk exists the direct benefit to subject is substantially greater; c) If an incompetent subject resist, he/she will not have to participate; d) If there exists any question about the subject's competency, the basis for decision on competency has been fully described. ☒ YES ☐ NO

6. If the subject is paid, the payment is reasonable and commensurate with the subject's contribution. ☐ YES ☐ NO ☒ NA

7. Members of minority groups and women have been included in the study population whenever possible and scientifically desirable. ☒ YES ☐ NO

8. Comments: (Indicate if Expedited Review) This study is approved for the period of 10/29/98 to 9/25/99. Extension beyond 9/25/99 requires reapproval of the SHS. Any adverse effects must be reported to the SHS and the Research Office.

RECOMMENDATION: ☒ APPROVED ☐ DISAPPROVE/REVISE

SIGNATURE OF CHAIRMAN [signature] DATE

Mona F. Melhem, M.D. 10/29/98

Department of Veterans Affairs

Memorandum

Date: July 12, 2006

From: Victor L. Yu, M.D

Subj: Written justification for closure requested

To: Michael Moreland, Director,

Thru: Frederick DeRubertis, Vice President, Medical Specialty Service Line
Thru: Rajiv Jain, Chief of Staff

I am responding to the memo signed by Dr. Jain on 7/5/06 and the verbal comments by Dr. Jain at the meeting between myself and Frederick DeRubertis on July 5, 2006. I was stunned by the decisions in the memo of 7/5/06. At the meeting, no clearcut justification for closure of the Special Pathogens Laboratory was given only - vague generalities that bordered on innuendo.

"The Special Pathogens Lab is a commercial lab that does not perform research." "The Special Pathogens Lab is a commercial lab that furnishes funds for your research." "Your research activities are not IRB-approved." All of the above statements are absurd and demonstrably false. If they are indeed the reasons, please place them in writing so that I can respond to them.

After I objected to this drastic action, Dr. Jain informed me I could appeal to Mr. Moreland. Two days later on 7/07/06, Nicholas Squeglia, Administrative Officer, informed me by telephone that the Special Pathogens Laboratory had been terminated, the 5 scientific personnel were to be fired that day, and Dr. Janet Stout had been demoted to a bench technician in the hospital microbiology laboratory.

My loyalty and commitment to the VA has been shattered in a very disheartening manner. The Special Pathogens Laboratory has existed for 25 years and is one of the great reference laboratories in the U.S. Documentation of the publications reporting on the patient lives in the VA that have been saved, and the discoveries that have affected management of patients in the VA and worldwide have already been given to you.

Given the abruptness and severity of the decision to close down the Special Pathogens Laboratory and terminate the employment of the individuals working in this laboratory with only 24 hour notice, detailed justification for this action should have been made in the memo of 7/5/06. In this memo, no justification whatsoever was given. I request the reasons for such a punitive decision in writing, so that we can adequately respond. Fairness in dealing with such a situation is a reflection of the integrity of the institution.

VICTOR L. YU, M.D.
Chief, Infectious Disease Section

Moreland SpecialPathogensLab
Yu/memo

VA FORM MAR 1989 2105

www.Legionella.org
The Legionella experts
Home Page

Best Website
www.legionella.org-
the most complete Legionella
website on the Internet
Selected on the basis of their
scientific content and
adherence to standards of
Internet publishing by Clinical
Infectious Diseases -
the official journal of the
Infectious Disease Society of
America (IDSA).

University of Pittsburgh
School of Medicine
Department of Medicine

January 17, 2007

Dr. Rajiv Jain
Dr. Steven Graham
Dr. Frederick DeRubertis
VA Medical Center
University Drive C
Pittsburgh, PA 15240

Dear Drs. Jain, Graham and DeRubertis:

We are writing this letter to protest and express our outrage and sorrow over the destruction of valuable and irreplaceable research material that is critical to future research efforts. This includes developing new laboratory tests for atypical pathogens, new media for identification of *Legionella*, assessment of new antibiotics for Legionnaires' disease and correlation of virulent isolates with proposed models of pathogenesis. Before release to physicians and microbiology labs worldwide, all FDA-approved lab tests and antibiotics used for diagnoses and therapy for Legionnaires' disease were tested in the Special Pathogens Laboratory using these materials

Consequences of the Action

This treasure trove of research material includes the most comprehensive set of *Legionella* isolates worldwide, including rare species isolated from fewer than 10 patients. The pathogenesis of *Legionella* is now being elucidated using new molecular methods. Our collaboration with basic scientists has been predicated on the use of isolates from this collection that are known to be virulent to patients and from environmental isolates that are not linked to disease.

Moreover, the collection included environmental isolates from the Pittsburgh VAMC and other VAMCs nationwide. It included isolates collected from patient homes in ongoing studies supported by the American Legion, Environmental Protection Agency, and 5 US state departments of health. Retrieval of these isolates allowed assessment of the success
of disinfection measures over time. It also allowed identification of the environmental source using molecular methods if patients contracted Legionnaires' disease in the future. The greatest harm from this action will be to patients from our VAMC and other VAMC's as *Legionella* outbreaks continue to affect VA patients because they have the highest risk factors for the disease -smoking, alcohol use, and age.

How Could This Have Happened?

Dear Drs. Jain, Graham and DeRubertis:

We have received no reply to our email of January 17, 2007.

We still need to verify the status of the collection of non-Legionella isolates. These isolates were accumulated from multiple observational studies and were the property of over 40 international collaborators.

We need an immediate answer to whether you have destroyed the entire collection for the following reason: A virulent Klebsiella has been seen in Taiwan that causes an invasive syndrome of liver abscess and endopthalmitis with high mortality rate. We were the first to demonstrate that it was a Taiwan phemenonon not seen in Europe, North America, South America, or Australia. At least 11 suspected cases have now been reported in the US, but confirmation is lacking. Klebsiella isolates from California, New York, and Barcelona from bacteremic patients with liver abscesses have been sent to us for storage and safekeeping. We injected these isolates in a mouse model of Klebsiella in a VA IRB-approved protocol, These 3 Klebsiella isolates killed mice similar to the Taiwan isolates in storage, and, in contrast, to Klebsiella from other continents which were avirulent in mice. Our collaborators from Taiwan have recently developed new methods of subtyping based on capsular serotype and presence of virulent factors. They have requested our 3 isolates to confirm the fact that the virulent Klebsiella has now reached Spain and the US. If we were able to confirm that the Taiwan isolates have indeed made it to the US, it would have immediate public health implications. Were over 400 Klebsiella isolates from 6 continents and the 3 Klebsiella isolates from US and Spain destroyed as were the legionella isolates?

If not, then it is imperative that the entire collection of microorganisms including the Klebsiella isolates should now be transferred to the University of Pittsburgh as planned months ago.

If Drs Sonel and Melhem indeed destroyed the entire collection, it becomes your responsibility to uncover the truth of why this despicable action could have occurred. On the other hand, if you stonewall or attempt to whitewash our inquiry, this irresponsible action would be consistent with your vindictive and unethical response to our attempts to save the Special Pathogens Lab. Eventually the truth would be revealed and besmirch all of you. As of now, your silence adds to the complicity of the entire Pittsburgh VA administration.

Victor L. Yu , MD and Janet E Stout, PhD

www.Legionella.org
The Legionella experts
Home Page

www.legionella.org-
the most complete Legionella website on the Internet
Selected on the basis of their scientific content and adherence to standards of Internet publishing by Clinical Infectious Diseases - the official journal of the Infectious Disease Society of America (IDSA).

Phoenix VA (Peterson) -Letter of support for VA Lab

Victor Yu victorlyu@gmail.com

On 9/1/06, Peterson, Rick C <Rick.PetersonCQ2@va.gov>wrote:

Dr. Yu,

I would like to thank you for processing the Legionella water samples from the Phoenix VAMC in
July, 2006. I know that pressure existed to not process these environmental samples. And, I
understand that the dedicated staff of the Special Pathogens Laboratory worked without pay on
these specimens to fulfill their public health mission.

Fortunately you were able to get them done. The results we received were important for the
healthcare of our veteran patients. 65% of our water samples were positive. These results have
confirmed that the recent addition of copper/silver ionization to our domestic water system was the right thing to do. The staff of the Pittsburgh VA Special Pathogens Lab has worked with us every step of the way in our fight to rid our water system of Legionella. Not only with lab analysis but with development of a treatment strategy. Your Lab has brought deserved prestige to the OVA Healthcare System and improved our care of the veteran patients at the Phoenix VAMC.

With the help of you and Dr. Stout, our facility is on the way to significantly reducing the odds of
an outbreak of Legionnaire's Disease.

Thanks to you and your group.

Rick Peterson
Plumbing and Mechanical Supervisor
Phoenix VA Medical Center
(602) 277-5551 ext 7122

BIOGRAPHY FOR VICTOR L. YU

Victor L. Yu, M.D., is a Professor of Medicine at the University of Pittsburgh, Pittsburgh, Pennsylvania. He majored in mathematics at Carleton College, earned his medical degree at the University of Minnesota, and performed his internship and residency at the University of Colorado and Stanford University. He performed his postdoctoral fellow in infectious diseases at Stanford University. His research interests include *Legionella* infections, antimicrobial resistance, and medical informatics. He had published over 300 scientific papers, contributed to chapters to over 70 books, and is Editor-in-Chief of three textbooks. He is also the editor of *www.antimicrobe.org,* a state-of-the-art website for antimicrobial agents and infectious diseases. A major accomplishment has been the 50 students and fellows he has mentored who are now active in research and academic positions throughout the world. Dr. Yu has accepted over 200 invited lectures and visiting professorships internationally. He has received numerous awards including these from the American Legion, Health Research and Services Foundation, American Society for Microbiology, National Institutes of Health, the Federal Research Executive Board, and Australasia Infectious Disease Society. He was elected to Best Doctors in America from 1996–present (Woodward, White, Inc.), and Top Doctor 2006–present (Castle–Connelly). He is the recipient of the Emmanuel Wolinsky Award given by the Infectious Disease Society of America for the Best Original Article published in *Clinical Infectious Diseases* for 2003.

Chairman MILLER. Thank you, Dr. Yu.

Dr. Snydman.

STATEMENT OF DR. DAVID R. SNYDMAN, CHIEF, DIVISION OF GEOGRAPHIC MEDICINE AND INFECTIOUS DISEASES, AND ATTENDING PHYSICIAN IN INFECTIOUS DISEASES, DEPARTMENT OF MEDICINE, TUFTS MEDICAL CENTER; PROFESSOR OF MEDICINE AND MICROBIOLOGY, TUFTS UNIVERSITY SCHOOL OF MEDICINE

Dr. SNYDMAN. Thank you, Mr. Chairman and Members of the Committee. Thank you for inviting me. I am Dr. David Snydman. I am Chief of the Division of Geographic Medicine and Infectious Diseases at Tufts Medical Center in Boston and professor of medicine and microbiology at Tufts University School of Medicine. I offer my CV, which outlines my training and expertise in the fields of microbiologic research as well as clinical research within the field of infectious disease.

Due to time constraints, I will not go into details about my training or publication record, which are listed on my CV, but I will state for the record that I conduct studies in infectious diseases using the microbiology laboratory and I am nationally and internationally recognized for my research. I have been funded by the NIH for many years for many of the studies that I have published. I have collaborated with Victor Yu in a variety of studies conducted over the past 20 years or more. Many of these have been published in the highest-level journals within the field of clinical infectious diseases and microbiology.

Let me also state that I have publicly praised the VA health care system in an editorial I wrote for the Mayo Clinic proceedings regarding quality of care around central line-associated infections, so I come to this proceeding as someone who recognizes the value of the VA health care system. I have never been an employee of the VA but have worked as a medical resident at the Boston VA and volunteered in the Atlanta VA while I was employed by the Centers for Disease Control. I am trying to offer as dispassionate and objective an opinion as possible.

I have been asked by the staff to comment on a number of issues pursuant to these proceedings including the value of the resource of the Special Pathogens Laboratory in the Pittsburgh VA Hospital as well as the studies which were foreclosed by the destruction of the isolates and the value of the research conducted by Drs. Yu and Stout. I have also been asked as to how I learned of the destruction of the isolates housed in the Special Pathogens Laboratory, to comment on my actions and to comment on changes in policies Congress should consider in order to prohibit such actions from happening in the future. First, let me say from the outset that the question should be broadened to include isolates other than *Legionella* since many of the isolates the Special Pathogens Laboratory housed were microbiologic species of bacteria and fungi other than *Legionella.*

I first learned there was a problem in the Special Pathogens Laboratory in July of 2006. I actually called Dr. Yu in late June or early July of that year to discuss a case of a very rare disease, *Legionella* endocarditis. I wanted him to try to isolate the organism from a heart valve that needed to be replaced in a patient I was consulting on. Our laboratory had not been able to isolate the organism but there was a strong suspicion that *Legionella* was causing the disease based on a number of clinical factors. Since treatment requires six months or more of therapy, I wanted to get as definitive an answer as possible. I knew that Dr. Yu had the expertise to perform specialized studies on the valve including the use of molecular diagnostic tools. He told me that he would try to perform the studies, to hold onto the blood cultures and he would give me instructions as to how to send them. After some time he told me he would not be able to perform the studies and indicated the laboratory would be shut down. I was quite disturbed and asked if there was anything I could do. I subsequently wrote to the VA hospital administration in Pittsburgh protesting this action as well as Senator Specter and some in the Pennsylvania Congressional Delegation. I later found out, much to my dismay, that the isolates from the whole collection were destroyed. I eventually wrote the viewpoints piece for the journal *Clinical Infectious Disease,* which is the official clinical journal of the Infectious Disease Society of America. I have appended this article for submission with my testimony.

With respect to the research done by Drs. Yu and Stout, one can only conclude that it is of the highest caliber in the world. They are internationally recognized for their work and expertise in *Legionella* as well as other pathogens and their laboratory set the standard for our understanding of the environmental control for *Legionella.* If I may read into the record part of the viewpoints piece, I believe the Committee will get a flavor for the value of the collection. "Dr. Yu established a series of national and international collaborations to elucidate our understanding of the microbiological and clinical management issues of bacteremia due to many different organisms. These studies were seminal in many respects. They changed our understanding of the relationship between appropriate and inappropriate therapy, the relationship between the minimum inhibitory concentrations of isolates to antimicrobial agents in outcome, and the molecular epidemiology of relapse and re-infection as well as relatedness of strains throughout

the world. The studies are far too numerous to articulate in detail or even list here in total but they include studies of the major pathogens that confound us today including *Staphylococcus aureus, Pseudomonas aeruginosa,* extended spectrum beta-lactamase producing *Klebsiella pneumoniae,* Enterobacter species, *Stenotrophomona maltophilia,* Enterococcus species, *Bacteroides fragilis, Streptococcus pneumoniae,* and Candida species. The concept was simple: observe the clinical presentation of bacteremia or fungemia and follow outcomes while correlating microbiology to outcome. The studies were prospective, and all the isolates were collected and sent to a central laboratory, the Pittsburgh VA Special Pathogens Laboratory, for more definitive analysis. Each of the studies emanating from this collection has changed our knowledge base and contributed significantly towards optimal management of patients with these infections. Capturing the isolates and making sure they were sent was an important and difficult task, especially for fastidious organisms like Strep pneumoniae and Bacteroides species. Given the international component as well as the requirements for sending specimens across national borders, these studies were difficult to perform. All studies were approved as per local IRB requirements and permits were obtained from regulatory authorities. Nevertheless, the number of studies and important insights total well over 100 peer-reviewed articles and have provided important information that correlate outcome with the use of certain antibiotic classes as well as levels of susceptibility. Some of the studies have challenged prevailing dogma and helped provide data for the CLSI, the Clinical Lab Standards Institute."

I go on to point out, "These isolates were accrued purely for the advancement of science and beneficiaries of these studies were the patients infected by these microbes. Moreover, these isolates and samples would have proven invaluable in the future in that these strains would enable comparison over time for changes in pathogen virulence, antimicrobial susceptibility correlation with outcome, and changing genetic diversity as well as the development of new molecular tests."

The value of the collection is that it was linked to clinical outcomes. This kind of collection does not really exist anywhere in the world, and these studies are really quite difficult to organize and complete. The reason this is so important is that one can correlate microbiologic factors to clinical outcomes, and with a large number of patients and specimens to study, one can control for confounding variables such as underlying host factors which might relate to the clinical outcome. The Committee should note that one of our studies on pneumococcal bacteremia was given a national award at the annual meeting of the Infectious Disease Society, the Emmanuel Linskey Award, as the best clinical paper for the year.

The studies which were foreclosed by the destruction of these isolates included any study of new pathogenic factors that might be related to microbial pathogenesis in a variety of organisms changing microbial diversity, which we recognize as continually evolving, and factors that might relate to antimicrobial resistance and susceptibility. While these organisms exist in nature and can be grown from the environment as well as people, the fact that there was a collection of organisms linked to outcomes made the collection in-

valuable to science. It would have been relatively simple to maintain the collection since many organisms are maintained in freezers in a holding solution. Some agreement should have been entered into between the parties that wanted to close the lab and Drs. Yu and Stout in order to give them time to make arrangements for transport of the specimens to another laboratory. To just destroy the specimens as was done was a wanton, thoughtless act. It is for this reason that I wrote my viewpoints piece for publication and appended a petition which has been signed by a number of clinical and microbiologic research scientists throughout the world, and I am happy to attend these proceedings. Thank you.

[The prepared statement of Dr. Snydman follows:]

PREPARED STATEMENT OF DAVID R. SNYDMAN

I am Dr. David R. Snydman, MD, Chief of the Division of Geographic Medicine and Infectious Diseases, Tufts Medical Center, Boston, MA and Professor of Medicine and Microbiology, Tufts University School of Medicine. I offer my C.V., which outlines my training and expertise in the fields of microbiologic research, as well as clinical research within the field of infectious diseases. Due to time constraints I will not go into details about my training or publication record which are listed on my C.V., but I will say for the record that I conduct studies in infectious diseases using the microbiology laboratory and am nationally and internationally recognized for my research. I have been funded by the NIH for many years for many of the studies I have published. I have collaborated with Dr. Victor Yu in a variety of studies conducted over the past 20 years or more. Many of these have been published in the highest level journals within the field of clinical infectious disease and microbiology. Let me also state that I have publicly praised the VA health care system in an editorial I wrote for the *Mayo Clinic Proceedings* regarding quality of care around central line associated infections. So I come to this proceeding, as someone who recognizes the value of the VA health care system. I have never been an employee of the VA but have worked as a medical resident in the Boston VA and volunteered in the Atlanta VA while I was employed by the Centers for Disease Control. I am trying to offer as dispassionate and objective opinion as possible.

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With respect to the research done by Dr. Yu and Dr. Stout, one can only conclude that it is of the highest caliber in the world. They are internationally recognized for their work and expertise in *Legionella* as well as other pathogens and their laboratory set the standard for our understanding of the environmental control for *Legionella.* If I may read into the record part of the Viewpoints piece, I believe the Committee will get a flavor for the value of the collection.

"Dr. Yu established a series of national and international collaborations to elucidate our understanding of the microbiologic and clinical management issues of bacteremia due to many different organisms. These studies were seminal in many respects. They changed our understanding of the relationship between appropriate and inappropriate therapy, the relationship between the minimum inhibitory concentrations of isolates to outcome, and the molecular epidemiology of relapse and reinfection as well as relatedness of strains throughout the world. The studies are far too numerous to articulate in detail or even list here in total, but they include studies of the major pathogens that confound us today, including *Staphylococcus aureus* (6–8), *Pseudomonas aeruginosa* (9), extended spectrum beta-lactamase producing *Klebsiella pneumoniae* (10–12) Enterobacter species (13), *Stenotrophomonas maltophilia* (14), Enterococcus species (15,16), *Bacteroides fragilis* (17), *Streptococcus pneumoniae* (18–20), and Candida species (21–23). The concept was simple, observe the clinical presentation of bacteremia or fungemia, and follow outcomes while correlating the microbiology to the outcome. The studies were all prospective and the isolates collected and sent to a central laboratory (the Pittsburgh VA special pathogens laboratory) for more definitive analysis. Each of the studies emanating from this collection has changed our knowledge base and contributed significantly towards optimal management of patients with these infections.

Capturing the isolates and making sure they were sent was an important and difficult task—especially for fastidious organisms like *S. pneumoniae* and *Bacteroides* species. Given the international component, as well the requirements for sending specimens across national borders, these studies were difficult to perform. All studies were approved as per local IRB requirements and permits were obtained from regulatory authorities. Nevertheless, the number of studies and important insights total well over a 100 peer-review articles and have provided important information that correlates outcome with the use of certain antibiotic classes as well as levels of susceptibility. Some of the studies have challenged prevailing dogma and helped provide data for the CLSI.

I also go on to point out "These isolates were accrued purely for the advancement of science and the beneficiaries of these studies were the patients infected by these microbes. Moreover, these isolates and samples would have proven invaluable in the future in that these strains would enable comparison over time for changes in pathogen virulence, antimicrobial susceptibility correlation with outcome, and changing genetic diversity as well as the development of new molecular tests."

The value of the collection is that it was linked to clinical outcomes. This kind of collection does not really exist anywhere in the world and these studies are really quite difficult to organize and complete. The reason this is so important is that one can correlate microbiologic factors to clinical outcomes, and with a large number of patients and specimens to study, one can control for confounding variables such as underlying host factors, which might relate to the clinical outcome. The committee should also note that one of our studies on pneumococcal bacteremia was given a national award at the annual meeting of the Infectious Disease Society of America, the Emanual Wolinsky award, as the best clinical paper for the year. The studies which were foreclosed by the destruction of these isolates included any study of new pathogenic factors that might be related to microbial pathogenesis in a variety of organisms, changing microbial diversity which we recognize as continually evolving, and factors that might relate to antimicrobial resistance and susceptibility. While these organisms exist in nature and can be grown from the environment as well as people, the fact that there was a collection of organisms linked to outcomes made the collection invaluable to science.

It would have been relatively simple to maintain the collection since many organisms are maintained in freezers in a holding solution. Some agreement should have been entered into between the parties that wanted to close the lab and Dr. Yu and Dr. Stout in order to give them time to make arrangements for transport of the specimens to another laboratory. To just destroy the specimens as was done was a wanton thoughtless act. It is for this reason that I wrote my Viewpoints piece for publication and appended a petition which has been signed by a number of clinical and microbiologic research scientists throughout the world.

VIEWPOINTS

Destruction of Isolates from the Pittsburgh Veterans Affairs Laboratory

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The Pittsburgh Veterans Affairs hospital administration closed the research laboratory directed by Victor Yu and Janet Stout and destroyed isolates collected as part of a series of clinical studies over 25 years. This article discusses the implications and protests such destruction as an affront to science and scientific study. A petition signed by 243 individuals accompanies this article.

The Pittsburgh Veterans Affairs (VA) Special Pathogens Laboratory, headed by Victor Yu, MD, and Janet E. Stout, PhD, was terminated by the Pittsburgh VA administration in July 2007, under protest from Dr. Yu. During the administrative dispute, the collection of clinical specimens and microbiological isolates obtained by investigators from around the world were destroyed. These materials were collected as part of numerous prospective observational studies and infection control–related studies. For almost 30 years, Drs. Yu and Stout set the standards for our understanding of the epidemiology of *Legionella* infection, as well as for our understanding of the control of environmental *Legionella* infection.

Dr. Yu also established a series of national and international collaborations to elucidate our understanding of the microbiological and clinical management issues of bacteremia due to many different organisms. These studies were seminal in many respects. They changed our understanding of the relationship between appropriate and inappropriate therapy, the relationship between the MICs of isolates and outcome, the molecular epidemiology of relapse and reinfection, and the relatedness of strains throughout the world. The studies are far too numerous to articulate in detail or even to list here in total, but they include studies of the major pathogens that confound us today, including *Staphylococcus aureus, Pseudomonas aeruginosa,* extended-spectrum β-lactamase–producing *Klebsiella pneumoniae, Enterobacter* species, *Stenotrophomonas maltophilia, Enterococcus* species, *Bacteroides fragilis, Streptococcus pneumoniae,* and *Candida* species. The concept was simple: observe the clinical presentation of bacteremia or fungemia, and follow outcomes while correlating the microbiology to the outcome. The studies were all prospective, and the isolates were collected and sent to a central laboratory for more-definitive analysis. Each of the studies emanating from this collection has changed our knowledge base and has contributed significantly toward optimal treatment of patients with these infections. Moreover, the careers of a number of prominent academicians were launched when they coordinated these large-scale studies and had the opportunity to analyze the data as trainees.

Capturing the isolates and making sure they were sent to the laboratory was an important and difficult task—especially for fastidious organisms like *S. pneumoniae* and *Bacteroides* species. Given the international component, as well the requirements for sending specimens across national borders, these studies were difficult to perform. All studies were approved in accordance with local institutional review board requirements, and permits were obtained from regulatory authorities. Nevertheless, the number of studies and important insights total >100 peer-review articles (see References [online only] for selected articles) and have provided important information that correlates outcome with the use of certain antibiotic classes, as well as levels of susceptibility. Some of the studies challenged prevailing dogma and helped provide data for the Clinical and Laboratory Standards Institute.

All of these isolates, many of which were still being studied, were destroyed. The samples were incinerated without warning or notification to Drs. Yu and Stout, such

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that it became an irrevocable action. These isolates were accrued purely for the advancement of science, and the beneficiaries of these studies were the patients infected with these microbes. Moreover, these isolates and samples would have proven to be invaluable in the future, because having these strains would enable comparison over time, for changes in pathogen virulence, antimicrobial susceptibility correlation with outcome, and changing genetic diversity, as well as the development of new molecular tests. Their destruction can by no means be considered to be justifiable. Add your name to the petition or review details at the Call for Inquiry Web site (http://www.legionella.org/vaspl.asp). It is in this context that this petition is being published.

PETITION FOR VA ACCOUNTABILITY

We, the undersigned, respectfully request that VA Central Office convene an investigative committee to review the actions of the Pittsburgh VA Healthcare System regarding the closure of the Special Pathogens Laboratory and the destruction of a scientifically valuable collection of microorganisms.

The collection of microorganisms was created and preserved by Victor L. Yu, MD and Janet E. Stout, PhD over a 25-year period in the Special Pathogens Laboratory in Pittsburgh. The entire collection was incinerated without informing Drs. Yu and Stout. This action was taken despite efforts by Drs. Yu and Stout to appropriately transfer the collection to the University of Pittsburgh.

The collection contained stored patient sera, urine samples from patients infected by unusual *Legionella* species and respiratory tract specimens yielding rare *Legionella* species dating back to 1979. Among the several thousand *Legionella* isolates destroyed were environmental and patient isolates from 20 VA hospitals experiencing outbreaks of hospital-acquired Legionnaires' disease. For some of us, *Legionella* isolates from our VA hospital were among those destroyed.

These *Legionella* isolates and specimens were being stored for future epidemiologic investigation; providing an invaluable resource for elucidating the source of Legionnaires' disease at VA Medical Centers. As importantly, emergence of resistance of *Legionella* to disinfectants has been reported by us and the storage of the original isolates from each hospital allows documentation of this possibility in the event of failure of disinfection. Finally, molecular fingerprinting would allow individual VA hospitals to ascertain the source of the infecting *Legionella* in VA patients should future outbreaks occur.

Among the isolates in the collection were several thousand well-characterized microorganisms from multinational observational studies. These disease-causing strains of *Pseudomonas aeruginosa*, *Enterobacter* species, *Enterococcus* species, *Bacteroides fragilis*, *Stenotrophomonas maltophilia*, *Klebsiella* species, *Candida* species and *Cryptococcus neoformans* were also destroyed.

This unique collection of specimens and isolates were being used to develop new diagnostic tests, new therapies, and to study resistance and mechanisms of disease transmission. The results of these studies benefited veterans nationwide.

To remove the appearance of impropriety, we request that an outside scientific body with no relationship to the VA be convened to ascertain the appropriateness of this action.

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The references are in the online edition of *Clinical Infectious Diseases.*

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Dr. Snydman has been involved in both antibiotic resistance related research, epidemiologic research and clinical care for over 30 years. He has had an ongoing interest in anaerobic infections as well as an interest in Cytomegalovirus in solid organ transplantation. He developed Cytomegalovirus Immune Globulin, brought it to licensure and was awarded a citation from the Massachusetts Department of Public Health for his efforts. He has been a Teaching and Research scholar of the American College of Physicians. He has published over 250 peer reviewed original articles, book chapters and reviews, co-edited 13 Year Books of Infectious Disease, five Yearbooks of Medicine and published one book. He was the recipient of the Ken Kaplan award, given annually to the "outstanding infectious disease clinician" by the Massachusetts Infectious Disease Society, and he has also received a Distinguished Faculty award from Tufts University School of Medicine. He is also a co-recipient of the Emanual Wolinsky award, given annually for the best clinical paper published in the *Journal of Clinical Infectious Diseases.* He sits on the editorial boards of the *Journal of Transplantation, Journal of Clinical Infectious Diseases,* and *Mayo Clinic Proceedings.* He is nationally and internationally recognized for his clinical and microbiologic research in the field of infectious diseases.

DISCUSSION

THE LABELING AND CATALOGING CHARACTERISTICS OF THE SCIENTIFIC COLLECTION

Chairman MILLER. Thank you, Dr. Snydman.

I understand that Mr. Moreland will testify. His written testimony submitted last night asserts that none of the samples were, and this is a quote from the testimony, "collected, labeled, cataloged and properly stored to constitute a scientific collection." One of the people who cleaned out the refrigerators at the lab on December 4 said that the individual vials had numbers, both numbers and letters on them, and Dr. Stout has attached to her testimony a catalog that looks, to our staff, who have more expertise than I do, like a thorough catalog. Is that how samples are collected, labeled, cataloged and stored to constitute a scientific collection?

Dr. SNYDMAN. Are you asking me?

Chairman MILLER. Yes, Dr. Snydman.

Dr. SNYDMAN. Absolutely. They typically will have a laboratory number that will refer in a notebook or some other central repository the linkage. For a couple of reasons that is done. One is to protect the identity of the individual from whom the isolate has been obtained, and also to have kind of a linear catalog that can refer to specimens and they are usually grouped in boxes in freezers so that they can be ascertained for subsequent analyses as needed. So that is very typical.

Chairman MILLER. All right. And Dr. Stout, were the numbers and letters part of our cataloging of the collection?

Ms. STOUT. Yes, and for those of you who have never seen a scientific collection, I wanted to show you with this visual aid. There are 81 little compartments in these boxes and this is what a freezer

vial, and what we would write on the side is the number and some information about the material in there. We would write the same number on the top so that when someone went into the box, they could see easily where they wanted to go to find the isolate, and then each of these boxes was put into a stainless steel rack and that rack held 20 individual boxes. Our collection of microorganisms were stored in this very orderly manner.

Chairman MILLER. Okay, and that is a standard procedure in cataloging?

Ms. STOUT. That is a standard procedure, and in our procedure manual—which the laboratory service had, because we were under laboratory service when we were performing clinical testing—it is the standard operating procedure describing that process.

Chairman MILLER. Your testimony has established well, as has our staff report, that there was a great deal of peer-reviewed research that resulted from research on this collection. Is a proper catalog of samples necessary for peer-reviewed research, Dr. Stout?

Ms. STOUT. Absolutely. One of the examples that I provided to the Committee was a paper where we were using new molecular tests to link the organisms from hospital water systems to patients. It is called pulse field gel electrophoresis. And that group of organisms was retrievable from the freezer because we had cataloged those organisms and we could go back and use new tests to evaluate those new tests, and in fact, we have had requests from other scientists for those very organisms, and in the publication is the stock number that is on the vial in the freezer and those individuals in other countries have asked for those organisms for further study.

Chairman MILLER. Dr. Snydman, do you agree with what Dr. Stout just said? Is proper cataloging a necessary part of peer-reviewed research?

Dr. SNYDMAN. Yes, I would say absolutely.

Chairman MILLER. So if this collection were not properly cataloged, it would not have resulted in the number of peer-reviewed articles that it appears to have resulted in?

Dr. SNYDMAN. Absolutely.

Chairman MILLER. Okay. Dr. Stout, when did you first hear these criticisms of your collection, that it wasn't done scientifically, it wasn't collected or labeled or cataloged or properly stored to make it a real scientific collection?

Ms. STOUT. I believe I was told that by the Committee staff after they had conducted interviews, and I didn't find that to be a credible statement.

Chairman MILLER. You never heard it from Dr. Melhem?

Ms. STOUT. No.

Chairman MILLER. You never heard it from Mr. Moreland?

Ms. STOUT. No, and I never had any direct conversations with them. I believe they have claimed that they asked me for information about the catalog collection and no one from either the research department or the clinical laboratory asked me for specific information. When I was in the process of working with the research group to make the transfer, all they were concerned about was the paperwork and, you know, they were apparently trying to help me do that.

Chairman MILLER. Dr. Yu, when did you first hear these criticisms of how your collection was cataloged, that it wasn't scientific?

Dr. YU. I wrote many communications to them, and the letters are documented in the Appendix. I never heard anything from them, and I never heard this particular excuse used to justify destruction of the organisms.

Chairman MILLER. Dr. Melhem never told you before or told you to your face or even in an e-mail, that is——

Dr. YU. That is right.

Chairman MILLER.—kind of like to your face, that there was some failure in the way that the collection was collected, labeled and cataloged and stored?

Dr. YU. Yes. I never had any communication with Dr. Melhem.

Chairman MILLER. My five minutes have expired. Mr. Rohrabacher.

Mr. ROHRABACHER. Thank you very much, Mr. Chairman, and again, I appreciate your leadership in directing your staff to come to this as early as you obviously have. I am a former journalist and I remind people that journalists really, we know this much about that much, but we don't know this much about anything, and I have to admit, some of the words that were being used today, I don't know what those words were and I am a man of words.

Chairman MILLER. I thought that Dr. Snydman was just showing off.

THE SPECIAL PATHOGENS LABORATORY (SPL)

Mr. ROHRABACHER. So let me ask a couple questions here about the nature of your laboratory. There are two natures to the laboratory that we are talking about. One is a research component and the other is a diagnostic and clinical component that basically services other hospitals. Is that right?

Dr. YU. I was also head of the Clinical Microbiology Laboratory and that laboratory handles specimens from the local VA hospitals, and then I was also head of the Special Pathogens Laboratory and that is a research laboratory. However, since we had outbreaks of Legionnaires' disease within our own hospital initially, sometimes there was interaction between the two. But the publications and the personnel in the Special Pathogens Laboratory were the main component of the research.

Mr. ROHRABACHER. The research has been going on since 1976, or how long?

Dr. YU. The Special Pathogens Lab really started in approximately 1979 to 1980, and that was when——

Mr. ROHRABACHER. Okay, so it has been going on since 1979 or 1980 and that is——

Dr. YU. Yes.

Mr. ROHRABACHER.—28 years, almost 30 years now.

Dr. YU. Yes.

Mr. ROHRABACHER. And during that time period, you have managed to actually discover the cause of Legionnaires' disease and identify this—what do you call it, bacilli or——

Ms. STOUT. Bacteria.

Mr. ROHRABACHER. Okay, bacteria, that actually has resulted in these deaths and these horrible problems for people. How long ago was it that that was discovered?

Dr. YU. Janet made the first discovery that it could be contracted from hospital water. It was published in 1982 in the New England Journal of Medicine and in 1983 in the *Lancet.*

Mr. ROHRABACHER. So, number one, let me just note, I, like everybody else, thought it was the air conditioning up until right now. If indeed you come to a point where you have identified what the cause is and you have had over 20 years of research into that, was there a need for further research as compared to utilizing the resources for diagnostic and helping with specific patients? Was there a need for further research on this?

Dr. YU. As a specific example, microbes are evolving and antibiotic resistance is now a major problem, and it turns out actually just two days ago we received commentary from one of my colleagues in France. They believe that *Legionella* has the capability to evolve resistant to levofloxacin, and they wanted us to test their hypothesis with the organisms that we had in our collection.

Mr. ROHRABACHER. So the actual—the discovery was made years ago but the ongoing research is vitally important because these things, these bacteria change and we need to keep on top of it. Is that it basically?

Dr. YU. Exactly.

Ms. STOUT. And if I may just add, in addition to therapy and treatment, we are also and have been for many years trying to put the tools in the toolbox to prevent the disease, which includes treatment of water distribution systems with various methods to control the presence of the bacteria in water, and just like with antibiotics, there is no perfect solution so we continuously do research to perfect those techniques.

Mr. ROHRABACHER. Let me note, I think that is very worthy research. We are going to be talking to someone in the Veterans Administration who you have been pointing to, decisions that he made, later on. What if he tells us that that research is something that he supports but isn't within his budget?

Ms. STOUT. Well, I am sure Dr. Yu has something to say, but what is interesting to me is that in the September issue of *Clinical Infectious Diseases,* there is a report demonstrating that there is an increase in the incidence or the number of cases of Legionnaires' disease that have been noted, and that document is, I believe, the last document in your report here.

Mr. ROHRABACHER. First of all, let me just say that I would be supportive of this research. This research sounds like it is very important. I am trying to make sure that we are not totally villainizing a man who we have given, and people we have given the responsibility to run certain budgets and——

Ms. STOUT. Well, I think the other point to be made is that veterans are disproportionately affected by this disease.

Mr. ROHRABACHER. And——

Dr. YU. And one other point. We receive funding from industry for the levofloxacin study and actually the first effective disinfection measure was placed at the Pittsburgh VA. The Los Angeles VA tried some things but the solution came from Pittsburgh. All

of those disinfection systems were put in gratis, and the levofloxacin and azithromycin, the other major antibiotic that we discovered effective for Legionnaires' disease, VA patients got the medicine for free from the pharmaceutical industry. So we actually brought funding into the Pittsburgh VA, and that was one of the reasons that we were made a special clinical resource center because we were—we could actually bring in funds.

Mr. ROHRABACHER. Well, again, it sounds like the research is really important and I have no doubt, and I would imagine no one disagrees with that, that the research is very important. You also serve an important function in your diagnostic help for people who actually have contracted that, and sometimes we do give people the authority to try to make decisions based on—and budget decisions sometimes lead people to do crazy things, so we will have to take a look and hear the whole testimony, but thank you very much and thank you for your good work. I know you have saved lots of lives. I appreciate that very much.

Ms. STOUT. Thank you.

Chairman MILLER. Thank you, Mr. Rohrabacher.

Dr. Broun.

WHY WAS THE SPECIAL PATHOGENS LABORATORY CLOSED?

Mr. BROUN. I want to remind my colleague from California that we are all ignorant about some things.

I thank you all for y'all's work. I am a practicing physician, and I certainly understand the importance of the clinical work that you are doing and how levofloxacin and azithromycin have been very instrumental in treating not only Legionnaires' disease but many others that my patients have enjoyed the fruits of y'all's efforts. I would like to ask Dr. Yu and Dr. Stout individually, why do you think y'all's lab was closed?

Dr. YU. We asked that question in writing and it is the letter in the appendix, why would you do this. I did want to say it had nothing to do with funds because we were bringing in funds from EPA and industry and so forth, and other laboratories that needed the work, they actually paid a small fee too. I don't know the answer but I think the people behind me can answer that question. It is inexplicable why that happened.

Mr. BROUN. Dr. Stout, do you have any knowledge or even speculation why the lab was closed?

Ms. STOUT. I think probably most of the people reading the information that has been provided and collected by the staff come down to the same question that you are asking because it is essentially inexplicable, given the value of the laboratory, not only for the clinical laboratory but the other infectious disease physicians that were practicing not only at the Pittsburgh VA but nationwide. We served that function and we supported them not only with regard to *Legionella* detection and diagnosis but also in their other investigations of other pathogens. I am reminded of a term about shortsighted businessmen where they act before they actually understand the scope and the value of that which they are proposing to cut. So I believe that there was a failure at all levels within this administration to not only protect the value of the laboratory but the value of the collection.

Mr. BROUN. Are either of you familiar with any of the processes or procedures that are required for a VA lab closure?

Ms. STOUT. I have read the document that was associated with the research centers of excellence and that there was terminology in there about orderly closure and having plans for those closures, yes.

Mr. BROUN. Dr. Yu.

Dr. YU. Yes, I was well aware of that, and actually I had to go through an interrogation. I pointed out the specific memorandum in my interrogation that one of the points that they made is that there was no mandate for this laboratory, something that was again so incredibly difficult to comprehend since the previous director had actually mandated that, and I pointed this out to Mr. Moreland and his group.

Mr. BROUN. Do either of you all know if the policies and the procedures for VA lab closures were followed in this case with SPL?

Dr. YU. The policy says that you have to arrange for orderly closure to ensure that patients are not affected and so forth, and that clearly wasn't done. It was a strike of lightning that I think really caught Senator Specter's eye as to that just didn't seem right, that a lab that is there for 30 years is there on Wednesday, you close it on Friday.

Mr. BROUN. So it is your contention that those procedures and policies that are put in place for VA lab closures were not followed in this case with SPL?

Dr. YU. They were not followed.

Mr. BROUN. There were clinical specimens that were undergoing those studies for antibiotic resistance or for identification and those types of things that were shut off without any final determination of what that isolate was, what any kind of antibiotic treatment was or anything else. Is that correct?

Dr. YU. That is correct.

Mr. BROUN. Would this, in your opinion, open some liability for patient safety?

Dr. YU. It turns out that there was a major affiliated hospital of one of the most prestigious universities in the United States had sent specimens to us and that individual was so perturbed when we were unable to give him the results when all we had to do was open the cabinet and look at it under the microscope, he wrote me a letter saying you have done great work but go out on the high road, give me those results. We sent that communication to the administration and to Senator Arlen Specter, and Specter asked them to release the results. They let those cultures die. But I understand a settlement was made with the Pittsburgh VA and the water contractor or water consultant who had sent the specimens to our laboratory, but that is what I heard. So they paid off this individual who actually, I think, was very, very concerned about the implications of not following through on a commitment.

Mr. BROUN. Thank you. My time has expired. Thank you, Mr. Chairman.

Chairman MILLER. Thank you. The Chairman welcomes both Dr. Broun's expertise and his use of the word "y'all."

I now recognize myself for a second round of questions. Mr. Moreland, his written testimony and presumably his oral testimony

under oath later today, will be that he was shocked, shocked to learn that there was research going on in his laboratory. Dr. Stout, I understand that part of your work including the research on the *Legionella* at that hospital, that VA hospital, resulted in your playing a significant role in developing a protocol for reducing the risk of *Legionella* in the VA hospital system. Is that correct?

Ms. STOUT. That is correct.

Chairman MILLER. Okay. Did the VA embrace that work? Did they know that you were doing it there? Did they say what on Earth were you doing, doing research.

Ms. STOUT. It is difficult for me to understand how the administration of the hospital in which we worked was completely unaware of the work that we had been doing for more than 25 years. The basis for the VA directive which was published in February of 2008 came from our work and came from direct collaboration with the VA medical inspector general. That piece of information was among the various pieces of information provided to the administration as justification for our continuing to serve the VA and the Nation. So I am not sure exactly when Mr. Moreland said that he was unaware but he certainly was aware of our accomplishments including that before they made the decision to close the laboratory.

TRANSFERRING THE SPL COLLECTION

Chairman MILLER. Okay. Just a couple of other questions about Mr. Moreland's written testimony. These can be very quick answers, yes or no. His testimony is that, "Following a technical review by the ACOS for clinical support, we found it presented a potential biohazard to both employees and our veterans. The SP lab lacked a defined and approved research activity." Dr. Yu or Dr. Stout, did anyone ever tell you that there was a technical review and a finding that your research or the maintenance of this collection presented a potential biohazard?

Ms. STOUT. No.

Chairman MILLER. When did you first hear that?

Dr. YU. Now.

Chairman MILLER. Right now this minute? Okay. Dr. Yu, Dr. Stout, you apparently conducted months of negotiations on the transfer of this collection to another facility where you could continue your research. Could you describe fairly briefly those negotiations, Dr. Yu or Dr. Stout?

Ms. STOUT. I probably should do that because it was my communication with the research department at the VA from August to December. There were numerous documents, mostly e-mails between myself and the research department. The first was with Dr. Graham, then Dr. Sonel subsequently and then Dr. Sonel directed one of his individuals, the research compliance officer, to work with me to effect that transfer, and if I may just correct a misconception, both Dr. Graham and Dr. Sonel each had conversations with Dr. Melhem in which she led them to believe that it was her intention to destroy the collection. Therefore, they were forewarned. It was not the fact that although they were misled in December, they all had an opportunity to protect the collection as early as September when they were informed of her intention to destroy it.

Chairman MILLER. Dr. Snydman, you have worked with Dr. Yu. You are an infectious disease researcher yourself, which is why you were able to show off rattling off the names of all those bacteria. Our second panel will be about policies and protocols of what perhaps should happen. It appears that a great many laboratories do not necessarily have written protocols but there is sort of a habit or common sense, common decency of seeing first if there is another researcher at the same institution when a researcher is leaving that would use the samples for their research, whether the researcher who is leaving would take it with them or whether it could be given to be somebody else if there is no one there that would continue the research or has any interest, and it is only if no one, no researcher appears to have any interest at all that samples are destroyed. Is that consistent with your own impression of what happens?

Dr. SNYDMAN. I would say yes. In general, if there is someone who is taking over or collaborating, there would be some preservation and transport of the specimens, but if there isn't anyone else, they might be destroyed.

Chairman MILLER. All right. Are you aware of other instances when a research institution destroyed a specimen collection without consulting with the research staff?

Dr. SNYDMAN. No.

Chairman MILLER. Are you aware of any circumstances—well, this seems to be a redundant question but if redundancy is a sin, all politicians are going to hell. Do you know of any circumstances in which or can you imagine a research institution destroying a collection while there were negotiations underway for what to do with the collection?

Dr. SNYDMAN. No.

Chairman MILLER. Mr. Rohrabacher.

REASONS FOR DESTROYING THE SPL COLLECTION: PROCEDURAL FLAWS OR PERSONALITY CONFLICTS?

Mr. ROHRABACHER. Thank you, Mr. Chairman, and again, we are novices here in a number of ways, both in terms of the subject of your research and also in exactly how the structure works.

First of all, I take it that your laboratory worked somewhat independently because—and that up until now you really haven't had any close relationship with top people in the Veterans Administration.

Ms. STOUT. I would say literally that would be not true because over the years I participated in numerous activities through the VA central office infectious disease group, as did Dr. Yu, and we were asked to be lecturers and to participate in the development of guide books on infectious diseases.

Mr. ROHRABACHER. But would that be people at the top, at the very top level of the VA or just people who are operating within the VA?

Ms. STOUT. Not in Pittsburgh, in Washington, that——

Mr. ROHRABACHER. Yes, but I mean——

Ms. STOUT. Yes.

Mr. ROHRABACHER. Okay. First of all, you have accomplished a lot and we should all be grateful for that, and when I mentioned

earlier that bureaucracy gets in the way of all this stuff, here in Washington you can trace things down to just the way people operate and rules of bureaucracy within a certain parameter there, and let me ask you this. There are controls that laboratories in the NIH and CDC and others whose only area is research and not necessarily helping with hospitals like you are also doing, but there is a lot of controls on human subject research. Now, are you—have you been under that same sort of umbrella of regulations as to how you can operate as would happen under the labs of NIH or CDC?

Ms. STOUT. Yes. For example, the Environmental Protection Agency study involved interactions with patients so it was approved by the IRB as well as the VA Merit Review study and numerous other studies by Dr. Yu.

Mr. ROHRABACHER. Okay. So you are not just operating out on your own and——

Ms. STOUT. No.

Mr. ROHRABACHER.—ignoring what all the other labs have to do because they are under——

Ms. STOUT. No, and in fact, there was tremendous oversight over what we did from very different bodies.

Mr. ROHRABACHER. All right. That is really an important element here because I think what we are being told is that somebody asked for a raise, which got somebody's attention, and all of a sudden they had never—somebody had not realized that you existed before. Frankly, if I had not realized that you existed before and then heard that you had been involved with such important work, I would be very happy and I would have tried to be your friend and take credit for everything you did. So the fact is, that is the way it works in Washington quite a bit, and instead, it seems here that personalities have come into play and that what often we see in Washington also within the bureaucracy is, at times people get a little bit miffed that their authority is being challenged in some way. Do you think that there is a personality end of this about people worrying that rather than looking at the value of what you are doing, that they were only looking at maybe their authority was being challenged?

Ms. STOUT. Well, what I am heartened by is the work that the Chairman and the Committee will do to prevent this from ever happening again.

Mr. ROHRABACHER. Right.

Ms. STOUT. I think that there were some checks and balances available within the administration in Pittsburgh to prevent this from happening and they were completely disregarded.

Mr. ROHRABACHER. And was that due to, as I say, people getting miffed or a personality situation being brought into what should have been a professional situation, or was this a real flaw in the system?

Ms. STOUT. I think it was both. I think hat there were people in the administration that cared more about themselves than science, medicine or veterans. I think that what the Committee has shown and the hard work of the staff is that the measures that we had faith in and we were working in good faith with the research department to transfer the collection, the atmosphere in this administration prevented them from acting respectfully and responsibly.

Mr. ROHRABACHER. Well, certainly any lab that is shut down should be—anybody who is told—with research as important as yours should be given enough advance notice that these type of problems, that the disaster that we are talking about wouldn't have happened. So thank you very much.

Ms. STOUT. Thank you.

Chairman MILLER. Thank you. I think we have gotten from you the particular points we wanted covered in your testimony, but I am a recovering lawyer, and it occurs to me that you all have been wronged. Obviously others have been wronged too. We will never know who has been wronged. We will never know that someone who died from an antibiotic-resistant staph infection might not have died had your specimens not been destroyed, but you all have been wronged professionally. Have you talked to a lawyer?

Dr. YU. I have talked to a lawyer.

Chairman MILLER. Okay.

Dr. YU. But so far, I am still recovering psychologically from this blow, frankly.

Chairman MILLER. Well, I am certainly not dispensing legal advice but my sense of how the law has developed over the last several hundred years is that some conduct, some event strikes us as unjust in our viscera, something seems unjust to us, and then we engage our intellect to explain why it is unjust, and from that comes legal concepts, whether it is the law of property or of contract or of tort, you all have suffered an injustice, and I would encourage you to talk about whether you might have some redress from that.

Dr. YU. Are you still practicing?

Chairman MILLER. I am not. There is an election in less than two months. It is my hope that I will have some continuity of employment here——

Ms. STOUT. You have our vote.

Chairman MILLER.—and I will be unavailable to practice law. Thank you.

Ms. STOUT. Thank you.

Chairman MILLER. Mr. Rohrabacher, anything else?

Mr. ROHRABACHER. I have one last point and that is when I first ran for office, my most successful slogan during my first campaign was, "Vote for Dana, at least he is not a lawyer."

Ms. STOUT. Well, I am glad you all have a sense of humor. We appreciate it very much.

Chairman MILLER. Thank you, and I thank all of you. We will now have our next panel, and we will have about a two-minute break while you all step down and the next panel steps up.

[Recess.]

Panel II:

Chairman MILLER. I would now like to introduce our second panel. Dr. Jim Vaught is the Deputy Director of the Office of Biorepositories and Biospecimen Research at the National Cancer Institute. Dr. Janet Nicholson is the Senior Advisor for laboratory science at the Coordinating Center for Infectious Diseases at the Centers for Disease Control and Prevention. You each have five

minutes for your oral testimony, and your written testimony will be included in the record of the hearing. When you complete your testimony, we will have questions. Each Member will have five minutes. We will proceed in rounds of five minutes each. It is the practice of the Subcommittee to take testimony under oath. Do either of you have an objection to being sworn in, to swearing an oath? Both have said or nodded no. The Committee also provides that you may be represented by counsel. Are either of you represented by counsel at today's hearing? Both have said or nodded no. Please stand and raise your right hand. Do you swear to tell the truth and nothing but the truth? Both witnesses did so swear.

Dr. Vaught, please begin.

STATEMENT OF DR. JIM VAUGHT, DEPUTY DIRECTOR, OFFICE OF BIOREPOSITORIES AND BIOSPECIMEN RESEARCH, NATIONAL CANCER INSTITUTE, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. VAUGHT. Thank you, and good morning, Mr. Chairman, Mr. Rohrabacher, Members of the Subcommittee. I am Dr. Jim Vaught, the Deputy Director of the Office of Biorepositories and Biospecimen Research, or OBBR, at the National Cancer Institute, part of the National Institutes of Health, an agency of the Department of Health and Human Services. I have been engaged in the area of biospecimen research and biorepository management for over 15 years and I have participated in the development of a number of practices and policies relevant to today's discussion. This testimony will highlight four specific activities relevant to the hearing topic; one, the NCI Best Practices for Biospecimen Resources; two, a trans-NIH effort to develop a policy framework for biospecimen collections; three, the NIH Scientific Directors Subcommittee on Biorepository Practices and Guidelines within the Intramural Research Program; and four, the Interagency Working Group on Scientific Collections. These activities were triggered in part by the acknowledgement that the value of biospecimens and other scientific research collections is not always recognized and that these collections need to be managed in an optimal way. Substandard practices can have a negative impact on research studies as well as the practice of medicine.

In September 2007, the HHS produced a personalized health care document that recognized the critical importance of biospecimens to the research infrastructure that will support personalized medicine. The vision of personalized medicine is one in which the standard of medical care is improved by adding an individual's genetic and molecular profile to the decision-making process. With the support of senior NCI leadership, the OBBR worked in a highly collaborative manner with many NIH and external experts to develop the NCI Best Practices for Biospecimen Resources. For the purpose of today's discussion, the recommendations in Section C–1 of the Best Practices concerning custodianship of specimen collections are the most relevant.

We consider the custodianship issue to be so important that we sponsored a workshop on ownership and custodianship issues in biospecimen research in October 2007 which resulted in a series of

more specific recommendations that we are considering for incorporation into the next version of the NCI Best Practices.

The NIH Scientific Director's Subcommittee was formed to make recommendations to the scientific directors concerning biorepository practices and policies within the NIH intramural research program. As a result of the work of this subcommittee during 2006 and 2007, the NIH published guidelines for human biospecimen storage and tracking within the NIH intramural research program. These guidelines make specific recommendations regarding one, the transfer of specimen custodianship and informed consent information when the responsible investigator leaves NIH or when the custodianship needs to be changed for other reasons; and two, reporting requirements for the specimen inventory and tracking systems being used.

In addition, NIH intramural investigators were directed in a June 2006 memorandum to include in their institutional review board packages the manner that specimens are stored, tracked and what will happen to the specimens at the completion of the protocol. As a result, any decision to destroy or transfer specimens out of NIH is carefully monitored by scientific directors as well as IRBs. At NIH, the specimens obtained belong to the government, not the researcher. Plans to move materials outside NIH must include appropriate material transfer agreements and must be approved. NIH policy does not permit a scientist leaving the NIH to disperse his or her materials without review.

A federal-wide Interagency Working Group on Scientific Collections (IWGSC) was formed in response to a call from the White House Office of Science and Technology Policy and the White House Office of Management and Budget for federal agencies to address the scientific, environmental, societal and national security needs for collections. As we had found in our assessment of the NCI and NIH collections, the IWGSC survey found that federal agencies often do not have standardized, comprehensive approaches to the long-term management and use of their scientific collections. The working group is evaluating recommendations that are consistent with NIH long-term management principles.

In conclusion, since many such collections are priceless and irreplaceable, adoption of practices such as those developed by NCI and other groups that I noted will be critical if we are to preserve them in the condition necessary to make the scientific discoveries and medical advances for which they were collected. Based on these considerations, the NCI Best Practices reflect the following themes with respect to developing a custodianship plan at the beginning of a study or program: one, appoint a custodian to address long-term management of specimen collections; two, manage conflicts of interest; three, follow all applicable regulations and policies; and four, include plans for management after a study ends, funding is lost or similar situations requiring custodianship changes. These are extremely important issues concerning critical resources that are central to our biomedical research infrastructure.

Thank you, Mr. Chairman.

[The prepared statement of Dr. Vaught follows:]

PREPARED STATEMENT OF JIM VAUGHT

Good morning Mr. Chairman, Mr. Sensenbrenner and Members of the Subcommittee. I am Dr. Jim Vaught, the Deputy Director of the Office of Biorepositories and Biospecimen Research (OBBR[1]) at the National Cancer Institute (NCI), part of the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS). I have been engaged in the area of biospecimen research and biorepository management for over 15 years, and I have participated in the development of a number of practices and policies relevant to today's discussion. This testimony will highlight four specific activities relevant to the hearing topic.

In 2007, NCI published its Best Practices for Biospecimen Resources, which provide guiding principles that define state-of-the-science biospecimen resource practices, promote high standards of biospecimen and data quality, and facilitate compliance with ethical standards and legal requirements. NCI has also been involved in a trans-NIH effort to develop a policy framework on legal and ethical issues that would apply to all NIH-supported human specimen collections. Additionally, I have been an active participant in the NIH Scientific Directors Subcommittee on Biorepository Practices and Guidelines within the Intramural Research Program, formed in 2006 to address biospecimen storage and tracking practices and policies at laboratories at NIH facilities. The recommendations of this group are currently being implemented.[2] In 2005, I was appointed to a federal-wide Interagency Working Group on Scientific Collections (IWGSC). This working group is a subcommittee of the Committee on Science (COS), within the National Science and Technology Council (NSTC), managed by the Office of Science and Technology Policy (OSTP). Our charge has been to identify resources and requirements, including research and development needs, for long-term stewardship of these collections, and to foster coordination of collections-related activities across the Federal Government.

These aforementioned activities—the development of the NCI biospecimen best practices document, the NIH guidelines for the intramural program, the trans-NIH policy framework on legal and ethical issues and the federal-wide Working Group—were triggered in part by the acknowledgment that the value of biospecimens and other scientific research collections is not always recognized and that these collections need to be managed in an optimal way. Substandard practices can have a negative impact on research studies as well as the practice of medicine. In a September 2007 report on Personalized Health Care,[3] HHS also recognized the critical importance of biospecimens to the research infrastructure that will support personalized medicine. The vision of personalized medicine is one in which the standard of medical care is improved by adding an individual's genetic and molecular profile to the decision-making process.

Scientists can now study cancer at the most fundamental level, identifying genes and their functions in the body, called genomics, and studying the corresponding set of proteins programmed by the genetic code, called proteomics. At NCI we recognize the critical role that biospecimens play in these endeavors. OBBR's mission is to ensure that human specimens are available for cancer research and that they are of the highest quality. The OBBR is responsible for developing a common biorepository infrastructure that promotes resource sharing and team science, in order to facilitate multi-institutional, high throughput genomic and proteomic studies. These types of studies will lay the groundwork that will lead us to personalized medicine.

With the support of NCI senior leadership, our office worked in a highly collaborative manner with many NIH and external experts to develop the NCI Best Practices for Biospecimen Resources. Following a careful analysis of NCI's biological specimen practices, NCI sponsored two workshops in 2005 that resulted in a series of recommendations that, along with existing guidelines, regulations and best practices from other organizations, became the NCI Best Practices. The Best Practices include recommendations from technical and ethical/legal standpoints. I have provided the full document to the Committee, but for the purpose of today's discussion, the recommendations in Section C.1 of the Best Practices, concerning custodianship of specimen collections, are the most relevant. We consider the custodianship issue to be so important that we sponsored a workshop on Ownership and Custodianship Issues in Biospecimen Research in October 2007, which resulted in a series of more

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[1] NCI Office of Biorepositories and Biospecimen Research (OBBR) web site: *http://biospecimens.cancer.gov/*

[2] NIH Intramural Research Program Biospecimen Guidelines: *http://www1.od.nih.gov/oir/sourcebook/oversight/Biospecimen%20Storage%20and%20Tracking%20Guidelines%2020080717.pdf*

[3] *Personalized Health Care: Opportunities, Pathways, Resources.* U.S. Department of Health and Human Services, *http://www.hhs.gov/myhealthcare/*

specific recommendations[4] that we are considering for incorporation into the next version of the NCI Best Practices.

The NIH Scientific Directors Subcommittee was formed to make recommendations to the Scientific Directors concerning biorepository practices and policies within the NIH Intramural Research Program. As a result of the work of this subcommittee during 2006 and 2007, NIH published Guidelines for Human Biospecimen Storage and Tracking within the NIH Intramural Research Program. These Guidelines make specific recommendations regarding: 1) the transfer of specimen custodianship and informed consent information when the responsible investigator leaves NIH or when the custodianship needs to be changed for other reasons; and 2) reporting requirements for the specimen inventory and tracking systems being used. In addition, NIH intramural investigators were directed in a June 2006 memorandum to include in their Institutional Review Board (IRB) packages the manner that specimens are stored, tracked, and what will happen to the specimens at the completion of the protocol.[5] As a result, any decision to destroy or transfer specimens out of NIH is carefully monitored by Scientific Directors as well as IRBs. At NIH, the specimens obtained belong to the Government, not the researcher. Plans to move materials outside NIH must include appropriate material transfer agreements and must be approved. NIH policy does not permit a scientist leaving the NIH to disperse his/her materials without review.

The federal-wide IWGSC was formed in response to a call from the White House Office of Science and Technology Policy (OSTP) and the White House Office of Management and Budget (OMB) for federal agencies to address the scientific, environmental, societal, and national security needs for collections. The Working Group's main activity to date has been to conduct a survey to examine the current state of federal scientific collections and to assess general thematic issues regarding collections management and stewardship. These collections are highly variable, from NIH's human biological specimens to NASA moon rock collections and Smithsonian museum artifacts (for example, from the Lewis and Clark Expedition). A report is being prepared to outline the Working Group's findings. As we had found in our assessment of the NCI and NIH collections, the IWGSC survey found that federal agencies often do not have standardized, comprehensive approaches to the long-term management and use of their scientific collections. The IWGSC is evaluating recommendations that are consistent with NIH long-term management principles.

In conclusion, there is broad agreement that collections of biological specimens, as well as other collections of materials of scientific value, are critical to the research enterprises that support, among other important endeavors, advances in the medical and technological fields. As such, standardized, high quality management practices and long-term plans for custodianship of these collections are needed. Since many such collections are priceless and irreplaceable, adoption of practices such as those developed by NCI and other groups that I noted will be critical if we are to preserve them in the condition necessary to make the scientific discoveries and medical advances for which they were collected. We are mindful that when patients and other study participants agree to provide blood or other samples for a research study, they generally do so with an expectation that their tissue will be used to provide insight into the causes and/or cures of their disease, or to advance medical research in general.

Based on these considerations, the NCI Best Practices reflect the following themes with respect to custodianship of biospecimens:

1. At the beginning of a study or program that will include biospecimen or other research collections, a custodian, either a person or a governance committee, should be appointed by the institution to develop a plan for addressing long-term management of specimen collections.
2. Responsible custodianship requires appropriate management of financial or scientific conflicts of interest that may interfere with appropriate judgment concerning the proper disposition of the collection, and the most appropriate scientific and/or medical use of the specimens.
3. All applicable regulations and policies concerning, for example, privacy, informed consent, and material transfer must be followed in decisions concerning the disposition of specimens and data.
4. Custodianship plans should state in detail how specimen collections will be managed or dispersed when funding is lost, custodial management changes,

[4] NCI OBBR Ownership and Custodianship in Biospecimen Research Workshop summary: *http://biospecimens.cancer.gov/global/pdfs/CaOSumm.pdf*

[5] June 12, 2006 memorandum from Dr. Michael Gottesman: Research Use of Stored Human Samples, Specimens or Data: *http://www.nihtraining.com/ohsrsite/info/DDIR.html*

or protocols are completed, including careful consideration of the future scientific value of the collection. The plan should recognize that specimens that are no longer valuable or necessary for their original purpose may be useful for other purposes, consistent with the requirements of informed consent and other applicable rules and policies.

These are extremely important issues concerning critical resources that are central to our biomedical research infrastructure.

We appreciate the opportunity to provide our views, Mr. Chairman. Thank you, and I would be pleased to answer any questions.

BIOGRAPHY FOR JIM VAUGHT

Dr. Vaught has a Ph.D. in biochemistry from the Medical College of Georgia, and has been with the National Cancer Institute for almost 10 years. He has been involved in the field of biorepository and biospecimen science for over 15 years. In 1999 he was one of the founding members of the International Society for Biological and Environmental Repositories (ISBER) and was its second President. He participated in the development of ISBER's Best Practices for Repositories, as well as the NCI Best Practices for Biospecimen Resources and the OBBR's other strategic initiatives. Since 2005 he has served as one of NIH's representative to the Interagency Working Group on Scientific Collections, which was created by the White House Office of Science and Technology Policy. He also served as a member of the NIH Intramural Scientific Directors Biorepository Committee. In addition to ISBER, Dr. Vaught is a member of the American Association for Cancer Research (AACR), the Association for Laboratory Automation, the American Society for Pharmacology and Experimental Therapeutics and the American Association for Clinical Chemistry. He is Senior Editor for Biorepository and Biospecimen Science for the AACR journal *Cancer Epidemiology, Biomarkers and Prevention,* and a member of the editorial board of the ISBER journal *Cell Preservation Technology.* He has been invited to write book chapters about biospecimen science and policy issues, as well as speak at national and international conferences on these topics.

Chairman MILLER. Dr. Nicholson.

STATEMENT OF DR. JANET K.A. NICHOLSON, SENIOR ADVISOR FOR LABORATORY SCIENCE, COORDINATING CENTER FOR INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. NICHOLSON. Thank you, and good morning, Mr. Chairman and other distinguished Members of the Subcommittee. I am Dr. Janet Nicholson and it is my pleasure to be here in my capacity as senior advisor for laboratory science to the director of the Coordinating Center for Infectious Diseases at CDC. I have nearly 20 years of experience working inside CDC's infectious disease laboratories and have provided expert guidance on infectious disease laboratory-related activities. I have also represented the CDC laboratory community on complex, overarching infectious disease-related scientific issues including specimen collection, use and storage. I have co-authored 95 research or review papers and have delivered roughly 80 presentations in the fields of emerging infectious diseases, laboratory response to bioterrorism threats and immune responses to HIV infection. I currently serve as the U.S. representative for the Global Health Security Action Group Laboratory Network as a member of the Trans Federal Task Force for Optimizing Biosafety and Biocontainment Oversight, as an ex officio member of the National Science Advisory Board for Biosecurity, and the President-Elect on the Board of Directors for the Clinical and Laboratory Standard Institute, or CLSI.

I am pleased to appear before you this morning to address CDC's laboratory specimen collections. I would like to give a brief overview on CDC's management of infectious disease specimens and then I would be happy to answer your questions.

Each year CDC laboratories receive hundreds of thousands of human and environmental specimens from its various partners in public health throughout the United States and abroad. Many of these specimens contain organisms or products that need to be identified. Other specimens are unique population-based collections. Virtually all of these specimens are automatically archived because of their potential importance to public health and safety. Upon receipt at CDC, specimens are logged in, tracked and examined. In the Coordinating Center for Infectious Diseases, my coordinating center, specimens are logged, tracked and reporting is managed by an automated system called Star Limbs. Any given specimens or samples we receive may be entirely consumed by the testing process or sufficient quantities may have been obtained for storage. In the case of diagnostics work, reports of laboratory results from tests done on these samples are provided to the submitter or other appropriate authorities. At times, portions of the samples may be placed in long-term storage and are retained for future use. In extremely rare circumstances, some of our archived specimens may be destroyed because of lack of relevance, loss of viability during storage, lack of appropriate documentation, space limitations or when IRB, or the Institutional Review Board regulations, require so.

Maintaining CDC's world-renowned culture collections of specimens is essential in carrying out the agency's public health functions, that is, to detect, control and prevent morbidity and mortality from diseases. CDC manages its specimens in a manner commensurate with the scientific integrity required by HHS guidelines and policies. Each collection has a curator, as you heard before, whose responsibility is to create, maintain and oversee the use of these special collections. These specimen collections are unique and unmatched anywhere in the world. Not only are they critical to CDC's mission, they are also critical to our commitment to the global community to serve as a reference diagnostic center. The collections support the work accomplished in our nearly 30 World Health Organization collaborating centers for reference research on virus, bacteria, parasites and fungi.

Rare and irreplaceable collections of specimens are stored at CDC. Some of these historical collections date back to before 1945, which was before the era of antibiotics. CDC routinely performs reference and research activities on rare and unusual and novel bacterial and viral pathogens. This specialized work requires comparison of the new unknown organism to isolates of these archive strains with similar characteristics. Through this work, new pathogens such as SARS may be discovered when novel isolates are shown to be unrelated to any archived organism or DNA sequences on record. We would not be able to conduct our comprehensive work on pathogen discover without these valuable strain collections.

In the early 1990s, CDC and the Agency for Toxic Substances and Disease Registry, or ATSDR, developed a specimen repository

that provides for secure, long-term storage and management of our valuable collection of specimens. The CDC–ATSDR Specimen Packaging Inventory and Repository, or CASPIR, is a significant resource for the management of specimen collections at CDC because it provides unique archival space and utilizes a documented management system for these archives. The CASPIR policy board developed policies which include admission of specimen collections, ensuring data quality and security, documenting data and specimen sharing, specimen and data withdrawal and use, human subjects review issues, review of specimen usage and disposal of unwanted specimens, and contingency and disaster management. Each collection must be unique and not redundant of other collections already stored.

CDC's diagnostic laboratories are certified under the standards of the Clinical Laboratory Improvement Amendments of 1988, or CLIA. CLIA requires specific policies and procedures regarding the collection, testing and storage of specimens. CDC conducts research on human specimens. The research plans for this work to include information about the procedures for the collection, testing and storage of these specimens.

To protect our collections, CDC's specimen archival storage facilities and containers consist of freezers at -70 degrees centigrade and liquid nitrogen containers that are monitored 24 hours a day, seven days a week, with up to three responsible people to be notified in the case of an alarm that would indicate a problem with temperature control that could threaten the contents. To further guard some of our bacterial collection, CDC and the American Tissue Culture Collection, or ATCC, have a verbal agreement that new and reclassified strains of certain bacterial pathogens are placed into the ATCC collection so that organisms are available from the ATCC to all scientists for purchase to use in their research.

Specimens at CDC that are collected for the purpose of human research must comply with the basic HHS policy for protection of human research subjects. CDC investigators who collect and use human specimens are required to receive training in scientific ethics for investigators who engage in research using human subjects. Unless exempt by certain classifications identified in the human subjects research policy, all such research must be approved by an institutional review board, IRB, prior to start of the research and specimen collection. IRB guidelines require that research protocols specify the disposition of remaining specimens after the completion of the research. The principal investigator must request permission from the participants via informed consent to store the remaining specimens for future use.

In closing, CDC reference collections are a core component of our mission, unique in the world and absolutely critical to research in medicine and public health. Storage and subsequent disposal of the specimens are carefully managed. These specimens provide the agency with the ability to not only detect, respond to and control diseases today but are vital to unraveling tomorrow's unexpected disease crises.

Thank you for the opportunity to appear before the Subcommittee to share this information with you about our invaluable

specimen archives and our critical work in protecting public health. I would be happy to answer any questions.

[The prepared statement of Dr. Nicholson follows:]

PREPARED STATEMENT OF JANET K.A. NICHOLSON

Good morning, Chairman Miller, Mr. Sensenbrenner, and other distinguished Members of the Subcommittee. I am Dr. Janet Nicholson, and it is my pleasure to be here today in my capacity as Senior Advisor for Laboratory Science for the Coordinating Center for Infectious Diseases (CCID) at the Centers for Disease Control and Prevention (CDC), an agency of the Department of Health and Human Services (HHS). In addition to advising the Director of CCID on all laboratory-related science issues, I also serve as the designated federal official for the CCID Board of Scientific Counselors, and the Co-Chair for the steering committee for the design and construction of four CDC Laboratory Buildings. I have co-authored 95 research/review papers and have made 80 presentations in the fields of emerging infectious diseases, laboratory response to bioterror threats, and immune responses to HIV infection. I also currently serve as the U.S. representative for the Global Health Action Group Laboratory Network, as a member of the Trans Federal Task Force for Optimizing Oversight of Biosafety, and as the President-Elect on the Board of Directors for the Clinical and Laboratory Standards Institute.

I am pleased to appear before you this morning representing the CDC, the Nation's leading public health protection agency, to address the CDC's Laboratory Specimen Collections.

CDC Policies and Procedures Governing the Collection and Study of Specimens:

Each year, CDC laboratories receive hundreds of thousands of human and environmental specimens from its various partners in public health throughout the United States and abroad. Many of these specimens contain organisms or products that other laboratories could not identify, and virtually all of these specimens are automatically archived because of their potential importance to public health and safety. These specimens are collected for the purpose of detecting, controlling, and preventing morbidity and mortality from diseases. Specimens are used for a variety of purposes, including research, pathogen discovery, diagnostics, reference diagnostics, vaccine development, and supporting external scientific research activities within multiple National Centers across CDC.

Upon receipt, CDC logs, tracks, and examines these specimens and provides reports of any laboratory tests to the submitter of the specimen or other appropriate authorities. Specimen logging, tracking, and reporting is managed by our automated Specimen Tracking and Retrieval Laboratory Information Management Systems (STARLiMs). Any given specimens or samples we receive may be entirely consumed by the testing process, or portions may be stored for safekeeping or retained for future use. In extremely rare circumstances, some of our archived specimens may be destroyed because of space limitations, lack of current relevance, loss of viability during storage, lack of appropriate documentation, or when required by an Institutional Review Board (IRB).

Maintaining CDC's world renowned culture collections of specimens is essential to carrying out the agency's core public health functions to detect, control, and prevent morbidity and mortality from infectious diseases. CDC manages its specimens in a manner commensurate with the scientific integrity required by HHS guidelines and policies. These policies and guidelines include, but are not limited to, the HHS Public Health Service Policies on Research Misconduct (42 CFR Part 93)[1] and the HHS Protection of Human Subjects regulations (45 CFR Part 46). Laboratories also have guidelines specific to the types of specimens collected, as most collections must be handled in very specific and often unique ways, for example, CDC's "West Nile Virus: Guide for Clinicians," and CDC's "Instructions for Testing by the Division of Vector-Borne Infectious Diseases Bacterial Zoonoses Diagnostic Laboratory."[2] Each

[1] Some of the areas covered in this policy include: "Protection of the confidentiality of respondents, complainants, and research subjects identifiable from research records or evidence, consistent with" 42 CFR 93.108; and, "A thorough, competent, objective, and fair response to allegations of research misconduct consistent with, and within the time limits of the final rule, including precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional, or financial conflicts of interest with the complainant, respondent, or witnesses," as explained at *http://ori.hhs.gov/policies/Requirements-Reg-6-05.shtml*

[2] *http://www.cdc.gov/ncidod/dvbid/misc/bacterial_zoonotic_shipping.htm*

collection has a curator, whose responsibility is to create, maintain, and oversee the use of these special collections. These specimen collections are unique and unmatched anywhere in the world. They are critical to CDC's mission and to our commitment to the global community as a reference diagnostic center, as well as supporting the work accomplished in our nearly 30 World Health Organization (WHO) Collaborating Centers for Reference and Research on viruses, bacteria, parasites, and fungi.

Rare and irreplaceable collections of specimens stored at CDC are subject to the limitations of research resources that could block our ability to uncover the benefits to health and medicine that are contained in these specimens, some representing historical collections pre-1945 (pre-antibiotic era). For example, CDC routinely performs reference and research activities on rare, unusual, and novel bacterial pathogens. This work requires comparison of the new, unknown organism to isolates of archived strains with similar characteristics. New pathogens are discovered when novel isolates are shown to be unrelated to any archived organism or DNA sequence on record. We would be unable to conduct our comprehensive work on pathogen discovery without these valuable strain collections.

The CDC's diagnostic laboratories save and store the significant organisms they identify; the laboratories are certified under the standards of the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and currently have policy statements and guidelines regarding archival and storage of laboratory specimens. Under CDC's Laboratory Quality Management System (QMS) approach to carrying out our laboratory science, all laboratories are required to document their policies and processes for specimen collection, disposal, and storage. The QMS is part of CDC's ongoing work to achieve even higher quality standards and is aimed at standardization of policies to the extent that is possible, given the distinct nature of each laboratory. CDC also is a participating member of the National Science and Technology Council's Interagency Working Group on Scientific Collections. CDC's specimen archival storage facilities and containers consist of -70°C freezers and liquid nitrogen containers that are monitored twenty-four hours a day, seven days a week, with up to three contacts available and listed on each storage container, should an alarm indicate a problem with temperature control that could threaten the contents. To further protect our collections, CDC and the American Type Culture Collection (ATCC) have an oral agreement that new and reclassified strains of enteric bacterial pathogens are placed into the ATCC collection so that the organisms are available from the ATCC to all scientists for purchase to use in their research.

Specimens at CDC that were collected for the purposes of human subjects research must comply with the HHS Protection of Human Subjects regulations (45 CFR Part 46). This includes specimens collected for research conducted by CDC employees or supported by CDC through funding or provision of other tangible support whether conducted inside or outside the United States. CDC investigators who collect and use these specimens are trained in compliance with the regulations that apply to investigators who engage in research using human subjects. Unless exempt, under the HHS regulations for the protection of human subjects, all research involving human subjects must be approved by an IRB prior to the start of the research and specimen collection. CDC IRBs are composed of members from various scientific disciplines including health fields, social sciences, methodology, laboratory sciences and toxicology; and non-scientific disciplines, including ethics, education, administration and youth advocacy. Most IRB panels have members with specialized knowledge of the interests of pregnant women, children, prisoners, and other categories of vulnerable groups and individuals, to protect them from inappropriate or unethical treatment. Each of CDC's seven IRBs is composed of 12 to 16 members, and at least one to three of these members are not affiliated with CDC. The guidelines of the CDC IRBs require that protocols specify the disposition of remaining specimens after completion of the research, and the principal investigator must request permission from the participants via informed consent to store the remaining specimens for future use, unless that requirement is waived by the IRB or the samples have been stripped of identifiers. These are common industry best practices.

How CDC laboratories evaluate the continuing need for, and scientific value of, the collections of specimens in its laboratories:

CDC reference collections are a core component of our mission, unique in the world, and absolutely critical to research in medicine and public health. When assessing archival specimens, we take into consideration a number of factors, including the needs of special patient populations (such as HIV-positive individuals, intensive care unit patients, ethnic populations, and women); novel or emerging agents of disease compared to archival isolates; pathogen discovery; pre-antibiotic era isolates (pre-1945); epidemics or pandemics; confirmation or development of taxonomic

additions or changes; and correlation of new isolates to disease. CDC evaluates the value of particular collections based on the uniqueness of the isolate, its potential value in future studies, and especially the quality of supporting data that accompanies the collection. Additionally, the number of external requests for archived samples is another indicator for the need of our collections. These materials are readily available to requestors through Material Transfer Agreements (MTAs) that outline roles and responsibilities of both the provider and recipient. Last year, for example, CDC executed approximately 200 MTAs for materials in our collections.

Collections are only as good as the clinical and epidemiological information available for the specimens. Clinical data can identify specimens from persons with well-defined diseases, or persons well-defined as "healthy" individuals. Some rare collections may represent historical importance documenting the first introduction of a disease caused by a particular strain. For example, our virus collections were critical when CDC responded to the world-wide outbreak of Severe Acute Respiratory Syndrome (SARS) in 2003. Other collections allowed CDC to recognize the agent of Legionnaires' disease in 1977 as a newly defined organism and to trace its origins. Diagnostic tests and laboratory identification procedures developed by CDC are validated using dozens of archived isolates as well as specimens from both normal donors and donors that are identified with specific diseases, such as influenza and respiratory syncytial virus.

Currently most of our laboratories have no uniform protocols in place regarding the destruction of specimen archives. When necessary, destruction occurs only after study and consultation and in a very controlled and documented manner. Indeed, we never want to purposely dispose of rare collections, and it is uncommon that any are destroyed.

The establishment of the CDC and Agency for Toxic Substances and Disease Registry (ATSDR) Specimen Packaging, Inventory and Repository (CASPIR) and its contribution to specimen resource management at the CDC.

In the early 1990's, CDC/ATSDR developed a specimen repository that provides for secure, long-term storage and management of our valuable collections of specimens. The CDC/ATSDR Specimen Packaging, Inventory and Repository (CASPIR) is a significant resource for the management of specimen collections at CDC because it provides archival space not available on the main CDC campus and utilizes a documented management system for these archives.

The roles of CASPIR are to: 1) ensure each collection has a scientific curator who is responsible for the information in the collection and who approves the use of the collection by persons or groups outside of the scientific program that collected the specimens; 2) ensure the quality of the specimens in storage by monitoring freezer temperatures and responding to alarms caused by temperature changes; 3) provide a single electronic database for the inventory; 4) provide a secure location for the specimens; 5) ensure that when investigators leave CDC, the collection is assigned to another CDC investigator; and 6) facilitate sharing of specimens, associated clinical and epidemiological data, and test results. CASPIR places critical record keeping in the hands of archivists, not busy laboratorians, and thus ensures availability of unique isolates to national and international research

Policies and procedures were developed through a CASPIR Policy Board. These policies include: apportionment of available storage space; admitting specimen collections; cataloging collections; ensuring confidentiality; ensuring data quality; documenting data and specimen sharing; ensuring data security; specimen and data withdrawal and use; additional testing of specimens; human subjects review issues; review of specimen usage and disposal of unwanted specimens; physical security of specimens; and contingency and disaster management. Storage space is allocated to a CDC program based on requests from each program, and space is reapportioned when necessary.

Collections for research are admitted to CASPIR when they meet basic criteria and have the appropriate approvals from CDC's National Center directors or their designees. The mandatory criteria for acceptance include submission of the following information: study design; study sites; duration of the study; study population; and a copy of the informed consent form for the overall study. Additional information needed includes whether epidemiological or clinical data were collected; types and number of specimens collected; types of tests performed directly on the study participants or the specimens; and contact information for the custodians of the collection. Lastly, each collection must be unique and not redundant of other collection already stored. Individual isolates will be stored in CASPIR only if they are deemed to be unique and cannot be easily recreated.

In addition to this information about the study, there are additional explicit mandatory criteria about the samples themselves for specimens to be deposited to CASPIR. The specimens must be sera, plasma lymphocytes, other body fluids, separated white blood cells, nucleic acids, cultures of microorganisms, or other miscellaneous biologicals. They must be of a certain volume, age, and condition, to ensure that meaningful testing can be performed on the specimen if retrieved at a later date. There also must be sufficient volume of remaining specimen to be of value for testing. When appropriate, the method of specimen collection that was used is included. An important example of this information would be the type of anticoagulant in which the specimen was collected. Sterility and viability must be documented. Finally, the specimens must be in storage vessels appropriate for the proposed storage condition. For example, the use of glass vials is not appropriate unless storage is in a refrigerator.

Detailed information about the collection is necessary for the specimens to be meaningful. This information includes: the name and contact information of the custodian and designated organizational contact if there is a recommendation to discard the collection; a brief description of the project and study design and why the activity led to the collection; information about the source of the specimens; the age and time period of the collection; the geographical location or locations where the specimens were obtained; the study population (e.g., uranium workers in New Mexico); demographic data such as age, gender, race, and ethnicity; whether the collection was the result of a research project and the consent form used, if available; types of tests performed directly on the study participants or the specimens; and, types, number, and volume of specimens in the collection.

Acceptance of collections requires completing a form with all the information noted above and with written approvals from the appropriate CDC officials. Externally-obtained collections are not accepted into CASPIR unless a National Center shares ownership of the collection and can assist in technical and scientific decisions regarding the use of the collection.

Distribution of specimens from the collection takes into consideration that though the investigators are custodians of the collection, CDC is the ultimate owner. This policy helps to assure that the investment made by CDC to conduct critical studies and analyze valuable specimens will be securely maintained. When collections are accepted into the CASPIR facility, a determination is made as to the availability of the collection for use by those outside of the scientific program that is the custodian. Each National Center must then establish a review process for requests of materials, including a process for assuring that IRB approval is obtained before human specimens will be provided for non-exempt human subjects research. Release of specimens and associated data must be approved by the National Center. There are provisions for appeals of denials of approvals.

All specimen and data bank information is treated in a confidential manner and safeguarded in accordance with the Privacy Act and any other applicable laws, regulations, and policies.

National Centers are required to review the usage of their collections annually to ensure the periodic disposal or transfer of materials that they determine are no longer used or needed. Before disposal or transfer, the appropriate CDC program officials must provide descriptions of the excess specimen collections to other National Centers, institutions, or organizations affiliated with the collection through the Associate Director for Science at CDC. Any disposal or transfer of specimens that can be directly linked back to the study subject must be consistent with what was stated in the consent form. When appropriate approvals are given, the recipient organization becomes the custodian of the collection and assumes responsibility for it. Any destruction of specimens must follow current biosafety guidelines established by CDC and the National Institutes of Health.

Conclusion

In closing, CDC reference collections are a core component of our mission, unique in the world, and absolutely critical to research in medicine and public health. CDC takes its use of and subsequent storage and disposal of specimens seriously. These specimens provide the agency with the ability to not only detect, respond to, and control diseases today but are vital to unraveling tomorrow's unexpected disease crises.

Thank you for the invitation to appear before the Subcommittee to share this information with you about our invaluable specimen archives. I would be happy to answer any questions.

BIOGRAPHY FOR JANET K.A. NICHOLSON

Prior positions: Acting Deputy Director, National Center for Infectious Diseases (NCID), CDC; Associate Director for Laboratory Science, NCID; Deputy Chief, Immunology Branch, Division of HIV/AIDS, NCID; Research Chemist, Immunology Branch, Division of Immunologic, Oncologic, and Hematologic Diseases, NCID; Postdoctoral Fellow, Division of Immunology, Bureau of Laboratories, CDC; Research Scientist, Emory University; Research Technician, University of Texas Medical Branch; Research Technician, University of Nebraska Medical Center.

Education: B.S., Buena Vista College; Ph.D., Emory University.

Honors: Charles C. Shepard Science Award; Excellence of research, National Student Research Forum; McLaughlin Award in infectious diseases and immunology, National Student Research Forum; President's Award, Association of Public Health Laboratories (awarded twice); Centennial Achievement Award, University of Iowa Hygienic Laboratory; John Fischer Alumni Award, Buena Vista University. Invited speaker at over 70 national and international conferences.

Significant National activities: Ex officio member, National Science Advisory Board for Biosecurity; Member, Interagency Biosecurity Subcommittee of Select Agent Committee; President-elect, Board of Directors, delegate, and subcommittee member, Clinical and Laboratory Standards Institute (CLSI), [formerly National Committee for Clinical Laboratory Standards (NCCLS)]; Member, Infectious Diseases Committee, Association of Public Health Laboratories; Coordinator, ASM/NCID Postdoctoral Fellowship; Member, Laboratory Response Network (LRN) Joint Leadership Council; President, Advisor, and Counselor, Clinical Cytometry Society; Former Member and past Chair, Flow Advisory Committee (FAC) for NIAID; Editorial Boards of Communications in Clinical Cytometry and Clinical and Diagnostic Laboratory Immunology; Member of six professional societies.

International activities: U.S. representative for the Global Health Action Group Laboratory Network; Member, Framework Initiative for a Safe and Secure Society (U.S.–Japan initiative); Expert, Biological Weapons Convention Expert Meeting on Biosecurity, 2003; Involved in efforts to develop alternative technologies for CD4 enumeration through WHO; Invited speaker at 15 international conferences.

Scientific interests: Emerging infectious diseases; laboratory response to bioterror threats; immune responses to HIV infection.

Publications: Author/co-author of over 95 research/review papers.

Additional significant activities: Co-chair, core team/steering committee for design and construction of four NCID/CCID Laboratory Buildings; CDC Co-lead for Laboratory Coordination of Anthrax Events of 2001; Public Health Leadership Institute, Year 12 Class.

DISCUSSION

SCIENTIFIC COLLECTION DISPOSAL AT NCI AND CDC

Chairman MILLER. Thank you. Both of you gave testimony that was reassuring that our agencies, the procedures for the disposition of scientific collections are done with some care and some thoughtfulness, some thought. Can you assure the Subcommittee that a similar incident would not have occurred at your institution? Dr. Vaught?

Dr. VAUGHT. Well, the NCI and the broader NIH have spent a lot of time in the past few years trying to put policies into place to anticipate and manage collections so that they are collected, processed and stored in an orderly way, and I believe the policy that has been most effective in this has been established within the last two years by the NIH and its intramural program that I mentioned where IRB packages and institutional review board packages have to have a custodianship plan included for specimens and data. When an investigator leaves NIH or otherwise something changes that causes the custodianship of the sample collection to

change, then that has to be done in an orderly way. If the person goes outside NIH, then there are material transfer agreements that control transferring specimens and data outside of NIH, and if some change occurs within NIH, then there is agreement among various investigators to change the principal investigator who will lead and control the specimen collection. So we believe we have those issues covered in that way.

Chairman MILLER. Dr. Nicholson, would the CDC have destroyed a collection in the circumstances that you have heard occurred here?

Dr. NICHOLSON. CDC has a similar approach to NIH in this regard. Quite honestly, the investigators at CDC have a very hard time removing any specimens from the collection and it is a very difficult decision when that would happen.

Chairman MILLER. Dr. Vaught, your testimony is that we need long-term plans for custodianship, really very standardized and excellent management practices, many of the collections really are irreplaceable and priceless, and that other agencies need systems in place, procedures in place, protocols in place like what NCI has. Would a Congressional directive to establish such policies and implement the policies throughout the various federal agencies that do such research help that goal?

Dr. VAUGHT. Well, I think there is no easy answer to that. I think the basic principles that I laid out that NCI and NIH use are very good ones for custodianship of specimen collections. I believe, Mr. Chairman, you touched in your earlier opening statement on the interagency issues, that the OSTP created this Interagency Working Group on Scientific Collections and we found in that group that I think it is something like only 35 or 40 percent of the agencies that reported have standard operating procedures and policies for managing long-term management of their collections. But we have to remember that scientific collections include not only the biological specimens that I mentioned for NIH but also in my written testimony I mentioned that the moon rock collections that NASA manages, for example, the Smithsonian artifacts from the Lewis and Clark expedition have to be managed and these are all important collections for different reasons so they would have differing management policies, depending on the type of collection that is involved. So I think it would be difficult to write a policy that covers all the bases there but I think it is probably something to be followed up with by this interagency working group.

Chairman MILLER. But biospecimens in particular, biobanking in particular, it does seem that they are somewhat different from the artifacts of the Lewis and Clerk expedition. Would a directive from Congress to adopt a standard set of policies help make sure—which obviously has not happened. Would it help that happen?

Dr. VAUGHT. Well, I think we have to remember that there are already policies and regulations in place including the federal regulations that govern informed consent from the Department of Health and Human Services and also the regulations and rules within NIH and other agencies that govern material transfer agreements, so you already have a basis for creating custodianship policies. So the question I think would be whether you go beyond the existing IRB and informed consent rules and regulations and the

existing material transfer agreement regulations and create something that is beyond that. I think there are already good policies in place to handle most of these kinds of situations.

Chairman MILLER. Are you aware of such policies at the VA?

Dr. VAUGHT. Actually I don't know—I know very little about the VA's policies. The informed consent policies that Dr. Nicholson and I operate under are governed by what is called the Common Rule, and that is a HHS regulation.

Chairman MILLER. My time is expired. Mr. Rohrabacher.

SHOULD THE SPL BEEN AT THE VA?

Mr. ROHRABACHER. Thank you, Mr. Chairman.

I take it that both of you knew that the major area that we were supposed to be looking at here today, the reason you are here, is to give us a broader image, a broader view as well, which you have and I appreciate that, but I would like to ask your opinion on this case. I believe that first of all the research that was being conducted which we now know contributed greatly to saving human life and is very admirable and positive research for the country and for the well-being of our people, should that research have been VA research or should it have been under NIH or CDC?

Dr. NICHOLSON. CDC does have a *Legionella* lab that does research. I don't know enough about what the VA's mission is to determine whether or not CDC should also do that type of research.

Mr. ROHRABACHER. So the CDC could well have offered an alternative to encompassing this research and bringing them in?

Dr. NICHOLSON. I am not the *Legionella* expert so I don't know what the focus of the research in our *Legionella* lab is so I can't really say.

Mr. ROHRABACHER. All right. What about with NIH?

Dr. VAUGHT. Well, I think I am even further removed from that. NIH has something like 26 or 27 institutes. One of them is the National Institute of Allergic and Infectious Diseases, NIAID, and NIAID works closely with the CDC on infectious disease issues, but I couldn't say whether this would fall under NIAID's mission or not.

Mr. ROHRABACHER. Were the people involved and was the lab that is now being looked at—you have listened to the testimony and I don't know if you read the testimony to come or not but is it your professional opinions that the job that they were doing met your professional standards?

Dr. VAUGHT. I honestly don't know enough about this situation to comment on that. I have of course read some of the testimony and background papers and so forth but really my major conclusion was that this was an issue of custodianship and so I have tried to address that from NCI and NIH's point of view and hopefully those sorts of policies and procedures that we developed at NIH would be applied in other situations but I really——

MORE ON SCIENTIFIC COLLECTION DISPOSAL AT NCI AND CDC

Mr. ROHRABACHER. We are talking about custodianship in a period of transition as well. They were closing the lab and who then

and what those procedures should be and how to make sure situations don't arise like this in which some very damaging decisions were made that ended up with the destruction of materials that could well have served us and served the lives of human beings in a very important way, and what would you say to that?

Dr. NICHOLSON. I don't really have any more to add. I also don't know any more than we just heard this morning about this particular case.

Mr. ROHRABACHER. And have any of your organizations had run-ins with the administration like this before?

Dr. VAUGHT. Run-ins with our administration?

Mr. ROHRABACHER. With people who are overseeing you within the administration for budgetary reasons making decisions that could lead to a negative impact.

Dr. VAUGHT. Well, I can only say from my own experience that there are policies and procedures developed at NIH for closing labs and an orderly transfer of equipment, materials and personnel. Those decisions are made above my pay grade but they happen.

Mr. ROHRABACHER. So there are decisions that you think that are in place at NIH that would have prevented this destruction of these specimens?

Dr. VAUGHT. I can only say that I believe that we have orderly processes in place at NIH.

Mr. ROHRABACHER. What about the CDC in this?

Dr. NICHOLSON. For the long-term collections, yes, that is absolutely the case. There are policies and procedures in place to ensure that appropriate approvals are received in order to destroy specimens.

Mr. ROHRABACHER. Well, I won't try to put you on the spot anymore because I understand the position you are in, but let us just—again, I realize, like I stated in the beginning, there are bad decisions that are made by people that should be held accountable. There are also bureaucratic problems that arise within a governmental approach to problems and governmental involvement in human activity. So we will find out what is at the bottom of this but certainly these are people that have contributed enormously to the well-being of our people. I mean, Legionnaires' disease, it is a very admirable thing to come up with some solution for that and some way they can be treated. We end up with a situation like this and I am very pleased that the Chairman to focus his attention on this issue. Thank you very much.

Chairman MILLER. Thank you, Mr. Rohrabacher.

Dr. Broun.

Mr. BROUN. Thank you all for coming to this hearing today. As a physician and scientist, I am very concerned about this issue. I just have a question of each of you. Do you see any reason, any compelling reason from a scientific perspective why these specimens should have been destroyed in the way that they were, from a safety perspective, a health perspective or anything else? Can you see any reason to just destroy these specimens the way that they were handled? And I would like both of you to comment on that, please.

Dr. VAUGHT. Well, again, I feel like as a scientist that I really don't know all the facts in this case to make that sort of judgment.

I can tell you that in our experience at NIH, there are a number of reasons that specimen collections would be destroyed after a long and careful process of reviewing their utility. Normally they would be destroyed if they are no longer useful for their original purpose, or if there isn't enough sample left to do any further work on. Or if they presented some other sort of biohazard may be one reason but usually those biohazard issues can be mitigated by regulations that are in place at NIH and CDC. So I just have to say that a lot of thought is given to destroying specimen collections, and as Dr. Nicholson stated, usually the problem is getting investigators to let go of their specimens because the tendency is to want to save them as long as possible and that is why we have huge warehouses full of freezers out in Frederick, Maryland.

Mr. BROUN. Dr. Nicholson.

Dr. NICHOLSON. I also don't know enough about this particular case. I will tell you, I don't have a whole lot more to add over what Dr. Vaught has said, but within CDC it would be very rare for a specimen collection to be destroyed. I am not aware of any of that. It is not all that unusual for specimens as part of collections to be destroyed because of a variety of reasons that you may understand and that I had already outlined.

Mr. BROUN. Certainly as a practicing physician, I don't anticipate my own patients' specimens to be continued on an ongoing basis once I get the clinical information I need as a practicing doctor. I make those clinical decisions that I make and then I don't expect those decisions, but also valuable research is absolutely critical for antibody development and to find out about pathogens changing their response to various anti-microbials, et cetera, and so I just—I can't imagine as a scientist just destroying a whole set of specimens just without any regard, particularly those that are involved in patient care and patient evaluation prior to having a determination about what the final results of that culture might be. In each of y'all's opinion, is destroying a specimen prior to developing the identification and antibiotic sensitivities to clinical specimens—to me, this seems to be just totally beyond comprehension. Can you see any compelling reason to destroy those when you have an ongoing process for clinical specimens on patients or environmental sources of those specimens prior to the determination of what the pathogen—well, whether this is pathogen there, what the pathogen might be and anything to help in determining how to deal with that pathogen at that point?

Dr. NICHOLSON. For clinical laboratories, and CDC does do reference diagnostic testing, primarily for the State public health laboratories, we have to abide by CLIA and every CLIA laboratory has written procedures and protocols about the collection and the use and the storage of such specimens. Specimens before they actually have been evaluated to determine what might be the causative agent may be actually rejected because they appear to CDC in such poor condition, they were exposed to high temperatures. There are other physical reasons for specimens to have never reached the testing component after they have been collected.

Mr. BROUN. But at this point, again, just for the record, when that determination is made, it is because of inadequacy of collection

materials or that the media has a problem with it or something else.

Dr. NICHOLSON. Exactly.

Mr. BROUN. It is not because it is a valid specimen that could be utilized in that investigation. Is that correct?

Dr. NICHOLSON. Exactly.

Mr. BROUN. Dr. Vaught, do you have anything to add?

Dr. VAUGHT. I don't think so. My experience at the Cancer Institute is not in infectious disease so our specimens are collected, for example, for clinical trials and epidemiology studies where cancer biomarkers are studied, and usually—or always, there is a study protocol where it is determined what the specimens are going to be used for, how long they are going to be saved, and there are primary hypotheses, secondary hypotheses. When all of those hypotheses are exhausted, then consideration will be given usually to sharing any additional specimens that are left over with investigators outside of NIH or colleagues within NIH. So discarding a sample collection is usually the last resort when it is no longer useful or there could be some circumstances where specimens are no longer useful or they are not in good condition to be used but those would be, as I said, as a last resort.

Mr. BROUN. Thank you very much.

Chairman MILLER. Thank you, Dr. Broun.

I think we have no further questions of this panel. Thank you very much for being here, and we will now take about a 15-minute break before the final panel. Thank you.

[Recess.]

Chairman MILLER. We will wait just a minute or two for Mr. Rohrabacher.

[Recess.]

Panel III:

Chairman MILLER. We are back.

I would now like to introduce our final panel today. Mr. Michael Moreland is the Director of the Veterans Integrated Service Network 4 at the Department of Veterans Affairs. Dr. Mona Melhem is the Associate Chief of Staff and Vice President of the Clinical Support Service Line for the Veterans Affairs, Pittsburgh Healthcare System. Dr. Ali Sonel is the Associate Chief of Staff for the Veterans Affairs Pittsburgh Healthcare System. Dr. Steven Graham is the Director of the Geriatric Research, Education, and Clinical Centers at the Veterans Affairs, Pittsburgh Healthcare System. And Ms. Cheryl Wanzie is the Chief Technologist for the Veterans Affairs Pittsburgh System. Dr. Sonel is the Associate Chief of Staff for Research, specifically, at the Veterans Affairs, Pittsburgh Healthcare System. I understand that only Mr. Moreland will be giving prepared testimony today, but the other witnesses will answer questions that may be directed to them.

Mr. SONEL. Actually, sir, each of the witnesses does have an oral statement.

Chairman MILLER. Oh, all right. We will take the oral statement. We did not get anything in writing beforehand but that is fine. As you know, from seeing the earlier two panels, we do take testimony

under oath. Do any of you have an objection to being sworn in, to swearing an oath? All the witnesses nodded their head that they had no problem, no objection. The Committee also provides that you may be represented by counsel. Do any of you have counsel with you at the hearing today? All witnesses nodded or said that they did not have counsel. Now, please stand and raise your right hand. Do you swear to tell the truth and nothing but the truth? All the witnesses said or otherwise—all the witnesses are now so sworn.

Mr. Moreland, you may begin.

STATEMENT OF MR. MICHAEL E. MORELAND, NETWORK DIRECTOR, VA HEALTHCARE—VISN 4, DEPARTMENT OF VETERANS AFFAIRS

Mr. MORELAND. Thank you. Good morning, Mr. Chairman, and Members of the Subcommittee. Thank you for the opportunity to discuss the events surrounding the closure of the Special Pathogens Laboratory at the VA Pittsburgh Healthcare Center. I am joined today by several colleagues from the VA Pittsburgh Healthcare System including Dr. Ali Sonel, our Associate Chief of Research and Development, Dr. Mona Melhem, our Vice President, Clinical Support Service line, Ms. Cheryl Wanzie, Medical Technologist, and Dr. Steve Graham, Director, Geriatric Research and Education Center. And sir, I assume our written testimonies will all be entered for the record.

Chairman MILLER. Mr. Moreland, I believe that only you have submitted written testimony. It will be submitted in full in the record.

Mr. MORELAND. Thank you very much. Today we will address the closure of the Special Pathogens Lab, the disposition of equipment and specimens, and the VA policies as they were in December of 2006. Additionally, I will discuss some changes that we have made and instituted in policy since that time.

In January of 2006, the Associate Chief of Staff for Clinical Support who oversees all of Pittsburgh's laboratory functions conducted a standard review of the Special Pathogens Lab workload. This review determined that the main clinical laboratory would be more efficiently managing these duties. It also revealed that the Special Pathogens Lab was acting beyond its intended scope. The lab lacked a defined and approved research activity and the volume of clinical work being performed was low. These plus other concerns led us to conclude that the Special Pathogens Lab would be moved into the main clinical lab and that additional reviews of the lab's research accounts would be unnecessary.

The Special Pathogens Lab closed on July 21, 2006. Approximately two weeks earlier, on July the 5th, the Director of the lab was notified by e-mail and in person about the lab's closure, and he and his staff were given two weeks to complete work currently in process. This notification included instructions to stop accepting specimens from external customers. The lab's close-out plans were forwarded to the lab's staff on July the 7th, and formal letters of notification were delivered on July the 10th. The members of the lab received clear direction regarding labeling of existing and new specimens and stored samples, and the members of the lab were

told to provide a map for this storage. These orders were specific, but they were ignored.

As the Medical Center Director, I initiated an Administrative Board of Investigation to review research and financial activities. The Administrative Board determined that the lab was operating outside of its established scope of services and had involved into an unauthorized commercial enterprise, testing samples for private companies including hotels, restaurants, and gas stations. It was also engaged in subcontracting for private environmental companies. The lab had a commercial client list well into the hundreds.

In September of 2006, we conducted a review of every publication generated in the lab and concluded its studies involving human subjects were conducted without required approval from the Institutional Review Board and/or the Research and Development Committee. To our knowledge, no individuals were harmed as a result of this research. We reported these findings to the VA Office of Research Oversight, ORO, in October of 2006. They concluded we had adequately addressed research non-compliance by preventing the lab from any future research projects, eventually closing the lab, and establishing safeguards to prevent similar non-compliance in the future. Following the lab's closure, all properly labeled and cataloged clinical specimens were moved to the main lab. Research specimens associated with an approved research protocol properly labeled and maintained by the principal investigator were transferred to the main clinical lab for storage as well. In these specimens that were either not labeled or not cataloged or properly sealed were considered biohazardous material and were safely disposed of in accordance with hazardous material procedures to safeguard patient care and public health. VA Pittsburgh water samples were transferred to the clinical laboratory and were sent to an outside vendor for *Legionella* testing subsequent to the lab's closure.

VHA policy in December of 2006 clearly stated that if an investigator leaves the VA facility, the original research records must be retained at the institution. Moreover, VA policy instructs that records and information collected and created by VA personnel, in the conduct of official business, belong to the Federal Government and not to the employee who initiated the collection or the creation.

We determined that the samples in question were not properly labeled and cataloged and did not constitute a sample of collection. Even if the samples had been properly labeled and stored, the collection could not have been banked at a non-VA institution without proper approval.

Following this incident, VA Pittsburgh Healthcare System has adopted new policy. On October 19, 2007, we issued Research Data Security and Privacy Policy that specifically outlines processes for disposition of research and clearly informs researchers that VA research is the property of VA and that investigators cannot take the collection away from the VA without appropriate approval. The VA Pittsburgh Healthcare System offers a robust research program committed to contributing to science and enhancing care to veterans in the broader community. We added compliance staff to increase research oversight, and leadership is continuing an ongoing, in-depth review to ensure all VA researchers adhere to the highest level of human subjects' protection.

That concludes my statement, Mr. Chairman. I will be happy to take questions.

[The prepared statement of Mr. Moreland follows:]

PREPARED STATEMENT OF MICHAEL E. MORELAND

Good morning Mr. Chairman and Members of the Subcommittee. Thank you for the opportunity to discuss the events surrounding the closure of the Special Pathogens Laboratory (SP Lab) at the VA Pittsburgh Healthcare System (VAPHS). I am joined today by Dr. Ali Sonel, Assistant Chief of Research and Development, VAPHS; Dr. Mona Melham, Vice President Clinical Support Service Line, VAPHS; Ms. Cheryl Wanzie, Medical Technologist; and Dr. Steven Graham, Director, Geriatric Research and Education Center (GREC).

VAPHS is an integrated health care system serving a population of over 360,000 veterans throughout Western Pennsylvania, Ohio, and West Virginia. In Fiscal Year 2007, VAPHS served over 58,000 unique veterans and completed over 489,000 outpatient visits. Between 2000 and 2007, the VAPHS research program grew from $11 million to over $24 million in funded research including an initiative for a VA-led cooperative study; this growth is indicative of a healthy program that promotes a positive environment for researchers.

Today I will address the closure of the SP Lab, the disposition of equipment and specimens, and VA policies as they were in December 2006. Additionally, I will discuss some changes we have since instituted to these policies.

Closure of Special Pathogens Laboratory

Let me say at the outset that the Special Pathogens Lab operated within the VAPHS as a part of the regular clinical laboratory services. As such, the primary mission was to support the clinical work of the organization. Its original focus was to perform clinical testing for *Legionella* bacteria for the VA.

Further, it should be understood that research projects may be and, are indeed encouraged, to be undertaken by VAPHS clinicians in the scope of their VA employment if their protocols are presented and approved by the Research and Development Committee.

The Research Foundation, an incorporated not-for-profit organization, has the mission to support VA research operations. External funding resources are often secured and managed by this foundation for properly approved and sanctioned activities of VA researchers.

In January 2006, the Associate Chief of Staff (ACOS) for Clinical Support, who oversees all VAPHS' laboratory functions, reviewed the workload of the SP Lab. She determined the clinical workload could be managed more efficiently within the main clinical laboratory. She also discovered the SP Lab was acting beyond its intended scope.

Following a technical review by the ACOS for Clinical Support, we found it presented a potential biohazard to both employees and our veterans. The SP Lab also lacked a defined and approved research activity. The volume of clinical work being performed in the SP Lab was low. The ACOS for Clinical Support determined that this function could easily be absorbed by the main clinical laboratory at reduced cost. The supplies necessary to effect such a change were minimal and the conversion would free up the time of the full-time VA microbiologist to do other VA work. These concerns were the basis for the ACOS for Clinical Support's recommendation that the VA work of the SP Lab be moved into the main clinical lab and that there be an additional review of SP Lab research accounts.

On July 5, 2006, the Director of the SP Lab was notified via e-mail and in person about the lab's closure and he and his staff were given two weeks to complete work currently in progress. This notification included instructions to stop accepting specimens from external consumers. The Lab's "close-out" plans were forwarded to the SP Lab staff on July 7, and formal letters of notification were delivered July 10. The SP Lab closed on July 21, 2006. The members of the lab received clear direction regarding labeling of existing and new specimens and stored samples, and the members of the lab were told to provide a map for storage. Although these instructions were specific, they were ignored.

Investigative Reports

As VAMC Director, I initiated an administrative board of investigation (ABI) on July 19, 2006, to review research and financial activities. In addition, I expanded the scope of the investigation on August 4, 2006, to include investigation of any breach of security and/or patient privacy surrounding activities in the SP Lab. The

ABI determined the SP Lab was operating outside the scope of services for which it was established. It had evolved into an unauthorized commercial enterprise, which tested environmental water supplies for private companies (including hotels, restaurants, and gas station bathrooms), and was engaged in subcontracting for private environmental companies. The SP Lab had a commercial client list in the hundreds that included private hospitals, businesses, municipal water authorities and other institutions.

Funds were collected and deposited within the foundation accounts. As part of an internal financial review at the VA Pittsburgh, financial concerns were raised. Records indicated that their non-VA invoiced revenue for 2005 was $396,631.41 and for 2006 was $311,337.71. Since this was found, the Research Foundation has hired financial staff and enhanced financial oversight. Non-VA revenue remained unobligated. The Research Foundation has a procedure in place for left over funds from research accounts. These funds were pulled into the foundation and used for other projects.

In September 2006, the VA Associate Chief of Staff for Research, conducted a review of every publication generated in the SP Lab and concluded that human subject microbiological diagnostic and interventional human research studies were conducted at the VAPHS without required approval from the Institutional Review Board (IRB) and the Research and Development Committee. To our knowledge, no individuals were harmed as a result of this research.

We reported all of these findings to the VA Office of Research Oversight (ORO) on October 12, 2006. In October 2006, after reviewing these reports of investigations and the actions taken by VAPHS, ORO concluded the VAPHS had adequately addressed research non-compliance by suspending the SP Lab from embarking on any future research projects, eventually closing the lab, and establishing sufficient safeguards to prevent similar non-compliance from recurring.

Removal of Equipment and Environmental Specimens

Following the closure of the SP Lab, furnishings and equipment purchased with clinical lab's funds or with VA Research Foundation funds were moved to the main clinical lab. SP Lab staff were allowed to transfer equipment acquired by non-VA funds to a site off federal premises. Properly labeled and cataloged clinical specimens from the SP Lab were also moved to the main lab. Research specimens associated with an approved research protocol, properly labeled and maintained by the principal researchers were transferred to the main clinical laboratory for proper storage. Those specimens that were not labeled, cataloged, or were in opened or damaged tubes were considered bio-hazardous material and were safely disposed of in accordance with hazardous materials procedures, safeguarding patient care and public health. VAPHS water samples were transferred to the clinical laboratory. For approximately two weeks, VAPHS sent water samples to an outside vendor for *Legionella* testing. After this period, VA's clinical lab developed the ability to conduct *Legionella* testing in-house and currently offers this service to several other VA Medical Centers.

Policy Governing Disposition of Research

In December 2006, VHA Directive 2000–043 (attached) governed the disposition of research collections. The Directive and a clarification memorandum from VHA's Chief Research and Development Officer (CRADO) addressed the collection and storage of clinical data that could be linked to the human biological specimens. Two additional policies discussed record retention. VHA Handbook 1200.05 (attached) states that "if an investigator leaves a VA facility, the original research records must be retained at the institution." VA Handbook 6300.1 (attached) states that "records and information collected and created by VA personnel in the conduct of official business belong to the Federal Government and not to the employee(s) who initiated their collection or creation."

We determined in December 2006 that no VA-approved research protocol existed to cover the samples in question. The samples were not collected as part of any previously approved research efforts, nor were they collected, labeled, cataloged and properly stored to constitute a scientific collection. Even if the samples had been properly labeled and stored, the collection could not have been banked at a non-VA approved institution without a VA investigator.

In response to the investigations of the SP Lab and after the loss of research data in another VISN, VAPHS took steps to enhance awareness among staff of VA research and lab policies and procedures. In March of 2007, VAPHS held a two-week Research Stand Down to ensure staff understood laboratory policies and the importance of securing sensitive research data.

New Policy Governing Disposition of Research

On October 19, 2007, VAPHS issued Research Data Security and Privacy Policy. The new policy specifically outlines processes for disposition of research and clearly informs researchers that VA research is the property of VA and that investigators cannot take what they collect as part of VA-approved research when they leave the institution. Additionally, local policies and procedures will continue to be revised as needed, including policy related to tissue, specimen and data banking.

The VA Pittsburgh Healthcare System operates a robust research program committed to contributing to science and enhancing care to veterans and the broader community. We have added compliance staff to increase research oversight and leadership is continuing an ongoing, in-depth review to ensure all VA researchers adhere to the highest level of human subjects' protection.

This concludes my statement. I would be pleased to answer any questions the Subcommittee may have.

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 2000-043

November 6, 2000

BANKING OF HUMAN RESEARCH SUBJECTS' SPECIMENS

1. PURPOSE: This Veterans Health Administration (VHA) Directive implements a new policy related to human biological specimens collected for research purposes and stored for possible later uses, including genetic studies. It also addresses the collection and storage of clinical data that may be linked to the human biological specimens.

NOTE: *For the purpose of this Directive, the term human biological specimens is defined as any materials derived from human subjects, such as blood, urine, tissues, organs, hair, nail clippings or any other cells whether collected for research purposes or as residual specimens from diagnostic, therapeutic or surgical procedures.*

2. BACKGROUND

a. The availability of human biological specimens for research purposes is crucial for the advancement of medical knowledge and in understanding, diagnosing, and treating diseases that affect the veteran population.

b. With the advent of new technologies and their abilities to uncover information that may adversely effect the donor in anticipated or unanticipated ways, it is imperative that all ethical and legal issues related to the use of these specimens and, if collected, their linked clinical data be identified and understood.

c. It is imperative that human research subjects donating the specimens receive the highest level of protection possible and that any questions or any legal or ethical ambiguities always be resolved in favor of the human research subject.

d. The use of Department of Veterans Affairs (VA)-sponsored tissue banks will facilitate the protection of an individual's rights without compromising the advancement of medical science. Further, it will allow investigators to pursue research projects that have been subjected to scientific merit review and the Institutional Review Board, to assure compliance with all applicable Federal regulations such as Title 38 Code of Federal Regulations (CFR) 16, and 45 CFR 46.

NOTE: *For the purpose of this Directive, a VA-sponsored tissue bank is defined as a tissue bank in VA facilities or approved off-site locations that operates in accordance with VA guidance and regulations.*

3. POLICY: It is VHA policy to ensure that human biological specimens, as well as the linked clinical data collected as part of research projects conducted by VA investigators in VA facilities or approved off-site locations, are maintained at VA approved tissue banks. ***NOTE:*** *This policy is applicable to all research projects that are conducted by VA investigators in VA facilities or approved off-site locations, whether the research is funded or unfunded, and regardless of the source of funding.*

VHA DIRECTIVE 2000-043
November 6, 2000

THIS VHA DIRECTIVE EXPIRES OCTOBER 30, 2005

4. ACTION

a. Effective on this date, all new projects collecting and storing human biological tissue specimens shall utilize VA-sponsored tissue banks. These tissue banks may also serve as the repository for the clinical data that have been collected and that may be linked to the specimens.

b. All previously established projects must develop plans to either obtain approval or to move specimens and linked clinical data to VA-sponsored tissue banks and begin implementation of these plans as soon as feasible.

NOTE: *Failure to comply with the policies stated in this Directive could result in immediate withdrawal of VA research funding for the programs in question and/or suspension of the research program.*

5. REFERENCES: None.

6. FOLLOW-UP RESPONSIBILITY: The Office of Research and Development (12) is responsible for the contents of this Directive. Questions may be referred to 202-408-3614.

7. RESCISSIONS: None. This Directive expires October 30, 2005.

Thomas L. Garthwaite, M.D.
Under Secretary for Health

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Department of Veterans Affairs
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Washington, DC 20420

VHA HANDBOOK 1200.5
Transmittal Sheet
July 15, 2003

REQUIREMENTS FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) Handbook prescribes procedures for the protection of human subjects in Department of Veterans Affairs (VA) research.

2. SUMMARY OF MAJOR CHANGES: VA is one of the seventeen Federal departments and agencies that have agreed to follow the Federal Policy for the Protection of Human Subjects (Common Rule), effective June 18, 1991 (56 Federal Register (FR) 28001). This policy is incorporated in Title 38 Code of Federal Regulations (CFR) Part 16. This Handbook defines the procedures implementing 38 CFR 16.

3. RELATED ISSUES: VHA Directive 1200.

4. RESPONSIBLE OFFICIALS: The Office of Research and Development (12) is responsible for the contents of this Handbook. Questions may be addressed to 202-254-0183.

5. RESCISSIONS: None.

6. RECERTIFICATION: This document is scheduled for recertification on or before the last working day of July 2008.

Robert H. Roswell, M.D.
Under Secretary for Health

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(3) Waiver or alteration of authorization for the use and/or disclosure of Protected Health Information (PHI) (see HIPAA Authorization).

b. **Procedures for Expedited Review.** In the expedited review process, the IRB Chair may carry out the review or delegate the review to one or more experienced reviewers from among IRB members.

(1) In reviewing the research, the reviewer(s) may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove the research. A research activity may be disapproved only after review in accordance with the full-review procedure.

(2) If a proposal has been initially approved through the full-review procedure, the continuing review may not be done by the expedited review procedure. ***NOTE:*** *Exceptions may be found in Appendix B, subparagraphs 2h(1)-(3).*

(3) The decision must be recorded and then communicated in writing to the investigator and the IRB.

c. **Record Keeping.** Each IRB that uses an expedited review process must adopt a method for keeping all members advised of research proposals that have been approved under this process. The minutes and/or the protocol file must reflect the expedited review eligibility category that the research meets.

d. The IRB approval is effective only after approval by the R&D Committee; therefore work on the research may not commence until R&D Committee approval is obtained. The date of continuing review is based on the date of IRB approval. ***NOTE:*** *Refer to subparagraph 7b for information on commencement of research.*

10. INVESTIGATOR RESPONSIBILITIES

a. The investigator must have the appropriate training and be credentialed to conduct research involving human subjects by a program that meets all VA requirements.

b. The investigator must develop a research plan that is scientifically valid, minimizes risk to the subjects, and contains a description of the data and safety monitoring plan that includes the reporting mechanism of AEs to the IRB, and when required to ORO, ORD, and other Federal agencies or sponsors. The plan may vary depending on the potential risks, complexity, and nature of the study. A DSMB or DMC needs to be part of the monitoring plan when required by NIH or FDA. The use of a DSMB or DMC needs to be considered if there are multiple clinical sites, the study is blinded, interventions are particularly high-risk, or vulnerable populations are included.

c. Investigators involving human beings as subjects in research must obtain

(1) Legally effective informed consent of the subject or the subject's legally authorized representative; and

(2) Legally effective authorization for the use and disclosure of the subject's PHI.

d. If someone other than the investigator conducts the interview and obtains consent, the investigator should formally delegate this responsibility and the person so delegated must have received appropriate training to perform this activity. The most recently IRB approved consent form must be used. ***NOTE:*** *The basic elements of informed consent are described in Appendix C.*

e. The informed consent must be documented in accordance with Appendix C of this Handbook.

f. SAE and/or UAE must be reported to the IRB and other required entities. If a DSMB or DMC is used, all events must be reported to the DSMB or DMC and a summary of the DSMB or DMC findings must be reported to the IRB and other entities as required. Other AEs, as defined by the monitoring plan in the protocol, must be reported in accordance with the monitoring plan approved by the IRB and as defined in FDA regulations, or other applicable Federal regulations.

g. All amendments to, or modification of, the research proposal including the consent form must be approved by the IRB prior to initiating the changes except when necessary to eliminate apparent immediate hazards to the subject.

h. The investigator is responsible for obtaining initial and continuing IRB review and approval and for submitting to the IRB requests for modifications to the protocol. The investigator is expected to know the date of the continuing review and to be aware that the project is automatically suspended when the continuing review does not occur on schedule.

i. If the investigator leaves the VA facility the original research records must be retained at the institution.

j. If the investigator requires a waiver or alteration of the HIPAA Authorization, the investigator must provide the IRB with information sufficient for the IRB to find that such waiver or alteration is necessary. The IRB must document its decision in its minutes. ***NOTE:*** *The elements of such documentation are listed in Appendix E and may be used by an investigator to determine what information needs to be provided to the IRB with a request.*

11. RESEARCH INVOLVING HUMAN SUBJECTS WITH SURROGATE CONSENT

a. Under appropriate conditions, investigators may obtain consent from the legally authorized representative of a subject (surrogate consent).

(1) This policy is designed to protect human subjects from exploitation and harm and, at the same time, make it possible to conduct essential research on problems that are unique to persons who are incompetent, or who have an impaired decision-making capacity (e.g., a study of treatment options for comatose persons can only be done with incompetent subjects).

(2) Such consent may be obtained from: a health care agent appointed by the person in a DPAHC or similar document; court-appointed guardians of the person, or from next-of-kin in the

Department of Veterans Affairs
Washington, DC 20420

VA Handbook 6300.1
Transmittal Sheet
January 12, 1998

RECORDS MANAGEMENT PROCEDURES

1. REASON FOR ISSUE. This handbook establishes Department of Veterans Affairs (VA) records management procedures that implement the policies contained in VA Directive 6300, Records and Information Management.

2. SUMMARY OF CONTENT/MAJOR CHANGES. This handbook describes procedures for carrying out the records management program. These procedures were developed based on records management requirements contained in various Federal regulations, and guides, bulletins, and memoranda published over the years by the National Archives and Records Administration (NARA). The Federal procedural requirements and those mandated by NARA have been combined into one handbook to facilitate accomplishment of VA's mission to carry out its records management program in a more efficient and effective manner.

3. RESPONSIBLE OFFICE. The Information Management Service (045A4), Office of the Deputy Assistant Secretary for Information Resources Management.

4. RELATED DIRECTIVE. VA Directive 6300, Records and Information Management.

5. RESCISSION: None

CERTIFIED BY:

BY DIRECTION OF THE SECRETARY OF VETERANS AFFAIRS

Nada D. Harris
Deputy Assistant Secretary
for Information Resources Management

D. Mark Catlett
Acting Assistant Secretary for Management

Distribution: RPC 0735
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d. If records or information being collected or created involve a computer matching program, the OMB Guidelines for Computer Matching Programs and VA Handbook 6300.7 apply.

e. If records or information being collected or created will be received from or provided to other agencies, it may be necessary to establish formal agreements with the agencies involved. Refer to 36 CFR 1228.70 for guidance.

f. If information may eventually be transferred to an archival agency for permanent custody because it has been determined to have permanent and enduring value, the record medium must meet the standards of and be approved by the Archivist of the United States, NARA. Refer to 36 CFR, chapter XII, subchapter B.

g. If VA records or information are to be turned over to, or collected, created, maintained, used, processed, or handled in any way by a contractor, Title 41, United States Code, Public Contracts, and 36 CFR, chapter XII, subchapter B, apply.

h. The records and information of VA must be protected and used, or disseminated or released only in accordance with applicable Federal laws and regulations.

i. Duplication, copying, and printing of records, information, and informational products will be in accordance with applicable Federal and VA regulations and policies. Refer to MP-1, Part II, Chapter 9, Printing and Reproduction.

j. The emergency-preparedness needs of VA will be met through the identification of vital records and pre-positioning copies of them at strategic locations for ready accessibility in the event of a national or local natural or technological disaster. Refer to VA Handbook 6300.2, Procedures for the Vital Records Program and VA Handbook 0320.1, Emergency Preparedness Planning Procedures and Operational Requirements.

k. The dissemination or release of any records and information within and outside VA must be in accordance with Federal statutes and VA policy. In some instances it may be necessary to maintain sensitive records and information in locked or password-protected files or restricted-access areas for reasons of security. Refer to MP-1, Part I, Chapter 5, Security; and VA Handbook H-003-1 entitled, "Information Resources Security Handbook."

l. Electronic media information systems may require special design to maintain appropriate security and confidentiality, particularly when sensitive information is transmitted via standard telecommunications networks. VA officials must be aware of the sensitivity levels of the information for which they are responsible and must be aware of the security capabilities of the technologies being used.

m. Information about an individual that is retrieved by means of that individual's name or personal identifier must be maintained in a system of records in accordance with a published Privacy Act System of Records Notice that describes the maintenance of that system. Notices of new proposed routine uses, including proposed computer matching activities, must be published in the *Federal Register* for public comment prior to implementation. The new use of the information cannot be implemented until at least 30 days after publication of the Notice. Refer to VA Handbooks 6300.4, 6300.5, and 6300.7, for guidance.

3. DOCUMENTING OFFICIAL ACTIONS AND ACTIVITIES

a. VA officials are responsible for incorporating into the records of the Department all essential information on their major actions. Significant decisions and commitments reached orally or by informal electronic mail should be documented and included in the record. Minutes should be taken at important meetings, and these, together with a copy of the agenda and all documents considered at or resulting from such meetings, should be made part of the record.

b. The programs, policies and procedures of VA should be adequately documented in appropriate directives. A record copy of each such directive and supporting documentation, including those superseded, should be maintained as a part of the official files. Refer to VA Directive 6330, Directives Management and VA Handbook 6330, Directives Management Procedures, for guidance.

c. Papers of a private or nonofficial character that pertain only to an individual's personal affairs that are kept in the office of a VA official shall be clearly designated by him or her as nonofficial and shall at all times be filed separately from the official records of the office. In cases where matters requiring the transaction of official business are received in private personal correspondence, the portion of such correspondence that pertains to official business shall be extracted and made a part of the official files.

d. In planning automated or manual information systems, the life cycle of the records and information must be considered. The administration and staff office Records Officers must be included in the initial planning to ensure the records and information created or generated are properly scheduled.

BIOGRAPHY FOR MICHAEL E. MORELAND

Michael E. Moreland was appointed Network Director of the VA Healthcare—VISN 4, on December 24, 2006. In this position he directs the operations, finances and clinical programs of a health care system that serves an estimated 1.5 million veterans throughout Pennsylvania and Delaware, as well as portions of West Virginia, New Jersey, Ohio and New York. The system is comprised of ten medical centers and 40 community based outpatient clinics.

Prior to this appointment, Mr. Moreland had been the Director of the three-division VA Pittsburgh Healthcare System (VAPHS) since June 18, 2000. Mr. Moreland is a Fellow of the American College of Healthcare Executives and received the Presidential Rank Award for Meritorious Achievement from President Bush in November 2002. He is a member of the VHA National Leadership Board Finance Committee.

Mr. Moreland began his service with the Department of Veterans Affairs in 1980 as a clinical social worker. He held progressively responsible positions with several VA Medical Centers, including serving as the Director of Butler VA Medical Center from August 1997 until his appointment to VA Pittsburgh. He was also Deputy Network Director of VA Health Care Network 2 in Upstate New York, Associate Director at Lebanon VA Medical Center in Pennsylvania, Chief of Social Work Service at the Highland Drive VA Medical Center in Pittsburgh, and held various assignments as a Clinical Social Worker in the 1980s. Mr. Moreland received a Bachelor of Arts degree from the University of Maryland at Baltimore in 1978 and earned his Masters degree in Social Work from the University of Maryland in 1980.

Chairman MILLER. All right. We do not have written testimony from any of the other witnesses, but I understand each of you wishes to give oral testimony, so why don't we just go down the line. Dr. Sonel?

STATEMENT OF DR. ALI SONEL, ASSOCIATE CHIEF OF STAFF, RESEARCH AND DEVELOPMENT, VA PITTSBURGH HEALTHCARE SYSTEM, DEPARTMENT OF VETERANS AFFAIRS

Dr. SONEL. Good afternoon, Mr. Chairman, and Members of the Subcommittee. I would like to thank you for providing this opportunity to discuss the events surrounding the disposal of various samples, from the now-closed Special Pathogens Laboratory at the VA Pittsburgh Healthcare System.

I am Dr. Ali Sonel, and I am the Director of the Cardiac Catheterization Laboratories and Associate Chief of Staff for Research and Development at VAPHS.

To provide some context, VAPHS is home to one of the largest research programs in the Nation with over $24 million in annual research expenditures and 276 active research protocols including 165 human research participant protocols conducted by 120 investigators.

Fostering scientific research and ensuring the safety, rights, and welfare of research participants through compliance with local, State, and national regulatory requirements for protection of human subjects are critical to our mission serving America's veterans.

In September 2006 I became the ACOS for research. Prior to this time, I was not involved with the closure of the Special Pathogens Lab. The Special Pathogens Lab Director did not contact me to request a transfer of any biological samples or specimens. The only request I received for transferring any specimens or samples was made by another member of the Special Pathogens Lab staff in October 2006. This researcher inquired about potentially transferring biological isolates derived from human subjects and related environmental samples referencing an earlier discussion with the prior

ACOS for research. After discussing this request with the Chief of Staff, I asked the researcher to present us with any required paperwork for such a transfer. In order to better understand the request, I also asked our research compliance office to determine what items specifically were being requested for transfer, their condition, and whether or not such a transfer would be permitted by existing regulation. However, I did not receive any formal paperwork or materials transfer agreements. A meeting was arranged at the end of November between the VAPHS Education and Compliance Coordinator and Special Pathogens Lab staff members so the Special Pathogens Lab staff could identify and catalog the samples and specimens in question. This meeting was scheduled for December 5, 2006.

On December 4, I sent an e-mail to the Chief of Staff to confirm that there were no administrative barriers for this meeting to take place. The Chief of Staff responded positively and included ACOS for Clinical Support on the e-mail string to confirm. The ACOS for Clinical Support indicated at 3:09 p.m. on December 4th that the freezers containing the samples were cleaned out and the freezers were returned. The Chief of Staff concluded that there were no materials left for the Special Pathogens Lab staff to review and suggested that they be directed to the ACOS for Clinical Support if they had any further questions regarding the samples.

At that point, I had asked the Research, Education and Compliance Coordinator to cancel the meeting with the Special Pathogens Lab staff and directed them to the ACOS for Clinical Support for any further inquiries.

There were no policies specific to VAPHS as of December 4, 2006, with regard to this position of tissue or data repositories in a situation where the investigator is no longer authorized to conduct research. VHA Handbook 1200.5 stipulates that if an investigator leaves a VA facility, the original research records must be retained at the institution. VHA Handbook 6300.1 further notes the records and information collected and created by VA personnel in the conduct of official business belong to the Federal Government and not to the employees who initiated their collection or creation.

On October 19, 2007, VAPHS Research Data Security and Privacy Policy was issued outlining local policies regarding the security of research information. This policy, which was written based upon guidance provided by the Office of Research Oversight and Office of Research and Development, clearly states that VHS research data belongs to the VA. The policy describing our procedures relating to the disposition of research collection states that any data to be retained, reused, or shared for future studies must be housed in a data repository and that the creation of the repository requires the development of policies and procedures that must be approved by the VAPHS IRB and the Research and Development Committee.

VAPHS is currently developing a comprehensive policy addressing the handling and disposition of research data and collections including situations where the investigator's appointment was terminated or in cases where research data or specimens were collected without proper regulatory approvals, thus constituted serious non-compliance.

Thank you again for your time, Mr. Chairman. I am prepared to answer any questions you may have.

[The prepared statement of Dr. Sonel follows:]

PREPARED STATEMENT OF ALI SONEL

Good morning Mr. Chairman and Members of the Subcommittee. I would like to thank you for providing this opportunity to discuss the events surrounding the disposal of various samples from the now-closed Special Pathogens Laboratory (SP Lab) at the VA Pittsburgh Healthcare System (VAPHS). My name is Dr. Ali Sonel and I am the Director of the Cardiac Catheterization Laboratories and the Associate Chief of Staff (ACOS) for Research and Development at VAPHS.

To provide some context, VAPHS is home to one of the largest research programs in the Nation with over $24 million in annual research expenditures and 276 active research protocols, including 165 human research participant protocols, conducted by 120 investigators. Fostering scientific research and ensuring the safety, rights and welfare of research participants through compliance with local, State, and national regulatory requirements for protection of human subjects are critical to our mission of serving America's veterans.

In September 2006, I became the ACOS for Research. Prior to this time I was not involved with the closure of the SP Lab. The SP Lab Director did not contact me to request a transfer of any biological samples or specimens. The only request I received for transferring any specimens or samples was made by another member of the SP Lab staff in October, 2006. This researcher inquired about potentially transferring biological isolates derived from human subjects and related environmental samples, referencing an earlier discussion with the prior ACOS for Research. After discussing this request with the Chief of Staff, I asked the researcher to present us with any required paperwork for such a transfer. In order to better understand the request, I also asked our Research Compliance Office to determine what items specifically were being requested for transfer, their condition and whether or not such a transfer would be. permitted by existing regulations. However, I did not receive any formal paperwork or materials transfer agreements. A meeting was arranged at the end of November between the VAPHS Research Education and Compliance Coordinator and SPL staff members so the SPL staff could identify and catalog the samples and specimens in question. This meeting was scheduled for December 5, 2006.

On December 4, I sent an e-mail to the Chief of Staff to confirm that there were no administrative barriers for this meeting to take place. The Chief of Staff responded positively and included the ACOS for Clinical Support on the e-mail string to confirm. The ACOS for Clinical Support indicated at 3:09 PM on December 4th that the freezers containing the samples were cleaned out and the freezers were returned. The Chief of Staff concluded that there were no materials left for SP Lab staff to review and suggested that they be directed to the ACOS for Clinical Support if they had any further questions. At that point, I asked the Research Education and Compliance Coordinator to cancel the meeting with the SPL staff and directed them to the ACOS for Clinical Support for any further inquiries.

There were no policies specific to VAPHS as of December 4, 2006 with regard to disposition of tissue or data repositories in a situation where the investigator is no longer authorized to conduct research. VHA Handbook 1200.5 stipulates that if an investigator leaves a VA facility, the original research records must be retained at the institution. VA Handbook 6300.1 further notes, "The records and information collected and created by VA personnel in the conduct of official business belong to the Federal Government and not to the employees) who initiated their collection or creation."

On October 19, 2007, VAPHS Research Data Security and Privacy policy was issued, outlining local policies regarding the security of research information. This policy, which was written based upon guidance provided by the Office of Research Oversight and the Office of Research and Development, clearly states that "VHA research data belongs to the VA." The policy describing our procedures related to the disposition of research collections, states that "any data to be retained, reused, or shared for future studies, must be housed in a data repository and that the creation of the repository requires the development of policies and procedures that must be approved by the VAPHS IRB and Research and Development Committee."

VAPHS is currently developing a comprehensive policy addressing the handling and disposition of research data and collections, including situations where the investigator's appointment was terminated or in cases where research data or speci-

mens were collected without proper regulatory approvals, thus constituting serious noncompliance.

Thank you again for your time, Mr. Chairman. I am prepared to answer any questions you may have.

BIOGRAPHY FOR ALI SONEL

Dr. Ali Sonel is currently the Associate Chief of Staff for Research and Development at the VA Pittsburgh Healthcare System as well as the Director of Cardiac Catheterization Laboratories at the same institution. Dr. Sonel has also has served as Chairperson of the Institutional Review Board at the VA Pittsburgh Healthcare System from 1999–2006. Dr. Sonel has also been the Director of the ACLS and BLS programs at the VA Pittsburgh Healthcare System since 1999. His research interests include management of acute coronary syndromes and disparities in health care as they relate to acute coronary syndromes. He has been the author of numerous peer-reviewed research publications in his field. Dr. Sonel is also a champion of promoting adherence to evidence-based practice guidelines in cardiac care and leads many quality improvement programs to improve delivery of care and outcomes of veterans. Dr. Sonel is also an Assistant Professor of Medicine at the University of Pittsburgh and Affiliate Faculty at the Center for Health Equity Research and Promotion.

Dr. Sonel is a graduate of the Hacettepe University, School of Medicine in Ankara, Turkey. He completed his internal medicine, cardiology and interventional cardiology training at the Indiana University School of Medicine in Indianapolis, Indiana. He has been at the VA Pittsburgh Healthcare System since 1998.

Chairman MILLER. Dr. Melhem? You need to turn your microphone on.

STATEMENT OF DR. MONA MELHEM, ASSOCIATE CHIEF OF STAFF, CLINICAL SUPPORT SERVICE LINE, VA PITTSBURGH HEALTHCARE SYSTEM (VAPHS), DEPARTMENT OF VETERANS AFFAIRS

Dr. MELHEM. Good afternoon and thank you for the opportunity to appear before you today. My name is Dr. Mona Melhem. I am the Associate Chief of Staff for Clinical Support of the VA Pittsburgh Healthcare System. I am also a Professor of Pathology at the University of Pittsburgh, School of Medicine. I have been a practicing physician and a pathologist at the Department of Veterans Affairs in Pittsburgh since 1986, and I did additional clinical special qualifications. I am a board-certified in anatomic and clinical pathology and hematopathology, and I have published more than 150, peer-reviewed articles and published abstracts of research presented in national and international conferences.

For the past 22 years, I have taken on greater clinical and administrative responsibilities within the pathology and lab medicine services of the VA, and I began my current position as Associate Chief of Staff and Vice President of Clinical Support since 2001. In this capacity, I am responsible for pathology and lab medicine including the clinical microbiology and Special Pathogens Lab.

In January 2006, acting in my oversight capacity, I requested a routine review of the clinical productivity and financial expenditure of the Special Pathogens Lab. This lab was chartered in the 1980's as the clinical resource for VA. The lab was to be financially independent and to serve the clinical needs of the VA Pittsburgh Healthcare System and other VA medical centers in what was then an emerging field of *Legionella* testing. Based on this review, it was clear the lab was not productive and was a drain on clinical resource. This led me to the decision to consolidate the Special

Pathogens Lab functions into the main clinical and microbiology labs in the main building.

Of note, the Chief of Infectious Disease by law cannot be also named administratively Chief of Microbiology Lab, and this constituted a conflict of interest and self-referral of any specimens that go to this lab.

In preparation for the lab's closing, I ordered lab personnel to move all recognizable, cataloged and well-marked intact tubes and specimens to the main laboratories to ensure the patients' confidentiality and the specimens' integrity. There were several efforts to enlist the cooperation of the then-director of the Special Pathogens Lab but to no avail.

Upon the Special Pathogens Lab Director's departure, we found a freezer filled with unidentified biological materials and microorganisms. There was simply no way of knowing the specimens' or danger to the public. Special pathogens are infectious agents that produce serious disease in humans; and so in July of 2006 in the interest of public safety and the health of our veterans, we requested the Vice President of Facility Management to coordinate the disposal of hazardous material and immediate cleaning of the Special Pathogens Lab.

These steps were consistent with established procedures and guidelines followed by both public and private laboratories across the world which dictate that unknown remaining specimens must be disposed of as soon as possible.

I was not aware of any effort by the staff of the Special Pathogens Lab to transfer any samples to qualified labs at the University of Pittsburgh. Some time around September '06, roughly one month after the closure of the lab, I had an informal conversation with the Associate Chief of Staff for Research and Development about the specimens that were preserved after the lab closure. I stated at that time that we preserved specimens we knew to be part of an approved research protocol or would otherwise be able to identify. Well-labeled, well-cataloged specimens from other investigators were moved to the main clinical lab under strict freezing condition to maintain their integrity.

On December 4, I asked that personnel about the status of the remaining sample, knowing then that it had been destroyed and taken care of some time between July and September. Based on my earlier instruction, I believed they had already been properly destroyed. I was informed there may be some biohazard material remaining in Building 2 where the Special Pathogens Lab was located.

Since this lab had been closed since July of 2006, I ordered an extensive cleaning and disposal process of all remaining unidentifiable, broken, or abandoned tubes.

Mr. Chairman, that concludes my statement. I am prepared for any questions.

[The prepared statement of Dr. Melhem follows:]

PREPARED STATEMENT OF MONA MELHEM

Mr. Chairman and Members of the Subcommittee on Science and Technology:

Good morning and thank you for the opportunity to appear before you today. My name is Dr. Mona Melhem, and I have been a practicing physician and pathologist

in the Department of Veterans Affairs (VA) Pittsburgh Healthcare System (VAPHS) since 1986. I am also a Professor in the Department of Pathology at the University of Pittsburgh, School of Medicine. I am a board certified Anatomic and Clinical Pathologist with Special Qualification in Hematopathology. I have published more than 150 articles in peer-reviewed journals and published abstracts of research presented at both national and international conferences. For the past 22 years, I have taken on greater clinical and administrative responsibility within the Pathology and Lab medicine services. I began my current position as Associate Chief of Staff and Vice President of the Clinical Support Service line in 2001. In this capacity, I am responsible for Pathology and Lab medicine, including the clinical, microbiology and Special Pathogens Labs.

In January 2006, acting in my oversight capacity, I requested a routine review of the clinical productivity and financial expenditures of the Special Pathogens Lab. This lab was chartered in the early 1980s as a clinical resource for VA. The lab was to be financially independent and to serve the clinical needs of VAPHS and other VA medical centers in what was then an emerging field. Based on this review, it was clear the lab was not productive and was a drain on clinical resources. This led me to the decision to consolidate the Special Pathogens Lab's functions into the main clinical microbiology labs in the main building.

Of Note: The Chief of Infectious Diseases, by law, cannot be also named Chief of the Microbiology Lab as this constitutes conflict of interest and self-referral.

In preparation for the Lab's closing, I ordered lab personnel to move all recognizable, catalogued, and well-marked, intact tubes and specimens to the main laboratories to ensure our patients' confidentiality and the specimens' integrity. There were several efforts to enlist the cooperation of the Director of the Special Pathogens Lab, but to no avail.

Upon the Special Pathogen Director's departure, we found a freezer filled with unidentifiable biological materials and microorganisms. There was simply no way of knowing the ?specimens' risk or danger. Dr. Yu's testimony attested that organisms were sent to the SP Lab from all over the world. Special pathogens are infectious agents that produce serious disease in humans, and so in July 2006, in the interests of public safety and the health of our veterans, we requested the Vice President of Facility Management coordinate the disposal of hazardous material and the immediate cleaning of the Special Pathogens Lab. These steps were consistent with established procedures and guidelines followed by both public and private laboratories across the world which dictate that unknown remaining specimens must be disposed of as soon as possible.

I was not aware of any efforts by the staff of the Special Pathogens Lab to transfer any samples to qualified labs at the University of Pittsburgh. Sometime around September 2006, roughly one month after the closure of the lab; I had an informal conversation with the Associate Chief of Staff for Research and Development about specimens that were preserved after the lab closure. I stated at that time that we preserved specimens we knew to be part of an approved research protocol or were otherwise able to identify.

On December 4, 2006, I asked lab personnel about the status of the remaining samples. Based on my earlier instructions, I believed they had already been properly destroyed. I was informed there maybe some biohazardous material remaining in Building 2, where the Special Pathogens Lab was located. Since this lab had been closed since July 2006, I ordered an extensive cleaning and disposal process of all remaining unidentifiable, broken or abandoned tubes.

Mr. Chairman, that concludes my statement, I am prepared to answer any questions you may have.

BIOGRAPHY FOR MONA MELHEM

Dr. Mona Melhem has served as the Associate Chief of Staff for Clinical Support Service Line, at VA Pittsburgh Healthcare System (VAPHS) since 2001. She received her MD degree from Cairo University, Cairo, Egypt, and completed a residency training program at the University of Pittsburgh Medical Center in 1986. She joined the VAPHS as a Career Development Awardee, Research and Development and staff pathologist in 1986. She was appointed Chief of the Hematology in 1990.

She is board certified in Anatomic and Clinical Pathology and Hematopathology and is a member of several professional and scientific societies, including the American Association for the Advancement of Sciences (AAAS), the American Association for Cancer Research (AACR), the International Academy of Pathologists (IAP) and the American College of Healthcare Executives (ACHE). She received several honors and awards, including a clinical fellowship of the American Cancer Society, the Young Investigator award by the American College of Nutrition. She is well pub-

lished in the medical literature with over 150 publications in refereed journals, invited articles and national and international scientific conferences. She is a professor of Pathology, University of Pittsburgh School of Medicine and is active in departmental and medical school committees, as well as the local community.

Chairman MILLER. Dr. Graham.

STATEMENT OF DR. STEVEN H. GRAHAM, DIRECTOR, GERIATRIC RESEARCH, EDUCATIONAL AND CLINICAL CENTER, VA PITTSBURGH HEALTHCARE SYSTEM, DEPARTMENT OF VETERANS AFFAIRS

Dr. GRAHAM. Thank you. My name is Steven Graham, and I am the Director of the Geriatric Research, Educational, and Clinical Center at VA Pittsburgh Healthcare System, and I am Professor of Neurology at the University of Pittsburgh. My own research program concerns the mechanisms of neuronal cell death and is funded by the National Institute of Health and Department of Veterans Affairs.

I served as Associate Chief of Staff for Research at VA Pittsburgh Healthcare System from July 2002 until September 2006. I am prepared to discuss my involvement and knowledge of the Special Pathogens Lab's closing and related issues.

In March 2006 I participated in a meeting with the senior VA Pittsburgh leadership regarding the Special Pathogens Lab. At that meeting, serious questions were raised about the lab's lack of peer-reviewed research grants and whether approved research was being conducted in the laboratory. There were also questions about the extent to which the lab's activity supported veterans' health care.

In April 2006, I met with the Special Pathogens Lab's Director and VA Pittsburgh senior leadership to discuss these concerns. At the meeting the lab director was asked to provide a list of institutions and companies for whom the lab was performing studies, the number of VA studies, and a list of all research studies approved by the Institutional Review Board.

We asked the Lab Director to comply with the requirements for IRB and R&D Committee review of his research program. The VAPHS Director directed that an audit be conducted of the Lab's accounts in the Veterans Research Foundation of Pittsburgh.

I understand that the hospital director later decided to close the Special Pathogens Laboratory, although I did not participate in any meetings where this was discussed.

The results of this foundation financial audit and review of additional documents by the research service suggested the strong likelihood that the lab had conducted research without prior approval from an IRB or the Research and Development Committee. The VAPHS Director and the Office of Research Oversight, ORO, were informed of these concerns.

The VAPHS Director convened a Board of Investigation on which I served. I referred this matter to VAPHS Research Compliance Committee for further investigation and action.

In July 2006 I met with the Director of the hospital, Chief of Staff, and the Research Administrator Officer regarding the lab's closure. The concern was raised that there might be biohazardous material in the lab that could constitute a safety hazard. The Di-

rector asked the Research Administrative Officer and me to address this problem. To the best of my knowledge, the Research Administrative Officer and the Biosafety Officer subsequently entered the laboratories and disposed of all cultures still growing in incubators as well as biological agents and chemicals stored in 4-degree refrigerators. Specimens kept in the minus-70 freezers were not disposed of at that time.

In August of 2006, I was contacted by a former Special Pathogens Lab staff scientist and the Director of the Special Pathogens Lab regarding the possible transfer of equipment and reference specimens from the lab. I informed the Special Pathogens Lab Director that equipment bought by the Veterans Foundation of Pittsburgh remains the property of the foundation, and regulations allow that equipment to be transferred only to another VA or VA Foundation.

I was informed that it would be difficult or impossible to transfer any human specimens, but it might be possible to transfer bacterial specimens to another institution. This would require a materials transfer agreement that must be endorsed by the accepting institution and approved by the VAPHS Administration. At that time, the new laboratory was not operational, so I considered it premature to consider this issue further. I did communicate this desire to transfer the specimens to the Research Administrative Officer. I have no direct knowledge of the destruction of specimens on December 4, 2006.

At the request of the Subcommittee, I have also been asked to comment on the efforts of a schizophrenia researcher who left VA Pittsburgh in 1995 to transfer specimens to another institution. In 1998 and 2000, requests were submitted to my predecessor as ACOS for Research to transfer cerebrospinal fluid and blood specimens that were obtained under an approved IRB protocol to another institution. The ACOS for Research eventually denied that request upon the advice of the VA regional counsel and the VA's Office of Research and Development. The transfer request was not compatible with VHA directive 2000-043 regarding Banking of Human Research Specimens. Another investigator at VAPHS agreed to take custody of these samples, and they remain at the hospital to this day.

This concludes my statement. I am prepared to answer any questions the Subcommittee may have.

[The prepared statement of Dr. Graham follows:]

PREPARED STATEMENT OF STEVEN H. GRAHAM

Good morning, Mr. Chairman and Members of the Subcommittee and thank you for this opportunity to discuss issues regarding the closure of the Special Pathogens Laboratory (SP Lab) at the VA Pittsburgh Healthcare System (VAPHS).

My name is Dr. Steven Graham and I am Director of the Geriatric Research Educational Clinical Center at VAPHS and Professor of Neurology at the University of Pittsburgh. I served as Associate Chief of Staff (ACOS) for Research at VAPHS from July 2002 until September 2006. I am prepared to discuss my involvement and knowledge of the SP Lab's closing and related issues.

In March 2006, I participated in a meeting with the senior VAPHS leadership regarding the Lab. At that meeting, serious questions were raised about the Lab's lack of peer-reviewed research grants and whether approved research was being conducted in the laboratory. There were also questions about the extent to which the Lab's activities supported veterans' health care. In April 2006, I met with the SP Lab's Director and VAPHS senior leadership to discuss these concerns. At the meet-

ing, the Lab Director was asked to provide a list of institutions and companies for whom the lab was performing studies, the number of VA studies, and a list of all research studies approved by the Institutional Review Board (IRB). We asked the Lab Director to comply with the requirements for IRB and R&D committee review of his research program. The VAPHS Director directed that an audit be conducted of the Lab's accounts in the Veterans Research Foundation of Pittsburgh. I understand the VAPHS Director later decided to close the Special Pathogens Laboratory, although I did not participate in any meetings where this was discussed.

The results of this foundation financial audit and review of additional documents by the Research Service suggested the strong likelihood that the Lab had conducted research without proper approval from an IRB or the Research and Development Committee. The VAPHS Director, the VA Office of Research Oversight were informed of these concerns. The VAPHS Director convened a Board of Investigation on which I served. I referred the matter to the VAPHS Research Compliance Committee for further investigation and action.

In July 2006, I met with the Director of VAPHS, the Chief of Staff, and the Research Administrative Officer regarding the Lab's closure. The concern was raised that there may be biohazardous material in the lab that could constitute a safety hazard. The Director asked the Research Administrative Officer and me to address this problem. To the best of my knowledge, the Research Administrative Officer and the Biosafety Officer subsequently entered the laboratories and disposed of all cultures still growing in incubators, as well as biological agents and chemicals stored in 4° refrigerators. Specimens kept in the -70° freezers were not disposed of at that time.

In August 2006, I was contacted by the former SP lab staff scientist and the Director of the SP Lab regarding the possible transfer of equipment and reference specimens from the Lab. I informed the SP Lab Director that equipment bought by the Veteran's Research Foundation of Pittsburgh remains the property of the Foundation and regulations allow equipment to be transferred only to another VA medical center or VA Foundation. I informed them that it would be difficult or impossible for any human specimens to be transferred, but it might be possible to transfer bacterial specimens to another institution. This would require a Materials Transfer Agreement that must be endorsed by the accepting institution and approved by the VAPHS administration. At that time, the new laboratory was not operational, so I considered it premature to consider the issue further. I did communicate this desire to transfer these specimens to the Research Administrative officer. I have no direct knowledge of the destruction of specimens on December 4, 2006.

At the request of the Subcommittee, I have also been asked to comment on the efforts of a schizophrenia researcher who left VAPHS in 1995 to transfer specimens. In 1998 and 2000, requests were submitted to my predecessor as ACOS for Research to transfer human cerebrospinal fluid and blood specimens that were obtained under an approved IRB protocol to another institution. The ACOS for Research denied the request upon the advice of VA Regional Council and VA's Office of Research and Development (R&D). The transfer request was not compatible with VHA Directive 2000–043 regarding Banking of Human Research Subjects Specimens. Another investigator at VAPHS agreed to take custody of these samples and they remain at VAPHS to this date.

This concludes my statement. I am prepared to answer any questions the Subcommittee may have.

BIOGRAPHY FOR STEVEN H. GRAHAM

Steven H. Graham, MD, Ph.D., received his doctorate degrees from the University of Texas in Houston. He then completed a neurology residency training and postdoctoral fellowship at the University of California San Francisco. He currently is the Director of the Geriatric Research Education Clinical Center at VA Pittsburgh Healthcare System and Professor and Vice Chair of Neurology at the University of Pittsburgh School of Medicine. Dr. Graham's research concerns the molecular mechanisms of neuronal cell death in stroke, traumatic brain injury, and neurodegenerative diseases. His work has been continuously funded by the Department of Veterans Affairs since 1988 and the National Institute of Health, National Institute of Neurologic Diseases and Stroke since 1998. Dr. Graham has received a number of awards and honors including being elected as a Fellow of both the American Heart Association and the American Academy of Neurology, is a member of Alpha Omega Alpha Medical Honorary Society and has been named as the Connolly Family Chair at the University of Pittsburgh. Dr. Graham has served on a number of a national scientific review and advisory groups at the National Insti-

tute of Health, Department of Veterans Affairs Medical Research Service and American Heart Association.

Chairman MILLER. Ms. Wanzie.

STATEMENT OF MS. CHERYL WANZIE, CHIEF TECHNOLOGIST, VA PITTSBURGH HEALTHCARE SYSTEM, DEPARTMENT OF VETERANS AFFAIRS

Ms. WANZIE. Good afternoon, and thank you for the opportunity to appear before you today. My name is Cheryl Wanzie. I am an American Society of Clinical Pathologists, Registered Medical Technologist since 1971. I have been employed with the Department of Veterans Affairs since 1973.

My current position is Chief Medical Technologist, Pathology and Laboratory Medicine at VA Pittsburgh Healthcare System. I was responsible for overseeing the quality of the process for clinical testing of samples from VA patients performed by the Special Pathogens Laboratory and ensuring that the laboratory met the standards for laboratory accreditation. I was and am currently responsible for allocating the clinical laboratories supply budget and monitoring associated workload data.

In January of 2006, I provided workload and cost data for the Special Pathogens Lab to Dr. Mona Melhem, Associate Chief of Lab, Clinical Support Service Line. After reviewing the data and obtaining other information, Dr. Melhem determined that the Special Pathogens Lab's clinical and environmental testing workload could be performed more efficiently in the clinical microbiology laboratory. Dr. Melhem asked me to facilitate and oversee the transition of the clinical and environmental *Legionella* testing to the main laboratory. In June 2006, Dr. Melhem informed me that the Special Pathogens Laboratory would close in July and that the clinical microbiology laboratory would assume both clinical and environmental *Legionella* testing.

On the morning of July 19, 2006, Dr. Melhem, a VAPHS research scientist, and I met with a staff member of the Special Pathogens Lab——

Chairman MILLER. Ms. Wanzie, can you pull the microphone closer? Apparently, the recorder is having a hard time hearing.

Ms. WANZIE. On the morning of July 19, 2006, Dr. Melhem, a VAPHS research scientist, and I met with a staff member of the Special Pathogens Lab to discuss the transfer of clinical and environmental specimens and clinical laboratory equipment from the Special Pathogens Lab to the main laboratory. Dr. Melhem instructed the Special Pathogens Lab staff to consolidate all clinical and environmental specimens in a clinical refrigerator and specimens belonging to other research scientists in a clinical ultra-low freezer which would be moved to the main laboratory that afternoon.

Special Pathogens Lab was also instructed to prepare an inventory of the clinical environmental specimens which they never provided. In the afternoon, Dr. Melhem and I supervised the transfer of the equipment and appropriately labeled clinical specimens from the Special Pathogens Lab to the main laboratory. At that time, VAPHS research scientist specimens were secured in an ultra-low

freezer in the main laboratory. The remaining specimens were left in the special pathogens lab which closed on July 21, 2006.

In the afternoon of December 4, 2006, Dr. Melhem inquired if there were specimens remaining in the Special Pathogens Lab. I responded that to my knowledge they were still in the Special Pathogens Lab. Dr. Melhem informed me that the Medical Center Director considered this to be a concern due to the presence of biohazardous material and directed that the refrigerators and freezers be cleaned out by the end of the day. I assembled some of the microbiology staff and we proceeded to remove all improperly labeled or uncataloged specimens from the Special Pathogens Lab using standard biohazardous waste protocols. I cautioned the staff to take extra precautions because some of the specimens were uncapped and in broken glass tubes. The specimens were placed in double-biohazard bags, removed from the building, placed in biohazard waste containers to be removed from the facility by a contractor.

In my position as Chief Technologist, I had no knowledge of any policies in effect on December 4, 2006, concerning the disposition of research collections. I am now aware of a VAPHS Research Data Security and Privacy Policy which ensures protection of private information and the disposition of research material.

Thank you. That concludes my statement. I am prepared to answer any questions you may have.

[The prepared statement of Ms. Wanzie follows:]

PREPARED STATEMENT OF CHERYL WANZIE

Good morning and thank you for the opportunity to appear before you today. My name is Cheryl Wanzie. I am an American Society of Clinical Pathologist's registered Medical Technologist since 1971. I have been employed with the Department of Veterans Affairs since 1973. In my current position as Chief Medical Technologist, Pathology and Laboratory Medicine at the VA Pittsburgh Healthcare System, I was responsible for overseeing the quality of the process for clinical testing of samples from VA patients, performed by the Special Pathogens Laboratory (SPL) and ensuring that the laboratory met the standards for laboratory accreditation. I was and am currently responsible for allocating the clinical laboratory supply budget and monitoring associated workload data.

In January 2006, I provided workload and cost data for the SPL to Dr. Mona Melhem, Associate Chief of Staff, Clinical Support Service Line. After reviewing the data and obtaining other information, Dr. Melhem determined that the SPL clinical and environmental testing workload could be performed more efficiently in the clinical microbiology laboratory. Dr. Melhem asked me to facilitate and oversee the transition of the clinical and environmental *Legionella* testing to the main laboratory. In June 2006, Dr. Melhem informed me that the SPL would close in July and that the clinical microbiology laboratory would assume both clinical and environmental *Legionella* testing.

On the morning of July 19, 2006, Dr. Melhem, a VAPHS research scientist and I met with a staff member of the SPL to discuss the transfer of clinical and environmental specimens and clinical laboratory equipment from the SPL to the main laboratory. Dr. Melhem instructed SPL staff to consolidate all clinical and environmental specimens in a clinical refrigerator and specimens belonging to other research scientists in a clinical ultralow freezer which would be moved to the main laboratory that afternoon. SPL staff was also instructed to prepare.an inventory of the clinical and environmental specimens, which they never provided. In the afternoon, Dr. Melhem and I supervised the transfer of the equipment and appropriately labeled clinical specimens from the SPL to the main laboratory. At that time, VAPHS research scientists specimens were secured in the ultralow freezer in the main laboratory. The remaining specimens were left in the SPL which closed on July 21, 2006.

In late afternoon of December 4, 2006, Dr. Melhem inquired if there were specimens remaining in the SPL. I responded that to my knowledge they were still in

the SPL. Dr. Melhem informed me that the Medical Center Director considered this to be a concern due to the presence of biohazardous material and directed that the refrigerators and freezers be cleaned out by the end of the day. I assembled some of the Microbiology staff and we proceeded to remove all improperly labeled or uncatalogued specimens from the SPL using standard biohazardous waste protocols. I cautioned the staff to take extra precautions because some of the specimens were uncapped and in broken glass tubes. The specimens were placed in double biohazard bags, removed from the building, placed in biohazard waste containers to be removed from the facility by a contractor.

In my position as Chief Technologist, I had no knowledge of any polices in effect on December 4, 2006 concerning the disposition of research collections. I am now aware of a VAPHS Research Data Security and Privacy Policy which ensures the protection of private information and the disposition of research material.

Thank you, that concludes my statement, I am prepared to answer any questions you may have.

BIOGRAPHY FOR CHERYL WANZIE

Cheryl Wanzie has worked for the VA Pittsburgh Healthcare System since January 21, 1973. After graduating from the University of Pittsburgh with a Bachelor's of Science in 1970, Ms. Wanzie continued her education in the field of Medical Technology at Presbyterian–University of Pennsylvania Medical Center in Philadelphia, PA. After graduating in June 1971, she received certification as a Medical Technologist by the American Society of Clinical Pathologists. After working for a year in Philadelphia, Ms. Wanzie relocated to Portland, Oregon in 1972 and accepted a Medical Technologist position at the VA Medical Center. She resigned her position for family reasons and returned to Pittsburgh in 1973. She was offered a position as a Medical Technologist in the Transfusion Service at the VA Pittsburgh and worked in the Blood Bank Laboratory until 1981. Ms. Wanzie transferred to the Immunopathology Laboratory in 1981 and was promoted to Supervisor in 1988. In this capacity, she supervised three Medical Technologists and one Medical Technician and was responsible for administrative and clinical duties in the laboratory. During this time, she was appointed as a Field Instructor for the Medical Technology Program at the University of Pittsburgh's School of Health Related Professions. Ms. Wanzie furthered her education at the School of Health Related Professions and received a Master's of Science in 1982. Ms. Wanzie was promoted to Chief Medical Technologist in 1990 and continues to hold that position. In this capacity, she is responsible for the administrative and clinical functions of Pathology and Laboratory Medicine Program. The Program provides both clinical and anatomic pathology laboratory services for three sites at the VA Pittsburgh Healthcare System, five Community Based Outpatient Clinics and nine other VA facilities in VISN 4. The Program provides laboratory services 24 hours a day, 365 days a year with a staff of 86 FTE. In 1990, Ms. Wanzie received a bronze award for Outstanding Technical Supervisor from the Pittsburgh Federal Executive Board's Excellent in Government Awards. In 1999, she was nominated and received the gold award for Outstanding Supervisor/Manager in a Technical Series.

DISCUSSION

Chairman MILLER. Thank you. I understand that all of you have been interviewed by the Subcommittee staff. That is correct. You can just nod your head. All of you remember? I would assume it would be an event you would remember, and do any of you now recall differently any event that you talked to our staff about? Do any of you wish to correct anything that you told our staff? Mr. Moreland?

Mr. MORELAND. The only thing I would say is I don't remember every single word that I said to the Committee staff. So it would be very difficult to assert that today.

Chairman MILLER. Well, I understand. I am not talking about every single word, but do you remember the gist of anything that you said differently now from what you recall saying something to the staff that you now believe, you now recall differently?

Mr. MORELAND. Not a significant content. I don't, and again, I am not trying to be argumentative——

Chairman MILLER. Okay.

Mr. MORELAND. I am just saying it was, you know, a few weeks ago and we had——

Chairman MILLER. I understand that nobody is going to remember every word that you said.

Mr. MORELAND.—extensive, long conversations.

Chairman MILLER. But you know the gist of what you told our staff. Do any of you now recall differently anything that you told our staff. Dr. Sonel?

Dr. SONEL. I do not recall anything different.

Chairman MILLER. Dr. Melhem.

Dr. MELHEM. I do not.

Chairman MILLER. Dr. Graham.

Dr. GRAHAM. No.

Chairman MILLER. Ms. Wanzie.

Ms. WANZIE. I do not.

Chairman MILLER. Okay. All of you did not submit written testimony in advance but all of you read verbatim from written testimony. Obviously, it would have been helpful to this committee to prepare for the hearing to have had that testimony in advance, and all of you obviously made a conscious decision not to provide written testimony.

Dr. Sonel, did anyone talk with you about whether you would provide written testimony in advance?

Dr. SONEL. I was told that we could prepare oral statements and that they would be our own statements.

Chairman MILLER. Well, but you also read verbatim from a written statement, isn't that correct?

Dr. SONEL. Correct.

Chairman MILLER. I just saw you do it. Why did you decide not to provide that statement in advance to the Committee which obviously would have been our preference?

Dr. SONEL. We were working with the central office and there was——

Chairman MILLER. I am not sure if your microphone is on or it is close enough to you.

Dr. SONEL. We were working with VA central office, and they were assisting us in the submission process. So I relied on them to——

Chairman MILLER. Okay. Who read your written testimony?

Dr. SONEL. Ms. Lanzendorfer I believe from the VA——

Chairman MILLER. Okay. Anyone else?

Dr. SONEL.—Legislative Affairs. I am not sure if it was circulated to other people, but it was made clear that it was to be our own statement.

Chairman MILLER. Did she make any suggested changes in your testimony?

Dr. SONEL. No material changes.

Chairman MILLER. Did you talk to any other witnesses today about your testimony?

Dr. SONEL. I shared my planned statement with them, yes.

Chairman MILLER. Did you see their statements?

Dr. SONEL. I did.

Chairman MILLER. All right. Dr. Melhem.

Dr. MELHEM. Yes, sir.

Chairman MILLER. Did you see anyone else's statements?

Dr. MELHEM. I did see Mr. Moreland's.

Chairman MILLER. Well, how about Dr. Sonel, Dr. Graham, Ms. Wanzie?

Dr. MELHEM. I did not read any of them.

Chairman MILLER. Okay. Did you provide your written statement to anyone else?

Dr. MELHEM. I did send it to Ms. Lanzendorfer in the central office.

Chairman MILLER. All right. Mr. Moreland, who saw your statement in advance?

Mr. MORELAND. I submitted it to Congressional Affairs like we usually do in Central Office, and they saw it and then I know that I have read the testimony in front of the people here on the panel so that we were aware of each other's statements.

Chairman MILLER. Okay. Yes? You were about to say something else.

Mr. MORELAND. But there wasn't direction from either of us about what to say, it was simply sharing the statements so we could make sure what the other one was saying.

Chairman MILLER. Dr. Graham.

Dr. GRAHAM. Yes, I submitted a draft of my oral statement as requested to the VA legal affairs. They counseled us not to say anything about impending personnel actions because that might violate the Privacy Act, and I actually recall that they asked Mr. Moreland to redact some of his oral statements because they might not be appropriate for a public statement.

Chairman MILLER. All right. Ms. Wanzie.

Ms. WANZIE. I was asked to provide the oral statement in written form to VA Central Office. I received some responses back, some questions about my statement. I did not make any substantive changes to my statement. I did read statements from the rest of the panel.

THE CATALOG FOR THE SPL'S COLLECTION

Chairman MILLER. Ms. Wanzie, one of the people, perhaps it was you, who dumped the vials into the biohazard bags and took them to be incinerated, said that the vials were labeled with or had both numbers and letters on them. Is that correct? Was that you that said that?

Ms. WANZIE. I said that.

Chairman MILLER. What?

Ms. WANZIE. Yes, I said that.

Chairman MILLER. Okay. All right. Mr. Moreland, you heard the testimony of the first panel. I assume that Dr. Snydman and both Dr. Stout and Dr. Yu said that those letters and numbers actually matched up to a catalog, and Ms. Stout attached a catalog or appended a catalog to her testimony. What is the basis for your statement that they were not cataloged?

Mr. MORELAND. My basis was that I had never seen the catalog and that despite numerous requests, it was not provided. The VA catalog is actually VA property so if——

Chairman MILLER. Did you ask Dr. Stout for a catalog?

Mr. MORELAND. I did not personally.

Dr. MELHEM. I did on several occasions, including in one of the e-mails.

Chairman MILLER. Okay.

Mr. MORELAND. By having asked for the catalog, it was not provided. So without the presence of a catalog, one cannot ascertain what the numbering system means. And so by the lack of provision, it becomes a catalog system that is not cataloged because it wasn't provided. And I wanted to make clear, as I was starting to say, the catalog actually is the property of the organization. So that catalog, if it has been removed from the VA and is in the presence of a non-VA employee and is not provided to the organization, that is a significant concern to me, sir, because it may have private information that was not available to the public and should not be. And so despite requests, it was not provided.

Chairman MILLER. Dr. Moreland, did you look on her computer?

Mr. MORELAND. I did not look on her computer. It was requested to be provided, and so it could have been e-mailed, it could have been provided in written copy. And I will mention, sir, that there were two other significant research projects going on in that building. When we asked them to provide a catalog of their samples, it was provided the same day. We easily had the catalog, we had the samples labeled. We were able to take those labeled catalog samples and move them properly to the clinical laboratory. That was not possible to do with the Special Pathogens Lab because they did not provide the requested catalog.

THE TECHNICAL REVIEW'S BIOHAZARD DETERMINATION

Chairman MILLER. All right. Mr. Moreland, you said in your written testimony and your oral statement that there was a technical review that found that the research specimens presented a potential biohazard to both employees and our veterans. Was that technical review in writing?

Mr. MORELAND. I will have to defer that question to Dr. Melham.

Dr. MELHEM. Sir, my technical review was mostly concerned with the clinical specimens, and the clinical specimens in a clinical lab can only remain up to two weeks after testing of the clinical specimen and——

Chairman MILLER. Right, but we are not talking about——

Dr. MELHEM.—and should have been destroyed at that time.

Chairman MILLER. We are talking about the research specimens. Was there a technical review that the research—I mean, that certainly is the implication of this testimony.

Mr. MORELAND. Well, again, what I would say is as Dr. Melhem mentioned, if you have samples in a freezer and samples that are not identified, I don't know what they are. I don't know what they could be.

Chairman MILLER. But you used the term technical review, and that was all oral? It was around the water cooler? It wasn't in writ-

ing? There was no scrap of paper generated as a result of this technical review?

Mr. MORELAND. That is correct. The technical review——

Chairman MILLER. My time is——

Mr. MORELAND. The technical review regarding whether it was biohazard is done basically done with the clinical staff, and they went over and looked. So there was not a technical review in writing.

Chairman MILLER. All right. My time is expired for this round. Mr. Rohrabacher?

Mr. ROHRABACHER. Thank you, Mr. Chairman, and Dr. Melhem, you have responsibility, it says, of Clinical Support Services. Do you have any responsibility for overseeing research?

Dr. MELHEM. No, I don't.

Mr. ROHRABACHER. So you would not have known any of this information anyway, would you?

Dr. MELHEM. Sir, the information I got is the specimen that would——

Mr. ROHRABACHER. You would not have known about the research information?

Dr. MELHEM. The information I had is that the specimens that were kept in the freezer had patients' identifications including first initial and four letters—the Social Security.

Mr. ROHRABACHER. But you had no idea what type of research that this dealt with?

Dr. MELHEM. Sir, I am a researcher.

Mr. ROHRABACHER. I know.

Dr. MELHEM. And I have been a researcher for many years.

Mr. ROHRABACHER. That is not your responsibility. That is not your responsibility, is it?

Dr. MELHEM. That is not my responsibility——

Mr. ROHRABACHER. All right, so——

Dr. MELHEM.—but I know a collection when I see a collection.

Mr. ROHRABACHER. You know a collection? And you spent a lot of time in their lab trying to familiarize——

Dr. MELHEM. I spent time looking through the freezers and asked several times of the Director who is answering to me——

Mr. ROHRABACHER. How much time did you spend did you spend looking through their freezer?

Dr. MELHEM. Well, I looked at the freezers, I determined what belonged to the catalogs that we had and what did not belong.

Mr. ROHRABACHER. How much time did you spend was the question?

Dr. MELHEM. I was——

Mr. ROHRABACHER. An hour?

Dr. MELHEM.—in the freezer——

Mr. ROHRABACHER. One hour?

Dr. MELHEM.—a couple of times.

Mr. ROHRABACHER. Two hours? Or are we talking about 30 minutes or 15 minutes?

Dr. MELHEM. Probably a couple of times, a half-hour or an hour each.

Mr. ROHRABACHER. A couple of times or a half-an-hour. Thank you. You know, when I was a young reporter, I worked for a news

organization that hired me to go to press conferences and rewrite statements by politicians, rewriting their press releases and supposedly covering the news. And I took it upon myself to actually go out and investigate some stories on my own. You know, I never had any appreciation from my bosses for the public service that I was actually providing by investigating corruption in our city because that wasn't their job. Their job was to rewrite press releases and fill copy. Excuse me if I don't notice the same sort of lack of appreciation. Have any of you, and you are all doctors and researchers and such, have any of you had the accomplishment of finding the source of a bacteria that was causing thousands of people or risking thousands of people to lose their lives? Have any of you reached that plateau yet in your career or is it that you are just looking through the refrigerators of people who are involved with that type of activity? I said earlier that, you know, in Washington we have to deal with a lot of bureaucratic problems. I certainly identify today after your testimony that we have got a bureaucratic attitude problem. Someone didn't ask permission, and this is my area. Listen, I have got to tell you, I can totally identify with what is going on. I can sense the personality problems that arose when someone didn't ask permission. You know, I will have to tell you, Dr. Moreland, you are complaining that they have a commercial client group. They are servicing the health needs of certain people in the community. They have something to complain about? They were offering a service to identify a deadly bacteria to the community. Is that what you are complaining about?

Mr. MORELAND. Well, sir, what I would respond to that is the VA has a very specific mission to take care of veterans.

Mr. ROHRABACHER. That is right.

Mr. MORELAND. And there are multiple commercial laboratories——

Mr. ROHRABACHER. Like I said——

Mr. MORELAND.—that do the exact kind of testing——

Mr. ROHRABACHER. Again, you are talking about the bureaucratic lines, and you are upset that the bureaucratic lines were stepped upon by these people. By the way, they may well have not been—you know, they have been out of the borders. I understand that. And I understand your job is to make sure that this thing runs smoothly. Take a look at the bigger picture here. What you are thinking of is a rogue element of scientists looking in through their microscopes without permission. The rest of us may look at it and say, hey, my uncle was saved because of what this lady did. I will have to tell you I think this type of bureaucratic attitude comes with the job. I am not blaming you as individuals. You have been given a responsibility to try to make a huge organization and a huge budget, make it work. I understand that, and I respect that. I think that when people have that type of responsibility, quite often they can't see the forest for the trees of what the purpose of all of this is. It is to save people's lives, trying to make the world a little better and these aren't rogues. These are people trying to do a good job, and certainly you can reply to that and I will shut up after that. Go right ahead, Dr. Moreland.

Mr. MORELAND. No, sir, I was simply going to say it wasn't that it upset me or it angered me, it was that it was not appropriate

use of government funds and government work. And there are multiple private-sector groups that do the exact same testing, and I don't think that it is my place to compete with these private-sector companies to do referral lab services. And so we are constituting our work to make sure that the clinical work of the VA and our patients are taken care of. And I wish Dr. Yu well in his private endeavor.

FEE FOR SERVICE TESTING POLICIES

Chairman MILLER. Thank you. The staff report found that the Research Foundation gave express approval in 1995 to do fee-for-service testing for *Legionella.* Is that an incorrect finding?

Mr. MORELAND. It is an incorrect interpretation. And so if——

Chairman MILLER. What do you mean? What is the distinction that you are making?

Mr. MORELAND. Are you referencing the July 5th memo that you have provided?

Chairman MILLER. Yes.

Mr. MORELAND. Yes. That is a discussion that went along about doing fee-for-service work for other VA hospitals, and in the memo, if you look, there is a term that is used that makes that pretty clear, when it talks about the—in the third paragraph, the last sentence, it says services provided to other VA medical centers can be paid on an expenditure transfer. This was about providing services to other VA hospitals and other systems in the VA. And they were doing that. And in fact, the VA Pittsburgh continues to provide those kind of services to other VA hospitals who are sending their *Legionella* samples to the VA Pittsburgh. And Dr. Melhem in the clinical lab is indeed processing those. This was really about that. And I will also mention it was 1995, and this is 2008 today and things do change on occasion.

Chairman MILLER. Did you get word that the approval had been revoked?

Mr. MORELAND. The approval was internal to the VA Pittsburgh.

Chairman MILLER. I am sorry, what?

Mr. MORELAND. The approval was internal to the VA Pittsburgh, and so when there is—that approval can be changed internal to the VA Pittsburgh.

Chairman MILLER. Was it?

Mr. MORELAND. Well, since I was the hospital director, I would have made that decision. So what I was looking at——

Chairman MILLER. Did you?

Mr. MORELAND. Yes, I did, sir.

Chairman MILLER. Did you do that in writing?

Mr. MORELAND. I informed Dr. Yu and others that I was concerned that we were taking samples from 600 companies across the United States, some of them outside of the United States, we were processing them and charging a fee. Those fees were not covering the cost of what was going on, and it seemed to me to be an inappropriate use of VA funds and VA services. And so it was better that we not do that business.

Chairman MILLER. Mr. Moreland, did you instruct anyone to destroy the collection? You told our staff earlier you did not recall doing that.

Mr. MORELAND. My memory as I think I said to the staff is that in July I had been very clear. I wanted any samples or identified collections that included labeling and mapping, that those samples should be moved in whole over to the clinical lab and stored property, and anything left would be disposed of as excess. And I thought that is what happened in July. And so when Dr. Melhem went to the other two researchers and asked for their catalog and got them, those samples were moved. Frankly, I didn't know what had happened to the samples that were constituted there because I assumed they either were moved as a collection because of mapping or they were disposed of as would have been the case with left over samples.

MORE ON TRANSFERRING THE SPL COLLECTION

Chairman MILLER. Were you aware that continuing discussions about transferring them, transferring the sample?

Mr. MORELAND. I don't recall being aware of that until December when I——

Chairman MILLER. Okay. Dr. Sonel, were you part of those discussions?

Dr. SONEL. Yes, as I indicated in October, by e-mail Dr. Stout contacted me, and I made some preliminary arrangements to explore that request further. And that is why I got the Research Compliance Office involved.

Chairman MILLER. Okay. And when did you find out that the collections had been destroyed?

Dr. SONEL. That was on December 4th in the afternoon when I e-mailed my supervisor, our Chief of Staff, regarding the planned meeting between the Special Pathogens Lab staff and the——

Chairman MILLER. What time of day was that?

Dr. SONEL. I believe that was around 3:09 p.m. is when I e-mailed our Chief of Staff.

Chairman MILLER. That you found out they had been destroyed?

Dr. SONEL. Shortly after that, within a few minutes when he responded and——

Chairman MILLER. And at that point, did you have an agreement to transfer the collection?

Dr. SONEL. No, we actually—Dr. Stout and I had communicated on e-mail that we would require materials transfer agreements, and I suggested to her that the recipient lab should initiate the paperwork. But I was never presented any paperwork for me to review to consider the transfer further, and part of the intent of the meeting was for the Special Pathogens Lab to provide paperwork, identify what they were talking about, and identify what they had desired to transfer and what condition they were in.

Chairman MILLER. Do you have any idea what Dr. Melhem knew about the discussions for the transfer of the collection?

Dr. SONEL. I actually want to clarify one thing that Dr. Stout indicated during her testimony that is factually inaccurate. She indicated that Dr. Melhem and I had had a discussion about her intent to dispose of any materials or samples, and we never had such a discussion. So the first that I heard about the disposal was December 4th or the intent to dispose was December 4th.

Chairman MILLER. I am sorry. I don't think that your answer actually provided an answer to the question I asked. Did you talk to Dr. Melhem about your negotiations to transfer the collection?

Dr. SONEL. Not during the negotiations themselves. I——

Chairman MILLER. Well, when did you? Did you at another time?

Dr. SONEL. When I first took over and we were going over research space, I do remember Dr. Melhem showing a freezer that was a remnant or residual of the Special Pathogens Laboratory in one of the research areas. And at that point, I thought we briefly discussed that potentially getting those out of there by properly identifying those samples and specimens. That was a verbal discussion, and I do not recall all the details of it. But during the e-mail communication between Dr. Stout and myself, we did not have any discussions with Dr. Melhem. At that time, my discussions were directed toward my supervisor.

Chairman MILLER. Just one second, please. Dr. Sonel, do you remember sending an e-mail to Rajiv Jain——

Dr. SONEL. Dr. Jain is our Chief of Staff.

Chairman MILLER.—on the day after the destruction of the vials, I think Tuesday, December 5th. Next day. Next day. Do you remember sending an e-mail?

Dr. SONEL. I do remember communicating with Dr. Jain multiple times by e-mail during that time. I don't remember the specific e-mail that——

Chairman MILLER. Well, let me read this one to you. It is number five in your book.

Dr. SONEL. Yes, I do have it here.

Chairman MILLER. Okay. "Dr. Jain, I appreciate your support and clarification. I am a bit disappointed that I was not give an opportunity to process this through the RCC." What is the RCC?

Dr. SONEL. That is our Research Compliance Committee.

Chairman MILLER. Okay. "Which I feel would have been the due process even if the end result may have been to destroy the samples. The samples and their proposed fate to de-identify and release was discussed in person with Dr. Melhem in end of September. Dr. Graham denies agreeing to destruction of samples as well. I sincerely hope we can avoid such a confusion, and I would truly appreciate being kept in the loop if data or specimen destruction is considered when it may be linked to approved or non-approved research." Is that the e-mail that you sent?

Dr. SONEL. Yes.

Chairman MILLER. Okay. So you did not think then that the procedures to decide to destroy the collection were appropriate?

Dr. SONEL. Actually, I don't think that e-mail necessarily says that. My intent in that e-mail is to indicate what the process would have been had we discovered unauthorized research. Now, in this case, I believe there was concern that there was no clear knowledge of what these remaining specimens and samples were and whether they were indeed clinical or research. But our normal process if an investigator conducts unauthorized research and collects a body of information or samples or specimens without authorization or informed consent from the subjects, then the Research Compliance Committee would make a determination as to the fate of those data and the samples and specimens collected in that process. And to

give you an example, there have been—if there is an instance where no informed consent was obtained but somebody collected blood samples from patients, for example, and stored them, then the Research Compliance Committee would evaluate that serious non-compliance and as part of that evaluation would then look at what would be done with those collected samples. And in the absence of informed consent, the usual action RCC takes in those cases is to actually destroy the samples because the primary determinant that the RCC considers is the subject's intent as to what was to be done with the samples.

Chairman MILLER. Dr. Sonel, you have just described this as kind of an abstract discussion of procedures, but this chain of e-mails all had to do with specific destruction of this set of *Legionella* and other bacteria samples, didn't it?

Dr. SONEL. This was related to the collection in question and the rest of this e-mail string, correct.

Chairman MILLER. All of you saw the first panel discussion, and you heard Dr. Yu and Dr. Stout and Dr. Snydman say that this was a very valuable collection that had been used in many peer-reviewed articles. Dr. Stout said, for instance, it had been useful to her in developing the protocols for dealing with *Legionella* in the water supply VA hospitals and that the research collection was invaluable for that work. We have just heard that this was just a bunch of broken bottles. Dr. Sonel, do you believe the testimony given by the first panel was not true with respect to the value and the scientific integrity of that sample?

Dr. SONEL. I cannot comment to the actual value of the scientific value of the collection that they are talking about, and that is due to the fact that the protocols that we have had at hand and the only existing protocol that was in effect at the time that the Special Pathogens Lab was closed, did not make any reference to retaining any collection of samples or specimens, though a scientific protocol should describe how the collection is going to be accumulated, what are going to be the storage conditions——

Chairman MILLER. That is an entirely——

Dr. SONEL.—and how they are going to be disposed of. So what I am trying to say is we can review research based on the protocol and the materials that are provided to us, and that is what guides how they are collected and how they are stored; and I did not have that information so I cannot tell you how valuable that collection was because I had no way of verifying that that, what was disposed of that we are discussing, is actually what they indicated is.

Chairman MILLER. I think what you just said is you don't know?

Dr. SONEL. I do not know.

Chairman MILLER. Okay. Did you do anything to find out?

Dr. SONEL. That was my intent when I arranged that meeting with the Research Compliance Office and the Special Pathogens Lab staff was to find out what the request was about, what it entailed, what sort of samples were in question. That is correct. I did not know what they were.

Chairman MILLER. Okay. And they were destroyed before you could in fact——

Dr. SONEL. Yes, apparently they were disposed of before we could have that meeting or that request further.

Chairman MILLER. Did Dr. Melhem consult with you at all knowing that you were in discussions about what to do with the samples, apparently her decision to destroy all the samples, all of the bacteria?

Dr. SONEL. She did not. The first time Dr. Melhem directly got into that e-mail string was that afternoon about that meeting. So prior to that there was no discussion, and after that, she did not discuss the disposition with me.

MORE ON REASONS FOR DESTROYING THE SPL COLLECTION: PROCEDURAL FLAWS OR PERSONALITY CONFLICTS?

Chairman MILLER. Dr. Melhem, you heard the testimony of the first panel. It was a first-rate collection of research samples that represented 30 years of research, that it was cataloged, it was stored in the appropriate manner, and now you have testified that these were just some loose broken bottles. Was the first panel testifying incorrectly? Did Yu testify to it incorrectly? Did Dr. Stout? Did Dr. Snydman?

Dr. MELHEM. Sir, Dr. Stout is a full-time clinical lab employee, and as such her mission was to test clinical patient specimens.

Chairman MILLER. That is really not the question at all.

Dr. MELHEM. The specimens in the freezer were, as far as I am concerned, clinical patient specimens that were not—were to be destroyed within two weeks after the clinical results have been released into the computer and the patients taken care of.

Chairman MILLER. You did not understand that any of the vials in the refrigerator were for research specimens, not clinical?

Dr. MELHEM. Sir, I have asked Dr. Stout to present us with whatever lists and maps or boxes or whatever in that freezer and she did not comply.

Chairman MILLER. Did you tell her that unless I get something from you by December 4th I am destroying all this stuff?

Dr. MELHEM. I did not, and I don't have to because I have asked her three times in a row between January and April or May, and there was no answer and no reply.

Chairman MILLER. Now, you mentioned earlier that that was in one e-mail. Were they all in e-mails? Were they all in writing?

Dr. MELHEM. We had a meeting with her that also included the Chief of Pathology and Lab Medicine and the then-Chief of Infectious Disease.

Chairman MILLER. Dr. Melhem, I think Ms. Wanzie also verified as did Dr. Stout and Dr. Yu that this collection, the vials, has numbers and letters on them, suggesting that there was a catalog system in place. Do you deny that?

Dr. MELHEM. I have not seen any log or any map of that——

Chairman MILLER. But you saw the vials?

Dr. MELHEM. They looked like patients' first letter and four-digit of Social Security number which we use to identify patient specimens.

Chairman MILLER. You thought they were clinical specimens?

Dr. MELHEM. I thought they were clinical specimens.

Chairman MILLER. Did you ask anyone whether that was—did Dr. Stout and Dr. Yu tell you that they were research specimens?

Dr. MELHEM. Dr. Stout and Dr. Yu were not cooperative in any of these encounters with them, with their staff, with anybody. Dr. Stout came to the lab at midnight between the 19th of July and the 20th of July and took away boxes and boxes of patients' care material and took them off-site with the help of two non-VA personnel. And I have no idea what was taken away. I have no idea what came back. This is not good faith.

Chairman MILLER. Is that why you destroyed the samples?

Dr. MELHEM. This was not why, I am just telling you that they have no cooperation. I had no cooperation of any kind from the people who are now claiming responsibility.

Chairman MILLER. Dr. Melhem, I really don't need to be persuaded that all of you all didn't get along all that well.

Dr. MELHEM. I had no problem with any of them. That is not true. That is not true.

Mr. MORELAND. Sir, I would just say that in every organization, there are certain procedures and rules that need to be followed, and one of the responsibilities that I had as a hospital director is that research must be done to protect humans and it has to be done in compliance with rules and regulations. And so that was one of the major issues that we had, and a scientific collection must have a catalog. And if a researcher is requested to provide that catalog, it should be provided immediately. All the other researchers in that building, two of them with substantial collections, immediately provided that catalog and assisted us in the move. What I was left with——

Chairman MILLER. Well——

Mr. MORELAND. What I was left with, sir——

Chairman MILLER. Mr. Moreland——

Mr. MORELAND.—was a collection of things that were unidentified.

Chairman MILLER.—from your testimony earlier today and from what you have said to our staff, other than a discussion in July, you were not part of this decision to destroy the samples, isn't that right?

Mr. MORELAND. Yeah, and my assumption was that in July, anything that was collected and had a catalog was moved, everything else was destroyed.

Chairman MILLER. You were not part of the decision on December 4th?

Mr. MORELAND. No.

Chairman MILLER. Okay. So your statement really doesn't pertain to any question I have asked. Well, the testimony has been quite at variance with the documents that were earlier provided and with the staff interviews, and I thought that this hearing today would probably be the end of our committee's involvement and may be the end of our committee's involvement. But it might be the end of this decision generally, this issue generally. But perhaps not. I have no further questions, and this hearing—I don't think that I have actually formally moved to enter documents into the record. But without objection, it is so ordered. And you all have written testimony in front of you. Will you provide that to the Committee now? All five of you? Okay. The hearing is adjourned.

[Whereupon, at 1:37 p.m., the Subcommittee was adjourned.

Appendix:

Additional Material for the Record

BART GORDON, TENNESSEE
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RALPH M. HALL, TEXAS
RANKING MEMBER

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MEMORANDUM

September 8, 2008

TO: Rep. Brad Miller, Chairman
Investigation and Oversight Subcommittee

FROM: Majority Staff

Attached is a report on the staff investigation related to the Subcommittee's hearing on "Biobanking: How the Lack of a Coherent Policy Allowed the Veterans Administration to Destroy an Irreplacable Collection of *Legionella* Samples."

Cc: F. James Sensenbrenner Jr.
Ranking Member
Investigations and Oversight Subcommittee

"Biobanking: How the Lack of a Coherent Policy Allowed the Veterans Administration to Destroy an Irreplacable Collection of *Legionella* Samples."

Staff Report
Subcommittee on Investigations and Oversight
Committee on Science and Technology
U.S. House of Representatives

September 2008

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SUMMARY

Late in the afternoon of December 4, 2006, laboratory staff from the Veterans Administration Pittsburgh Health Service (VAPHS) – based on an order from Dr. Mona Melhem, the associate chief of staff for clinical services, a few minutes earlier – in less than three hours destroying a unique collection of *legionella* and other isolates that had been collected by two prominent infectious disease researchers over their almost three decades of research.

The destruction was the culmination of an acrimonious process that resulted in the closing of the nationally acclaimed Special Pathogens Laboratory by the VAPHS, the firing of Dr. Victor Yu, its long-time chief of infectious disease, and the involuntary resignation of Dr. Janet Stout, the other researcher and director of the laboratory. But it occurred only after a number of false statements about the existence of the collection were made by Dr. Melhem to the VAPHS officials just hours before final steps were to be taken to facilitate transfer to a laboratory at the University of Pittsburgh for continued use by the researchers.

Such a collection of many disease strains that has been built over the years can never be replaced. It was particularly valuable because it was not a simple collection of disease strains, but correlated microbiologic factors to clinical outcomes. Researchers around the country and the world were outraged at this action by the VA. Hundreds signed a petition asking for an independent investigation. The Subcommittee decided to examine this event, not just for what it would tell us about how such a unique collection could be destroyed, but for what we could learn about the Federal policies for management of bio-materials collections across the government.

It is very common for researchers who have left one laboratory for another to take their collections with them if there are no other researchers in the first laboratory who are interested in continuing that work. This was certainly true of this collection. But while the research side of the VAPHS was attempting in good faith to transfer the collection, Dr. Melhem appeared determined to destroy it before such a transfer could take place, even to the point of making false statements to her supervisors.

What Committee staff uncovered in its investigation was that the VAPHS had no clear, written policies in place to determine what to do with such collections and to protect biospecimens collected with federal funds. The processes the VAPHS appeared to have used in the past which involved the Research Compliance Committee in these situations appear to have been ad hoc and were not used in this instance. But the person who ordered the destruction of this collection did so without any consultation with the head of the research office or the Research Compliance Committee.

After the destruction was completed, Dr. Melhem tried to justify her action by claiming that a research official had approved it months before. That official denied ever having done that. Michael Moreland, the medical center director at the time, doesn't remember having given her such an order on December 4 and didn't appear to have a clear idea about what was contained in the collection. Both of them are now taking the position that it wasn't really a

"research" collection, despite the fact that dozens of peer-reviewed papers had come out of the laboratory over its 25 years of existence.

Additionally, we found years of management neglect by the board of directors at the Veterans Research Foundation of Pittsburgh – which included top officials at VAPHS -- that resulted in minimal knowledge of its funded projects and extremely sloppy financial practices. The Research and Development Committee at VAPHS also did not appear to have adequate control over and knowledge of its approved research projects. This failure to institute and follow clear procedures spilled over into the process for closing the SPL and the various investigations into its finances and Dr. Yu. VA procedures and conflicts-of-interest guidance were violated; conclusions were drawn without adequate documentation; and Dr. Yu was not allowed to respond to serious allegations about non-compliance with research protocols. It appeared that the most important thing to the VAPHS hierarchy was to close the lab and rid itself of Dr. Yu and Dr. Stout quickly by whatever manner necessary.

It is breathtaking that a federal health agency official would order the destruction of a human tissue specimen collection without discussing it with and receiving approval of the agency's research officials. It is even more breathtaking that the top officials at the VAPHS and the Veterans Affairs Department have taken no formal action since to make sure that such an action never occurs again.

These events point to a broader problem. Although scientists at other federal agencies assured the staff that such an action would never occur at their laboratories, we found that there are no clear policies across federal agencies for the control and disposition of biomedical collections. In the case of the Veterans Affairs Department, Committee staff found some policies at the agency level requiring the banking of all human tissues collected for research, but no one in Pittsburgh seems to be aware of them, and they produced no written policies of their own in response to a document request.

To date, the National Institutes of Health (NIH) and more specifically the National Cancer Institute (NCI) are the furthest along in developing a biobanking policy, which was hastened after a scandal uncovered the sale of specimens by one of their researchers. NCI's guidelines recommend open and transparent policies for biospecimen retention, establishing points during the study to review the collection, and that biospecimens be advertised for transfer to other institutions if they can no longer be maintained by the original host institution or if there is no further interest in using the materials there. For biospecimens used in research, the guidelines state "...permanent storage generally is preferred...."[1]

Based on its work, the staff recommends that the Committee consider legislation directing the Office of Science and Technology Policy be directed to establish an interagency effort to create a core set of policies for the handling, maintenance and disposition of biomedical collections. Taxpayers spend millions of dollars supporting research that creates valuable and unique research resources. It is incomprehensible that there are no policies in place to ban

[1] NCI Best Practices; p. 16 (Sections C.1.2 and C.1.3).

arbitrary and capricious management decisions by administrators without any assessment of the value of the collection and its potential use in other research.

The work of Dr. Yu and Dr. Stout cannot be recovered. However, the work of the thousands of other professionals working at the VA or other Federal agencies or building collections with Federal money should not be subject to similar mishandling simply because they run afoul of a powerful administrator in their management chain.

INTRODUCTION

At 3:40 p.m. on December 4, 2006, the police at the Veterans Administration Pittsburgh Health System (VAPHS) unlocked the doors of the Special Pathogens Laboratory (SPL) in Building 2. Five VAPHS employees entered: Cheryl Wanzie, the chief technologist for the clinical microbiology laboratory; Kevin Frank, a lab supervisor; and Joseph Crowley and Tina Cozza, lab employees and Dr. Dmitriy Gutkin, the lab's director.[2] According to the police report, these employees had been ordered by Michael Moreland, then VAPHS director, to "remove all lab specimens from the second floor."[3] The employees, however, had received their direct orders from Dr. Mona Melhem, assistant chief of staff for clinical support, who told them that Mr. Moreland had ordered the immediate destruction of the specimens by close of business on that day.

Before that order was given, however, Dr. Melhem had asked Ms. Wanzie about the status of the isolates in the laboratory. Ms. Wanzie said nothing had been done to them since closure of the SPL in July because she considered them to belong to the research office. Dr. Melhem then told Ms. Wanzie that Mr. Moreland wanted them destroyed by the end of the day. Ms. Wanzie did not call the research office to check if its chief concurred with that directive, but "just followed orders."[4] Dr. Melhem also called Mr. Frank and told him to go to the SPL lab, "bag everything up and get rid of it by the end of the day."[5] In approximately two hours, the employees had taken all of the biological materials that constituted a 25-year collection of *legionella*, *klebsiella* and other isolates and environmental specimens compiled by Dr. Victor Yu and Dr. Janet Stout, two of the nation's premier *legionella* researchers, thrown them in biohazard containers and given them to the VAPHS contractor for disposal as biohazards.[6]

The Committee's investigation revealed no clear evidence that Mr. Moreland had ordered the destruction of those isolates on that day or on any other day[7] and that the VAPHS assistant chief of staff for research and development – who was in charge of the collection – was actively working to transfer it to the University of Pittsburgh and was unaware of any order to destroy the collection. What is clear is that (1) the destruction was ordered by Dr. Melhem within minutes of receiving an e-mail informing her that Dr. Stout had set up an appointment on December 5 with the VAPHS' research compliance officer to begin "de-identifying" the isolates prior to transfer and (2) Dr. Melhem made numerous false statements to her staff and to VAPHS officials and

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[2] Dr. Gutkin was identified in the police report as "Dimtriy Gutky." There is no indication that Dr. Gutkin himself participated in the destruction of the collection, although he certainly was aware of it. Veterans Affairs VA Police Uniform Offense Report, UOR # 06-12-04-1540, Dec. 4, 2006.

[3] *Ibid.*

[4] Committee staff interview with Cheryl Wanzie, July 11, 2008.

[5] Committee staff interview with Kevin Frank, July 11, 2008.

[6] Committee staff interviews with Cheryl Wanzie, Kevin Frank, Tina Cozza and Joseph Crowley, July 10-11, 2008; memorandum from Kevin Frank to Dr. Mona Melhem, Dec. 5, 2006.

[7] The Committee asked for all documents relating to this order, but the Department said it had none, and reported that Dr. Melhem said the order came in a conversation between Dr. Melhem and Mr. Moreland. Mr. Moreland said he had no memory of telling anyone to destroy the isolates on Dec. 4, 2006, but thought they were destroyed earlier. Committee staff interview of Mr. Moreland, July 11, 2008.

ordered actions that violated agency and VAPHS procedures to accomplish this destruction of human tissue specimens.

Dr. Melhem's motivations are unclear. She told Committee staff she was simply trying to accomplish what she had already "committed" to in an e-mail minutes earlier to Dr. Ravij Jain, the VAPHS chief of staff, and to Mr. Moreland: that the isolates had been destroyed. In her view, "It was the right thing to do."[8] But in her interview with Committee staff, she also expressed personal animosity toward both Dr. Yu and Dr. Stout and made several unsubstantiated allegations.[9]

What is evident is that the destruction was the climax of a highly charged process that had begun early in 2006 when high-level VAPHS officials decided to close the Special Pathogens Laboratory, which had been in operation for over 25 years, without following any of the procedures it had previously used to close laboratories. During the process, they made decisions before determining all of the facts; blamed others for sloppy financial and research practices which had been in place for years at both the VAPHS and the Veterans Research Foundation of Pittsburgh (VRFP); convened a two-member "independent" board of investigation to justify closing the laboratory that included one person intimately involved in the SPL controversy; kept the assistant chief of staff for research and development uninformed about the disposition of the collection; and, most importantly of all, allowed a research collection to be destroyed without any institutional process on the orders of one person. Subsequently, the VAPHS claimed the destruction was proper because the isolates were not a "research" collection, although dozens of peer-reviewed articles had resulted from the groundbreaking work of the SPL.[10] For example, just this year, the Department adopted a water system testing protocol for its national hospital system that was a direct result of the work of the SPL.[11]

When it was discovered that this collection had been destroyed outside of the normal processes and based on misrepresentations, not a single VAPHS official took steps to make sure that such destruction could never occur again. These events were so unprecedented that hundreds of infectious disease researchers signed a petition requesting an investigation. It was like a "book burning," said Dr. David Snydman, an infectious disease expert at Tufts Medical Center, who had collaborated with Drs. Stout and Yu and had lost samples from his patients housed in the collection.[12]

Committee staff has interviewed numerous scientists and physicians from other federal agencies and academia. While it is clear that formal protocols governing the disposal of research collections are surprisingly rare, none of them indicated that such a destruction would have happened in their institutions. But this event -- bizarre and rare as it may have been -- destroyed much of the life's work of two scientists. It points to a critical need for the federal government

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[8] Committee staff interview with Dr. Mona Melhem, July 10, 2008.

[9] Several VAPHS officials had strong, negative opinions of Dr. Yu. See, *e.g.*, Committee staff interviews of Dr. Mona Melhem, Dr. Steven Graham and Dr. Frederick DeRubertis, July 10-11, 2008. But Dr. Melhem even suggested that Dr. Stout might poison the water supply. Committee staff interview of Dr. Melhem, *supra.*

[10] See, e.g., Committee staff interview of Mr. Moreland, *supra.*

[11] VHA Directive 2008-010, "Prevention of *Legionella* Disease."

[12] "Researchers Protest Destruction of Bacteria Collection," *NatureNews*, http://www.nature.com/news/2008/080320/full/news March 20, 2008.

and individual agencies to establish clear policies for the protection of its researchers and the biospecimen collections that they have accumulated, often at significant taxpayer expense.

HOW DID THIS HAPPEN?

The critical events that led up to the fateful day of December 4, as determined from documents provided by the VAPHS, Dr. Yu and Dr. Stout and Committee staff interviews, are as follows:

The Special Pathogens Laboratory was closed on Friday, July 21, 2006. After that, Dr. Yu, Dr. Stout and the lab's technicians could not enter the laboratory without permission and a police escort. According to VAPHS documents, all clinical and environmental specimens that were in the process of being tested and/or cultured were removed, as was a refrigerator belonging to the clinical microbiology laboratory and the research collections of Dr. Nina Singh and Dr. Robert Muder, infectious disease clinicians who had used SPL's resources for their research.[13] Although the lab facilities were under the auspices of the research office and most of the equipment was purchased by funds from the Veterans Research Foundation of Pittsburgh, Dr. Melhem appeared to have assumed control because clinical *legionella* specimens from VAPHS patients were tested and cultured there.

Beginning in August of 2006, Dr. Yu and Dr. Stout expressed concern about the safety of the isolates they had left in the laboratory. Dr. Stout described them as representing "30 years of work" and including "isolates that were collected for study over many years. In addition to our own research, we have assisted other investigators over the years by providing these unique and well-characterized isolates to them for their investigations." If the freezers in the now-closed laboratory were shut off, the collection would be lost. She later told Dr. Ali Sonel, the current VAPHS assistant chief of staff for research, that her "future research depends on this collection." Dr. Yu described it as a "treasure trove of isolates."[14]

Both Dr. Yu and Dr. Stout received assurances from Dr. Steven Graham, the former assistant chief of staff for research and development, and Dr. Sonel, who assumed those responsibilities in September of 2006, that they would assist in transferring the isolates to the University of Pittsburgh's molecular genetics and biology laboratory.[15] Dr. Melhem was aware of the process as she was copied on some of the e-mails and also had an "in person" meeting with Dr. Sonel during which he discussed the plan to de-identify and transfer the isolates.[16] But Dr. Melhem also talked to Dr. Graham (although he was no longer the research chief) about disposing of the collection. Dr. Graham described Dr. Melhem as "very anxious to get rid of those samples," but he told her it was not a good idea, and that efforts were underway to de-

[13] Telephone interview with Dr. Janet Stout, Sept. 3, 2008.

[14] E-mail entitled "Re: Material Transfer Agreement - Special Pathogens Lab isolates," from Dr. Stout to Dr. Sonel, Oct. 5, 2006; e-mail entitled "Re: My research equipment," from Dr. Stout to Dr. Yu, Aug. 12, 2006, and forwarded to Dr. Graham, Dr. DeRubertis and Dr. Muder in an e-mail from Dr. Yu entitled "Re: Invaluable isolates for research," Aug. 15, 2006.

[15] See, e.g., e-mail entitled "Re: Invaluable isolates for research," from Dr. Graham to Dr. Yu, Aug. 15, 2006 (1:53 p.m.); e -mail entitled "Re: Material Transfer Agreement – Special Pathogens Lab isolates," from Dr. Sonel to Dr. Stout (cc: Nicholas Squeglia, Dr. Melhem and Dr. Ravij Jain), Oct. 5, 2006.

[16] E -mail entitled "Re: Material Transfer Agreement – Special Pathogens Lab isolates," from Dr. Sonel to Dr. Stout (cc: Nicholas Squeglia, Dr. Melhem and Dr. Ravij Jain) Oct. 5, 2006; e-mail entitled "Re: SPL Samples" from Dr. Sonel to Dr. Jain, Dec. 6, 2006 (7:50 a.m.).

identify the collection and transfer it.[17] The task of facilitating the transfer was delegated by Dr. Sonel to Barbara Strelec, then the research compliance officer. During November, e-mails between Ms. Strelec and Dr. Stout made clear that they were both working on getting the paperwork done to facilitate the transfer, although neither one had ever done such a transfer. The work appears to have been delayed by general confusion about the necessary forms and vacation, conference and holiday schedules.

The isolates remained intact and identifiable in November when a University of Pittsburgh graduate student was granted access to the SPL and the isolates to complete his research.[18] On November 28, 2006, Ms. Strelec and Dr. Stout agreed to meet on December 5 at 10 a.m. to work on the de-identification process.[19] Because no one was allowed to enter the SPL without a police escort, on December 4 at 2:34 p.m., Dr. Sonel e-mailed Dr. Jain to "confirm that it is OK for Janet Stout and Sue Mietzner [a former SPL employee] to complete their inventory under police supervision tomorrow." Ms. Strelec would review the samples they requested and "we will proceed with releasing the samples that are deidentified. We will have them sign a statement that they will not use any serial number or another key to attempt to reidentify any subjects. Please let me know if you have any concerns about this approach."[20]

At 3:06 p.m., Dr. Jain agreed, but included Dr. Melhem on his e-mail "in case she would want someone from the Lab to be there also."[21] Three minutes later, Dr. Melhem responded that "Per Mr. Moreland's orders, all the freezers were cleaned out. The freezers are turned in."[22] Drs. Sonel and Jain were bewildered since they had been under the impression for months that they were attempting to transfer isolates that they were now told didn't exist. Dr. Melhem's statement appeared to be backed up by an e-mail minutes later from Mr. Moreland who said that it was his understanding that:

> The refrigerators were reviewed, there were samples, but that the samples were from work that was not authorized and was in fact redone outside the special path lab (i.e., the company that redid samples and completed in another lab and we paid for) . . . . so, the samples and material from the refrigerators was disposed of and the refrigerators returned to VA inventory.[23]

In retrospect, it is evident that Mr. Moreland was discussing the environmental samples being processed in the SPL at the time of closure that were later re-processed by a private company, but no one appeared to understand that at the time. This e-mail was followed by an e-

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[17] Committee staff interview with Dr. Graham, *supra*.

[18] Committee staff telephone interview with Dr. Stout, Sept. 4, 2008.

[19] E-mail entitled "Re: Transfer of Isolates," from Ms. Strelec to Dr. Stout, Nov. 28, 2006. That meeting was confirmed again in an e-mail entitled "Re: Transfer of Isolates," from Ms. Strelec to Dr. Stout, Dec. 4, 2006 (9:04 a.m.)

[20] E-mail entitled "SPL Samples," from Dr. Sonel to Dr. Jain, Dec. 4, 2006 (2:34 p.m.)

[21] E-mail entitled "RE: SPL Samples," from Dr. Jain to Dr. Sonel (cc: Dr. Melhem) Dec. 4, 2006 (3:06 p.m.)

[22] E-mail entitled "RE: SPL Samples," from Dr. Melhem to Drs. Jain and Sonel (cc: Mr. Moreland), Dec. 4, 2006 (3:09 p.m.)

[23] E-mail entitled "Re:SPL Samples," from Mr. Moreland to Drs. Jain, Melhem and Sonel, Dec. 4, 2006 (3:22 p.m.). It appears that Mr. Moreland was referring to the clinical specimens from VAPHS patients and the water samples that were being tested in the SPL at the time of closure and were sent to another laboratory for completion. Only one refrigerator was returned to the VA inventory because it was the only one owned by the VA.

mail from Dr. Jain to Mr. Moreland and Drs. Melhem and Sonel, stating that Dr. Stout should be denied access to the SPL because "there are no materials left for them to review." That e-mail included a mysterious paragraph that Dr. Jain denies authoring, and no one else admits writing.[24] It allegedly described how and why the samples were destroyed.

> They have already destroyed all the computerized documents and evidence that would have supported the VA in the latest decisions concerning the Special Pathogens labs, during their last visit (Janet and Dr. Yu), under the pretext of "tagging" their equipment to be transported to the university.
>
> Since then, and as discussed with Mr. Moreland and Dr. Steve Graham, then the ACOS for research, a decision was made to get rid of all the infectious agents in that lab, in preparation for it to be demolished.[25]

These alleged facts and chronology in this paragraph, however, did not match the actual events. There is no evidence that Dr. Stout and Dr. Yu destroyed any computerized documents and evidence during a visit to tag equipment while Dr. Graham was the head of research – or at any other time. The "tagging" visit appears to have occurred on October 6 under police supervision and a month after Dr. Graham left that position.[26] Dr. Graham also has denied agreeing to the destruction of the collection.[27]

In his responsive e-mail, Dr. Sonel expressed surprise that he had not been made aware of this destruction and his concern that the "normal process" of involving the Research Compliance Committee had not been used.

> I don't think we were ever made aware of the samples being destroyed. Since the activities that generated the samples included research, albeit unauthorized, our normal process would have been to involve the Research Compliance Committee prior to destroying specimens derived from human subjects <u>as we have done in the past</u>. In addition a representative of the RCC has been present in the past to observe and verify sample or data destruction processes required by the RCC. <u>The last I had spoken to Dr. Melhem in September, they were in the freezer in her lab during my visit there and I discussed with her our prior conversations regarding potential release of samples with certain safeguards</u>. (emphasis added)[28]

While Dr. Sonel refers to a "normal" process, the Subcommittee was not provided any relevant documents concerning that process. Committee staff subsequently discovered VA documents that appear to require the deposit of biospecimens retained for research into tissue

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[24] Committee staff interviews with Dr. Jain, Dr. Sonel and Dr. Melhem, July 10, 2008.
[25] E-mail entitled "RE: SPL Samples," from Dr. Jain to Mr. Moreland and Drs. Melhem and Sonel, Dec. 4, 2006 (3:40 p.m.).
[26] E-mail entitled "RE: Yu equipment purchased through VRF" from Dr. Sonel to Dr. Yu (cc: Mr. Squeglia and Drs. Jain, Graham, DeRubertis and Stout), Oct. 5, 2006. Dr. Yu was told to report to the VA police office to obtain access.
[27] E-mail entitled "RE: SPL Samples" from Dr. Sonel to Dr. Jain, Dec. 6, 2006.
[28] E-mail entitled "RE: SPL Samples" from Dr. Sonel to Dr. Jain (cc: Mr. Moreland and Dr. Melhem), Dec. 4, 2006 (4:36 p.m.)

banks.[29] In a directive dated March 31, 2003, the collection and banking of biospecimens were put "under the jurisdiction" of local Institutional Review Boards (IRB) and Research and Development (R&D) Committees.[30] The Department has not yet responded with information explaining the status of this policy. Nor does it appear, after reviewing minutes from the VAPHS IRB and R&D Committee meetings, that these policies were put into effect.[31] (An expanded discussion of this issue follows in a later section of this report.)

But the isolates had not been destroyed prior to 3:09 p.m. on December 4 when Dr. Melhem sent her e-mail. However, by approximately 6 p.m., Dr. Stout's and Dr. Yu's 30-year research collection was gone.[32] As Mr. Frank wrote the next morning, ". . . all frozen isolates that you referred to were discarded. We personally met the Environmental Service people (Kathy Long), boxed up the waste, and sent it to Bio-Ox to be incinerated."[33]

In the meantime, Dr. Sonel was trying to decide what to tell Dr. Stout. First, Ms. Strelec called Dr. Stout and told her that the "front office" had put the "process" on hold. By 5:44 p.m., Dr. Stout e-mailed Dr. Sonel to ask why the meeting had been cancelled. Dr. Sonel said he would update her "soon regarding this request," but didn't mention that the isolates had been destroyed.[34] On Dec. 5, Dr. Jain told Dr. Sonel that Drs. Melhem and Dmitriy Gutkin of laboratory services would provide a memo describing the process "followed to move the samples or to dispose of them." Dr. Yu and Dr. Stout should be referred to Dr. Melhem with "any questions" they might have about the isolates.[35]

Later that day, Dr. Melhem sent an undated, unsigned memorandum to Drs. Jain and Sonel, stating that "[p]er the instructions of Mr. Moreland and Dr. Graham (ACOS, R&D), an inventory of all of the freezers in the SPL was conducted after which clinical specimens (approximately 10 percent) were sent to the microbiology lab for processing; Dr. Nina Singh's liver transplant specimens were saved for future studies (approximately 30 percent) and specimens "without clear labels or accompanied by appropriate paperwork were discarded according to biohazard and infection control protocols" (approximately 60 percent). No time frame for all of these activities was given in the memo, but in a subsequent response from the VA, Dr. Melhem said she "believed" it was written "on or around July 19, 2006." However, it is undisputed that no destruction occurred or was ordered at that time.[36]

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[29] VHA Directive 2000-043. November 6, 2000. Accessed September 3, 2006, at http://www.vbri.org/Research/documents/TissueBanking.pdf. The Directive states that it was to expire on October 30, 2005.

[30] VHA Directive 1200. "Banking of Human Biological Specimens Collected From Veterans for Research." Veterans Health Administration, Department of Veterans Affairs, Washington, D.C. March 31, 2003; pp. 1-3. See Sections 2(b) and 3(h). The Directive indicates it was to be recertified at the end of March 2006.

[31] Yet the Standard Operating Procedures for the VAPHS Subcommittee on Human Studies (the IRB), approved January 18, 2005 and again November 14, 2007, both make reference to the Directive from 2000.

[32] Committee staff interviews with Cheryl Wanzie, Kevin Frank, Tina Cozza and Joseph Crowley, July 10-11, 2008; E-mail entitled "Frozen Isolates" from Kevin Frank to Dr. Melhem. Dec. 5, 2006 (8:41 p.m.).

[33] *Ibid.*

[34] E-mail entitled "Re: Material Transfer Meeting Cancelled?" from Dr. Stout to Dr. Sonel, Dec. 4, 2006 (5:44 p.m.); e-mail entitled "Re: Material Transfer Meeting Cancelled?" from Dr. Sonel to Dr. Stout, Dec. 4, 2006 (6:34 p.m.)

[35] E-mail entitled "RE: SPL Samples" from Dr. Jain to Dr. Sonel (cc: Mr. Moreland and Dr. Melhem), Dec. 5, 2006 (11:18 a.m.)

[36] Undated memorandum to Drs. Jain and Sonel, attached to e-mail entitled "SPL.doc" from Dr. Melhem to Drs. Jain and Sonel and Mr. Moreland, Dec. 5, 2006 (11:42 a.m.) SPL staff remained in the laboratory until July 21, 2006.

Moreover, as Dr. Sonel stated in a subsequent e-mail to Dr. Jain, "Dr. Graham denies agreeing to destruction of the samples."[37] Dr. Graham also told Committee staff that his conversation with Dr. Melhem about the isolates did not occur until a few months ago.[38] And there also were samples belonging to Dr. Muder which were removed from the SPL in July and were not listed.

Dr. Sonel expressed his "disappointment" that as head of the research and development side of VAPHS, he was

> . . . not given an opportunity to process this through the RCC [Research Compliance Committee], which I feel would have been the due process even if the end result may have been to destroy the samples. The samples and their proposed fate (to deidentify and release) was discussed in person with Dr. Melhem in September . . . . I sincerely hope we can avoid such a confusion and I would truely [sic] appreciate being kept in the loop if data or specimen destruction is considered when it may be linked to approved or non-approved research. (emphasis added)[39]

No one from the VAPHS could summon up the courage to tell Dr. Stout of the destruction of the isolates. As part of a process of appealing Dr. Stout's 30-day suspension, Dr. Yu and Dr. Stout received information in early January that the research collection had been destroyed.[40]

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[37] E-mail entitled "RE: SPL Samples" from Dr. Sonel to Dr. Jain, Dec. 6, 2006. In an interview with Committee staff, Dr. Graham recalled a conversation with Dr. Melhem in the fall of 2006 in which she appeared "very anxious" to get rid of the isolates. Dr. Graham told her it was not a good idea, and that the Research Compliance Committee was working to de-identify the isolates for transfer. Committee interview with Dr. Steven Graham, July 10, 2008.
[38] Committee staff interview with Dr. Graham, *supra.*
[39] E-mail entitled "RE: SPL Samples" from Dr. Sonel to Dr. Jain, Dec. 5, 2006 (4:40 p.m.)
[40] Letter from Drs. Yu and Stout to Drs. Jain, Graham and DeRubertis requesting verification of the status of the non-*legionella* isolates in their collection, specifically the 400 *klebsiella* isolates, referring to previous letter of Jan. 17, 2007, requesting verification of destruction of *legionella* isolates.

CLOSURE OF THE SPECIAL PATHOGENS LABORATORY

Troubles for the SPL can be traced back almost one year prior to the destruction of the collection that had been contained in that lab. In early January of 2006, Dr. Yu asked Dr. Melhem for a raise for Dr. Stout, who was on the payroll of the clinical microbiology laboratory. Dr. Stout was by that time a well-respected and published infectious disease researcher. The request, and the participation of Dr. Yu in making the request, seems to have sent Dr. Melhem on a path towards closing the lab. Dr. Melhem responded by asking for a spreadsheet of patient workload and control point expenditures for the Special Pathogens Laboratory,[41] and soon decided that she wasn't getting enough clinical value for Dr. Stout's salary.[42] Dr. Graham then began a review of the SPL's funding.[43] He immediately raised questions about a $100,000 unrestricted educational grant from Binax Inc.[44] On April 20, Dr. Melhem met with Dr. Stout and said she was going to pull all the VAPHS clinical work from the SPL and move Dr. Stout into the clinical microbiology lab. [45] On May 1, Dr. Melhem transmitted the same information to Drs. Jain, Graham and DeRubertis even though the financial review of the SPL's activities requested two days before by the executive committee of the board of the Foundation had not yet begun.

On May 2, Mr. Moreland sent Dr. Yu a list of actions Dr. Yu was to take and procedures to follow in operating the SPL. If that was not done, his Foundation accounts were to be frozen.[46] It is not clear whether Dr. Yu complied with the entire list. But the "limited financial review" of the SPL submitted by James Baker, VAPHS chief financial officer, on June 15 concluded most of the SPL's income did not come from research grants, but from testing services provided to VA and non-VA customers and that the *legionella* study approved by the research and development committee in December of 2005 was actually a business. Baker recommended that the Foundation board make a determination about continuation of the study, questioned both the Binax and E-Sun Technology grants and recommended tighter financial controls over grants. He also made an unsupported allegation that no entity within the VAPHS wanted to take responsibility for the laboratory.[47]

There is no doubt that Dr. Yu had been allowed to run the SPL for years without significant outside oversight or review and with the full approval of the Foundation's executive director. However, because all of the billings and receipts were handled by the Foundation, there was little or no evidence of actual misuse of funds. Nor did the board meet to determine that the

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[41] E-mail entitled "Special Pathogens Data FY04-05.xls" from Cheryl Wanzie to Dr. Melhem, Jan. 11, 2006.
[42] The Subcommittee requested documents on any review of the SPL that had occurred after 2000. No documents were provided dated prior to 2006.
[43] Memorandum entitled "Re: Delineation of Current Research Activity" from Dr. Yu to Dr. DeRubertis (cc: Drs. Graham and Jain), March 29, 2006.
[44] E-mail entitled "Victor Yu" from Dr. Graham to Dr. DeRubertis (cc: Dr. Jain), April 4, 2006.
[45] E-mail entitled "Special Pathogens FTE and Janet Stout," from Dr. Yu to Dr. Jain and Mr. Moreland, May 1, 2006.
[46] Memorandum entitled "Re: Supervision of Activities in the Special Pathogens Laboratory," from Mr. Moreland to Dr. Yu, May 2, 2006.
[47] "Veterans Research Foundation of Pittsburgh Limited Financial Review Accounts of Dr. Victor Yu," June 15, 2006.

lab should be closed. Nonetheless, the result of the review was that Dr. Jain told Dr. Yu on July 5 that the lab would be closed. According to Dr. Yu, the reasons given were confusing: the lab did not perform research, but another allegation was that payment from non-VA customers for testing services were paying for research which was not approved by the Institutional Review Board.[48] Dr. Stout and the clinical work the SPL had done for VAPHS would be transferred to the clinical microbiology laboratory, all non-clinical work would end in five days, and the SPL employees would be terminated.[49]

Two days later, after 25 years of operation, Dr. Yu was told that the employees would be terminated that day, and his other accounts would be frozen until October 1 so that any deficit from the *legionella* study would be covered by those accounts.[50] (Dr. Yu subsequently requested and received a 10-day reprieve on the closing date.) On July 10, Dr. DeRubertis raised concerns about work done in the SPL by two other researchers. "The closure of the SPL will have consequences for the current clinical Infection Control, and research activities of VAPHS and its ID [infectious disease] division," Dr. DeRubertis wrote, asking who was going to provide these services.[51]

After the abrupt decision by Mr. Moreland and Drs. Jain and Graham to immediately close the established laboratory of two of its most recognized researchers, it is undisputed that chaos erupted. Dr. Yu refused to stop taking samples to analyze and told the lab staff to continue processing them in hopes that he could somehow save his laboratory.[52] Dr. Stout made arrangements with the head of laboratory services to move equipment to the clinical lab on July 25, but he went on vacation, and Dr. Melhem then ordered that it be done on July 19 and the locks changed on July 21, telling everyone that the entire building was to be demolished within weeks. Dr. Jain was also pushing to close the lab quickly. Mr. Moreland caused further disruption by instituting a Board of Investigation whose members insisted on deposing SPL employees as they were trying to finish their work.[53] Guards were placed at the doors so employees could not leave. Dr. Stout went to the emergency room for several hours with cardiac-related symptoms, but returned and took out 49 boxes of research papers, which were later found to include some patient records.[54]

In the end, the laboratory was closed on July 21, and Dr. Yu, VAPHS's chief of infectious disease for 28 years, was fired for refusing the order of Dr. Derubertis to stop

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[48] E-mail entitled "Written justification for closure requested" from Dr. Yu to Dr. Jain and Mr. Moreland (cc: Dr. DeRubertis), July 12, 2008. No written document was forthcoming. Dr. Yu has stated to Committee staff that all of his research was properly approved. Telephone interview of Dr. Yu, Sept. 7, 2008.

[49] Memorandum entitled "Special Pathogens Laboratory" from Dr. Jain to Dr. Yu, July 5, 2006.

[50] E-mail entitled "Legionella Lab Closeout Plan.doc" from Nicholas Squeglia to Dr. Yu (cc: Drs. Graham, Jain and DeRubertis), Jul7 7, 2006.

[51] Memorandum entitled "Closure of the Special Pathogens Lab (SPL" from Dr. DeRubertis to Dr. Melhem, July 10, 2006.

[52] Deposition of Dr. Victor Yu before the Board of Investigation, July 21, 2006, pp. 42-43.

[53] E-mail entitled "Obstacles to Completion of Legionella responsibilities" from Dr. Yu to Dr. DeRubertis (cc: Drs. Jain and Stout, members of Congress and the American Legion), July 21, 2006. According to the VA Handbook, the Board's authority extends only to employees. VA Handbook 0700, Chap. 4(B)(3-4). After July 21, SPL employees would no longer be under the Board's authority.

[54] See, *e.g.*, Notes of Dr. Janet Stout on July 12, 2006, meeting with Drs. Gutkin and Melhem and attached documents; letter entitled "Proposed Removal" from Dr. Melhem to Dr. Stout, Aug. 18, 2006.

processing samples. Dr. Stout was placed on administrative leave and faced a removal action. But the Revco refrigerator belonging to the Foundation remained in operation, and the Yu/Stout isolate collection remained intact inside until December 4.

Following the firing of Dr. Yu, the research compliance officer was tasked with a "publications audit" of Dr. Yu's research articles over the past 10 years. There were two drafts, the final one of which concluded that Dr. Yu had conducted unapproved research. Dr. Yu was not given any opportunity to respond, and has subsequently pointed to numerous errors in the report.[55] The Research Compliance Committee met on September 5, 2006, discussed the report and decided to close Dr. Yu's "science only" (no human subjects) study because the "continuing review for this study had lapsed."[56] This was not accurate as the study had been reviewed by the Research and Development Committee and was approved through December 11, 2006.[57]

The reasons for the haste in closing a lab that had been operating 25 years and produced groundbreaking research which improved VA patient care remain unclear. What is evident is that VAPHS officials made a decision to close the lab and had no intention of working with Drs. Yu and Stout to resolve any questions about its practices and operations before doing so. Dr. Yu had been told a decade earlier that he could bill non-VA customers for testing their samples through the VRFP, and no one ever changed that directive. The excuse that Dr. Melhem gave about the building being demolished within weeks was a red herring. When Committee staff visited the VAPHS in July of 2008, the building was intact, and at least one other laboratory was operating in it. Except for the loss of the isolate collection, its handwritten catalog and some computer terminals, the Special Pathogens Laboratory premises look just as they did when the staff was locked out – Christmas and other cards and family photos are still on the walls; books are in the bookshelves; and unused, but still operating, refrigerators hum in the background.

In the meantime, Dr. Stout and Dr. Yu have opened a second special pathogens laboratory and are trying to rebuild their careers.

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[55] Committee staff telephone interview with Dr. Yu, Sept. 7, 2008.
[56] Minutes of the Research Compliance Committee, Sept. 5, 2006.
[57] Expedited approval was granted on Dec. 12, 2005, and reported to the full committee on Jan. 25, 2006. VAPHS, Protocol History for "Various Studies Examining Treatment, Prevalence and Eradication of Legionella."

HISTORY OF THE SPECIAL PATHOGENS LABORATORY

The Special Pathogens Laboratory (SPL) was established at the Pittsburgh Veterans Affairs Medical Center in 1981 as a special microbiology laboratory to respond to endemic hospital-acquired Legionnaires' disease at that hospital. It was under the direction of Dr. Victor Yu, then chief of infectious disease and the microbiology lab. Later Dr. Janet Stout became the director. It was established by the Central Office of the Veteran Affairs Department (VA). Originally, the staff included three microbiologists funded by the Department. In addition to perfecting techniques to determine the presence of the *legionella* bacteria in human isolates, Dr. Yu, Dr. Stout and other researchers discovered the link between the presence of the bacteria in hospital water systems and hospital-acquired Legionnaires' disease. This work ultimately resulted in a protocol adopted by the VA system in 2008 for the annual testing of the water systems in all VA hospitals.[58] Most recently, Dr. Stout worked with the American Society of Heating, Refrigerating and Air-Conditioning Engineers on its proposed standard entitled "Minimizing the Risk of Legionellosis Associated with Building Water Systems." The standard could result in requiring certain building owners to establish *legionella* auditing and prevention programs.[59]

In addition to its work for the Pittsburgh Veterans Affairs Medical Center (VAMC), because of its expertise, the SPL began providing services to other VA centers and non-VA hospitals. On June 30, 1995, a meeting was held at the VAMC to "finalize the mechanism for billing of microbiological testing performed at the Special Pathogens Laboratory and Clinical Microbiology Laboratory." According to a memo from Dr. Yu, cost estimates for *legionella*, checkerboard antibiotic synergy and mycobacteria testing were provided. It was decided that compensation for all *legionella* testing services would be deposited in the Veterans Research Foundation of Pittsburgh, and on a quarterly basis, payment would be made to the "Hospital Care Appropriation" for VA institutional costs. Services provided to other VA Medical Centers would be paid through an "expenditure transfers" account. A "sharing agreement", which normally would be used to provide services to outside parties, was determined to not only be "unnecessary, but unwieldy, given that requests for testing are usually sporadic and total funds received from 'regular' users is well below $25,000 annually."

Marketing of services was also discussed, and it was "the understanding of the group" that advertising was permissible if it was done through the VRPF Corporation. Advertising fliers were to be drafted.[60]

Although Dr. Yu had requested that the SPL be designated as a national VA reference laboratory, it was decided that *legionella* reference testing could be accommodated through the existing structure of the Special Clinical Resource Center of the Pathology and Laboratory

[58] VHA Directive 2008-010, "Prevention of *Legionella* Disease."
[59] ASHRAE Guideline 12-2000.
[60] Memo from Dr. Yu to William Boyle, Raymond Laughlin and Ron Michaels (cc: Thomas Capello, Dr. Ernest Urban, Dr. Martin Sax and Jack Rihs) July 5, 1995. According to Dr. Yu, these fliers were never drafted. Deposition of Dr. Victor Yu, July 21, 2006, p. 55.

Medicine Services instead of establishing a separate unit.[61] This set-up was acknowledged by Dr. Graham, the former assistant chief of staff for research, who stated in July of 2006 that "Years ago, the VAMC gave him a lab with technician support to provide clinical services to VAMCs and non-VAMCs for culturing the Legionnaire disease pathogen." Dozens of peer-reviewed articles resulted from the researchers' work on *legionella* and other infectious bacteria. Dr. Yu was the recipient of an award by the Infectious Disease Society of America for the Best Original Article in 2003 involving his work on the effective use of penicillin for some infections. Dr. Graham inaccurately claimed in 2006 that Dr. Yu and Dr. Stout had "no active research protocol for some time," although one had been approved in December of 2005.[62]

[61] Memo entitled "Establishment of a VA Reference Laboratory," from Dr. Yu to Dr. Urban, July 3, 1996; memo entitled "VA Reference Laboratory, As per memo from Dr. Yu, dated June 3, 1996," from Dr. Gurmukh Singh to Dr. Urban, June 4, 1996.
[62] VAPHS, Protocol History for "Various Studies Examining Treatment, Prevalence and Eradication of Legionella."

FOUNDATION OVERSIGHT

Over the years, the SPL brought in significant amounts of funds to the Pittsburgh foundation from its sale of testing services and research funds. It is clear from the Foundation's records, however, that the board of directors – which included the Pittsburgh VA's medical director, its chief of staff, and its assistant chief of staff for research and development – paid very little attention to how those funds were accounted for or what research was being undertaken. The board only met annually until 2003 when it met biannually for two years. The receipt and disbursement of funds were left to the judgment of the Foundation's executive director, who was also the chief administrative officer of the VAMC's research and development office, and he appears to have paid little attention. Co-mingling of funds from one project to cover shortages in another project was common and approved.[63] The board appears to never have taken any recorded votes, even when it changed the by-laws, so it is unclear when and if "official" actions were taken.[64] Accounts in deficit were brought to the board's attention, but little action was taken, even when the entire foundation had a deficit of over $600,000.[65]

In 2005, the board reviewed revised bylaws that permitted an executive committee. Without a vote approving those bylaws and without the policy for the committee -- which was to be presented at the next board meeting -- a three-member committee met in April of 2006 to discuss Dr. Yu's accounts. First it requested an audit. Then on June 30, it decided to disband Dr. Yu's laboratory, allegedly based on the results of the "audit", from which the committee determined "that this program no longer meets the goals" of the VRFP. No further explanation was given. It was to be done as soon as possible, and the employees would be fired.[66] It is unclear whether the executive committee had that authority, since the lab was established by the VA, and the facilities were under VAPHS control, not the Foundation's. The Foundation basically operated as a financial conduit.

The alleged "audit" was actually a "limited financial review" by James Baker, the VAPHS' chief financial officer (CFO) and was quite incomplete. During the review, the CFO interviewed only one VAPHS official, which was Dr. Melhem. The CFO concluded that $27,000 in clinical supplies may have been misused by the SPL based on unverified costs estimates and questioned Dr. Stout's work and expenses, without ever interviewing her. Based

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[63] See, *e.g.,* Committee staff interview of Nicholas Squeglia, July 11, 2008

[64] According to the minutes of the board of directors, Veterans Research Foundation of Pittsburgh, for Sept. 28, 2005, revised bylaws were distributed and discussed which permitted the establishment of an executive committee. No other details, including membership, were provided, and no vote is recorded. However, a policy for that committee was to be presented to the board at its next meeting. But before the next meeting, an "executive committee" of three members met to discuss Dr. Yu's accounts and order an audit. Minutes of "Executive Committee Meeting," April 28, 2006.

[65] See, *e.g.,* minutes of board of directors, Veterans Research Foundation of Pittsburgh, April 26 and Sept. 23, 2004, and Sept. 28, 2005. Ironically, at the meeting where the deficit was mentioned, the board asked for an edit of a draft self-evaluation form on board performance which included the following in its "Roles and Responsibilities": "The board is exercising appropriate fiscal oversight, including ensuring that financial controls are in place, approving the annual operating budget, ensuring that the budget reflects priorities, and monitoring financial performance during the year." Minutes of board of directors, *supra,* Sept. 28, 2005.

[66] Minutes of the executive committee, VRFP board of directors, April 28 and June 30, 2006.

only on Dr. Melhem's statements, he concluded that the clinical support, medical specialty and research elements of the VAPHS were not willing to accept responsibility for the SPL. There is no evidence that he met with the heads of the medical specialty or research offices.

The CFO noted that $900,000 of the SPL's income had come from testing revenues without mentioning that this source of income was approved for years, and the Foundation had been designated as the conduit. He acknowledged also that the Foundation had a practice of allowing researchers to "borrow" funds from projects not in deficit to cover projects in deficit – as Dr. Yu had done. He then gave his opinion – without the benefit of hearing from the VAPHS research office and while admitting that research was actually being published by SPL staff – that the *legionella* study was a business receiving free space from the VAPHS, and that the Foundation board of directors should review its activities and determine whether it was a "relevant research study" or a business. If it was a business, it should be shut down.[67]

There is no evidence that the Foundation board ever met to consider the limited financial review, the closure of the SPL or to hear from Dr. Yu or Dr. Stout. Nor did the executive committee, which immediately decided to close the laboratory.

The careless management of the Foundation by its board and officers over the years was especially evident in the following "precepts" adopted by the board in September of 2006, none of which appeared to be in place previously:

A. All research must be conducted within the scope of a VAPHS R&D Committee-approved research study.
B. Agreements in support of the approved research must be in the form of a memorandum of understanding, contract, CRADA or clinical trial agreement as approved by the VA technology transfer office.
C. All investigators must submit a signed conflict of interest statement for each research or educational activity.
D. Financial oversight to assure funds and expenditures of such funds are linked to an R&D Committee-approved project.[68]

What is most disturbing about the Foundation board's behavior is not that it decided at some late date to operate in a more professional manner, but that it turned on Dr. Yu, blamed him for operating under the lackadaisical system that the board itself and its executive director had not only tolerated, but encouraged, for many years and then demanded that the lab be shut down immediately for not meeting standards that had not yet been adopted. There is no indication that any other researcher was subjected to such a review.

But the Committee's investigation indicates that it was not the limited financial review or any other investigation that resulted in this precipitous closure of a prestigious laboratory that had been in existence for more than 20 years. In April, Dr. Melhem had told Dr. Stout that she intended to move all clinical work from the SPL to her clinical microbiology laboratory. On May 1, Dr. Melhem told Drs. Graham, Jain and DeRubertis that she intended to take that action

[67] Baker, James, "Veteran Research Foundation of Pittsburgh, Limited Financial Review, Accounts of Dr. Victor Yu, June 15, 2006, pp. 3-6.
[68] Minutes of the board of directors, VRFP, Sept. 18, 2006.

by July 1. "I can wait till the audit is completed if this will make it easier for you. I believe this is the right thing to do. It will save all of us a lot of trouble in the long run," she wrote in her e-mail.[69] There is no evidence that anyone objected.

[69] E-mail entitled "Re: Draft of Yu memo for your comments," from Dr. Melhem to Drs. Graham, Jain and DeRubertis, May 1, 2006.

THE INVESTIGATIONS OF DR. YU

After the Foundation's executive committee decided to close the Special Pathogens Laboratory, Mr. Moreland initiated two additional investigations of Dr. Yu. Both began as reviews of the Binax grant. The internal Board of Investigation set up by Mr. Moreland violated many of the procedures set up by the Department's guidelines, including going far outside of the scope of its charge. The agency's inspector general conducted a standard investigation, but the local U.S. Attorney's office refused to prosecute either criminally or civilly.

Additionally, the research office initiated a review of publications review of Dr. Yu to attempt to determine if Dr. Yu's research had the proper IRB approvals. A draft report stated that Dr. Yu had conducted research without the proper approvals, but Dr. Yu – who did not know of the existence of the report and was never consulted – in a review requested by the Committee has stated that the report was rife with errors and misrepresentations.

A. The Board of Investigation

In his limited financial review of Dr. Yu's accounts at the Foundation, Mr. Baker did not raise any questions about the $100,000 Dr. Yu had received from a company named Binax. None of the money had been spent except for the 10 percent administration fee taken by the Foundation. Nonetheless, on July 19, 2006, Mr. Moreland decided to convene a Board of Investigation (BOI) to look into all aspects of the research, financial arrangements and agreements that may have existed between the SPL and Binax.[70] He named David Cord of the VAPHS Human Resources Office as chair, and Dr. Graham as a member.

Dr. Graham's appointment was in clear violation of VA Handbook 0700 on Administrative Investigations which directs that the members of a board of investigation "must be objective and impartial, both in appearance and in actuality . . . . should not have had direct involvement in matters that are being investigation, and should not supervise or have close personal relationships with any individual whose conduct is a subject of the investigation."[71] Not only was Dr. Graham a member of the board of the Foundation which was the recipient of the Binax grant and head of the research office, but he also was the person who had suggested that the grant be investigated because it was "questionable."[72] He was intimately involved in facilitating the closure of the SPL, and the day after he was appointed, Dr. Graham reported to the director of the Office of Research Oversight for the VA's Atlantic region that he was investigating an unspecified instance of research noncompliance – an issue for which he would have been responsible -- that had been uncovered by the financial review of Dr. Yu's accounts.[73]

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[70] Memorandum entitled "BOARD OF INVESTIGATION" from Mr. Moreland to David Cord and Dr. Graham, July 19, 2006.

[71] "Administrative Investigations," VA Handbook 0700, July 31, 2002, Chapter 3(B)(2)(b), p. 3-1.

[72] E-mail entitled "Victor Yu" from Dr. Graham to Drs. DeRubertis and Yu, April 4, 2006. Dr. Graham incorrectly stated in that e-mail that Dr. Yu's *legionella* study had not been reviewed since 1996 even though the most recent approval occurred in December of 2005.

[73] [73] E-mail entitled "Pittsburgh VA research lab closing" from Dr. Min-Fu Tsan, director, VA Office of Research Oversight Mid-Atlantic Region, to Tom Puglisi, VHACO, July 14, 2006. The Committee asked for documents relating to a conflict-of-interest review of the BOI members, but was told there were none.

And shortly after Mr. Cord was appointed to the BOI, Mr. Moreland contacted him to tell Mr. Cord that Dr. Yu had violated a direct order from Dr. DeRubertis.[74] This was not within the scope of the BOI charge, but it found its way into the BOI report, another violation of the Handbook.[75] The Handbook also suggested an odd number of members to a board to facilitate decision making and strongly suggested that the board be a fact-finding body only and not provide recommendation because "a focus on developing recommendations may tend to distract AIB members from their primary role as objective factfinders."[76] Mr. Moreland ignored this guidance.

On August 4, 2006, the charge to the BOI was amended to direct the members to "investigate any potential breach of security and/or patient privacy by any employee associated with" the SPL.[77] This was the result of an allegation that Dr. Stout had removed research records from the SPL that contained patients' private information.

The final report – issued on August 11 – went far beyond the scope of the two charge letters in its facts, determinations and recommendations. The BOI found that the Binax funds were untouched. No research was underway with those funds because additional funding from other parties had not been obtained. But the BOI did not limit its conclusions to the charge regarding Binax. It went on to state that Dr. Yu had not obtained continuing reviews on his *legionella* study, although it had been re-approved in 2005. It also concluded that the SPL was not involved in MRSA research, although a collection of MRSA isolates belonging to Dr. Muder, another infectious disease researcher, were removed from the SPL when it was closed.[78] The report went into great detail about the over $500,000 the lab was expected to generate from testing environmental samples for *legionella*, but claimed it was not financially self-sufficient.

The BOI also stated that Dr. Yu had disregarded orders in July from Dr. Jain and Dr. DeRubertis to halt testing environmental samples from outside sources and opined on the role of special reference laboratories while denying that the SPL was a special reference laboratory.

Concerning Dr. Stout's privacy violations, the BOI disregarded her testimony that she had told the SPL staff not to box up any material that contained patient information and determined that she had committed a security breach and provided false testimony by stating that the boxes were taped shut.

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[74] E-mail entitled "Re: Hopkins request for their results (fwd)" from Mr. Moreland to Drs. DeRubertis and Jain and Mr. Cord, July 24, 2006.

[75] "The Scope statement of the Charge Letter provides the outer boundaries of the investigation. . . . While the Convening Authority may provide additional direction to the AIB during the course of the investigation by any means, changes in the scope of the investigation must be documented by an amendment to the Charge Letter." (emphasis added) VA Handbook 0700, *supra,* Chap. 3(C)(3). The Committee was informed by the VA that the only change to the charge was to add the allegation against Dr. Stout.

[76] VA Handbook 0700, *supra,* Chap. 3(C)(6)(c).

[77] Memorandum entitled "Board of Investigation" from Mr. Moreland to Dr. Graham and Mr. Cord, Aug. 4, 2006.

[78] [78] Memorandum entitled "Closure of the Special Pathogens Lab (SPL" from Dr. DeRubertis to Dr. Melhem, July 10, 2006. Dr. Yu also said previous MRSA research had been approved. Committee staff interview with Dr. Yu, Sept. 7, 2008.

In its conclusions, the BOI made recommendations that for the most part were not related to the original charges. These included proposals for disciplinary action against Dr. Yu for violating a direct order from his supervisors; for closure of the lab because it was running a deficit and was doing fee service work; and a thorough audit of all the records of the SPL and the VAPHS' Research and Development Committee and Institutional Review Board to determine if there was "serious research noncompliance that meets reporting criteria."[79] Except for the recommendation concerning Dr. Stout's security violation, none of these recommendations were within of the scope of the charge letters.

B. The Inspector General's Investigation

At the same time, Mr. Moreland tasked the BOI with investigating the Binax grant, he sent a letter to the VA Inspector General requesting a review of the same grant and other "irregularities" on the initiative of Drs. Graham and Jain.[80] The letter was sent on July 18 and alleged that there were concerns that "Dr. Yu had misused or diverted some of his project funding."[81] The next day, Mr. Moreland convened the Board of Investigation to examine the same alleged irregularities in Dr. Yu's Binax account.

But Dr. Graham already knew the Binax money had not been used by Dr. Yu. Dr. Jain had forwarded Dr. Graham's e-mail to Mr. Squeglia and asked about the amount still remaining in the Binax account and the length of time the funds had been there.[82] Mr. Squeglia replied an hour later that "the funds are still in the account.... Total received is $100,000. Administrative assessment of 10% was charged and yields balance of $90,000." The funds were received in $10,000 increments approximately every month between September 2004 and May 2005.[83]

In the end, the Office of the Inspector General reported to Ms. Terry Gerigk Wolf (Mr. Moreland's successor as Director of the VAPHS), that there was no diversion or misuse of Dr. Yu's grants, but that the purchase of a database service by the Pittsburgh VAMC from a company owned by Dr. Yu was a possible criminal violation, and that his acceptance of an honorarium from Binax for presentations made in Europe was a "possible violation" of the Department's standards of conduct.[84]

With regard to the issue that was the original reason for seeking the IG's involvement, an interview with a Binax company official indicated that the $100,000 fund had "no strings

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[79] Memorandum entitled "BOARD OF INVESTIGATION" from Mr. Cord to Mr. Moreland, Aug. 11, 2006.

[80] "Nick [Squeglia] and I are concerned that no expenditures have been charged against the Binax account.... This raises questions as to who did the work in the scope of this agreement and from what sources were they paid?" E-mail entitled "Concern Regarding Binax Account" from Dr. Graham to Dr. Jain (cc: Mr. Squeglia and Michele Michaels), July 14, 2006; E-mail from Moreland to Nealon and Dr. Jain. Subject: "Re: Concern regarding Binax account." July 14, 2006 (1:12 PM).

[81] Gelles, Lynnette. "Comprehensive Report of Investigation." Pittsburgh Resident Agency, Office of the Inspector General, Department of Veterans Affairs, Pittsburgh, Pennsylvania. August 27, 2007; p. 1. Hereafter cited as *IG Report*.

[82] E-mail from Dr. Jain to Dr. Graham (cc: Squeglia and Michele Michaels). Subject: "RE: Concern regarding Binax account." July 14, 2006 (12:47 PM).

[83] E-mail from Mr. Squeglia to Dr. Jain and Dr. Graham (cc: Michele Michaels). Subject: "RE: Concern regarding Binax account." July 14, 2006 (1:47 PM)

[84] *IG Report, supra;* Letter from Jeffrey G. Hughes, Special Agent in Charge, Northeast Field Office, Office of the Inspector General, Department of Veterans Affairs, Newark, New Jersey, to Terry Gerigk Wolf, Director, VA Pittsburgh Medical Center. February 11, 2008; p. 1.

attached," and was for developing a rapid test kit for pneumonias similar to the kit Binax had developed -- with the help of the SPL -- to quickly identify if a patient was infected with the predominant strain of *Legionella*. Binax had also paid Dr. Yu's expenses and an honorarium (totaling $4,107.48) to attend conferences in Germany and Spain.[85]

The Inspector General requested a review from the VA Office of General Counsel on the facts it had collected regarding Binax. The Counsel's office in Philadelphia responded that, while Dr. Yu had not sought an opinion on the propriety of accepting the honorarium, it has no process for approving such a request. Further, criminal prosecution would be called for only if Dr. Yu served on VA Pharmacy and Therapeutics Committees or had procurement authority. Neither situation applied.[86]

Finally, the allegation concerning E-Sun Technologies and Dr. Yu concerned the purchase of access to a website -- antimicrobe.org -- by the Pittsburgh facility. The period of service covered 18 months and the cost was $16,500.[87] IG interviews with VAPHS staff determined that the local Contracting Officer was not aware that E-Sun was Dr. Yu's company and that the website was an E-Sun product, and therefore Dr. Yu had benefited from a conflict of interest. Dr. Yu appeared to be involved in the preparation of a Justification for Other than Full and Open Competition needed for the purchase order. But the librarian who asked for the subscription did know of the conflict, and the purchase orders at issue were approved without passing through some of the appropriate checks in the purchasing system.[88]

This purchase was the only allegation presented for consideration to the Office of the United States Attorney for the Western District of Pennsylvania for possible criminal prosecution. The Assistant U.S. Attorney declined to do so stating that it was not clear that Dr. Yu knew the proposed transaction was prohibited. The documentation made it clear that the librarians who prepared the purchase orders were aware of Dr. Yu's interest in E-Sun, yet proceeded to approve the order. Since Dr. Yu gave the agency a free year's subscription before seeking payment, he could not be shown to have "taken advantage" of the VA. In the end, "Without some evidence of unjust enrichment or fraudulent activity, a . . . prosecution of Dr. Yu is rendered more problematic by his long-standing international reputation . . . ." The criminal branch did, however, recommend that a civil recovery of the funds might be justified due to the conflict of interest.[89]

But the civil branch of the U.S. Attorney's office also declined prosecution. The Assistant U.S. Attorney doubted he could convince a judge or jury that Dr. Yu knowingly violated regulations and detailed the multiple failures of VA employees that allowed the

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[85] *IG Report*; pp. 5-6.
[86] *Ibid.*; p. 6.
[87] *Ibid.*; p. 3.
[88] *Ibid.*; pp. 3-5.
[89] Letter from Mary Beth Buchanan, United States Attorney, and Leo M. Dillon, Assistant U.S. Attorney, U.S. Department of Justice, Western District of Pennsylvania, Pittsburgh, Pennsylvania, to Jeffrey G. Hughes, Special Agent in Charge, Northeast Field Office, Office of the Inspector General, Department of Veterans Affairs. October 11, 2007.

transactions to proceed which would undercut the Government's case. He recommended additional training for VAPHS procurement and contracting employees.[90]

C. The Publications Review

VAPHS administrators now claim that their decision to destroy the SPL biospecimens was based on the fact that the specimens were not collected as part of an approved research protocol. This determination appears to be based on a review of Dr. Yu's publications conducted by the Research Compliance Committee staff.[91] Initially drafted by Research Compliance Officer Stacey Edick in the summer of 2006, it was redone by Education and Compliance Coordinator Barbara Strelec when Dr. Sonel asked for an update.[92]

Like all of the other investigations and reviews undertaken by the VAPHS concerning Dr. Yu, this audit raises more questions that it answers. The original drafters of the report attempted to compare Dr. Yu's publications with protocols approved by the Research and Development and IRB Committees. Ms. Strelec told Committee staff because it was difficult to be sure about whether the work represented human subjects research solely from the discussion of methods and data in the papers, she said that her revisions attempted to make the report "less conclusive."[93] Several things are clear, however: (1) the records of the R&D and IRB committees were incomplete and therefore not reliable as supporting documentation, but even this incomplete documentation indicated that some of the research was approved; and (2) and Dr. Yu was not given the opportunity to rebut the statements in the report in violation of the VAPHS' own guidelines.

According to the June 2005 policies for the Research Compliance Committee, Dr. Yu should have been afforded "…an opportunity to respond in writing to all instances of non-compliance uncovered during the course of an audit prior to consideration by the RCC. Investigators may refute audit findings."[94] Dr. Yu, who did not have a copy of the audit until it was provided to him by the Committee, maintains that he does indeed have documentation for all of his research.[95]

The publications chosen for audit were selected by searching the PubMed database[96] for Dr. Yu's name in articles appearing during the previous decade. All references other than journal manuscripts were removed from consideration. A total of 39 articles were reviewed by Ms.

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[90] Letter from Mary Beth Buchanan, United States Attorney, and Paul E. Skirtich, Assistant U.S. Attorney, U.S. Department of Justice, Western District of Pennsylvania, Pittsburgh, Pennsylvania, to Jeffrey G. Hughes, Special Agent in Charge, Northeast Field Office, Office of the Inspector General, Department of Veterans Affairs. February 5, 2008.

[91] The Board of Investigation recommended that "[t]he Research Compliance Office should conduct a thorough audit of all the records of the Special pathogens Laboratory and records of IRB and R/D committee approval and determine what approvals were necessary…." Cord, David P.. Memorandum to Michael E. Moreland. Subject: "BOARD OF INVESTIGATION." August 11, 2006; Recommendation 5 [p. 12]. However, the audit probably began before the delivery of the Board's report, as July 26, 2006 appears on some printouts.

[92] Committee staff interview with Barbara Strelec, July 10, 2008.

[93] Interview with Strelec, *supra*.

[94] Policies of the VA Pittsburgh Healthcare System Research Compliance Committee, June7, 2005; p. 6.

[95] Telephone communication with Dr. Yu, September 7, 2008. He also provided a "Response to Publication Audit," September 5, 2008.

[96] PubMed is a National Library of Medicine database with citations to articles in the scientific literature.

Strelec.[97] At the same time, the Coordinator for the IRB, Kathy Parks, reviewed all "IRB and R&D records", where Dr. Yu was listed as principal investigator, providing eight items (one of these was a study at the University of Pittsburgh). Ms. Strelec then attempted to match the published works with the research protocols. Ms. Strelec indicated to Committee staff that she was operating under a "hard deadline" of September 5, 2006, for completion of the audit.[98]

On September 8, Dr. Sonel forwarded an "updated draft" of the report, including "additional IRB documentation… from prior to 2001…" to Dr. Jain.[99] Dr. Sonel submitted the report in full to Dr. Jain on September 11. In his e-mail, Sonel states that Yu "…clearly has conducted human subjects review at VAPHS without prior approval from the IRB and/or R&D Committees on a number of occasions."[100] His comment is similar to Item 1 in Part IV, "Summary."[101] Ms. Strelec provided the Committee staff a copy of the audit as she submitted it on September 5, and denied being the author of the "Summary" in the September 11 version.[102] It is also interesting to note that a reference in the earlier version of the report noting that all discussion of data collection involved items before the enactment of the Health Insurance Portability and Accountability Act (HIPAA) [103] was removed in the later version sent to Dr. Jain.[104] HIPAA introduced significant changes in the regulations governing the oversight of research involving human subjects, and studies that were acceptable before HIPPA are now subject to more rigorous scrutiny.

From the documents submitted to the Subcommittee in response to Mr. Miller's requests, it is not possible to determine if the papers in the *Publication Audit* indeed represent research activities that were not considered by the VAPHS approval process. Indeed, not all of the protocol histories for Dr. Yu's 11 projects identified by Ms. Park were submitted by the Department to the Subcommittee. Of those that were provided, they show that Dr. Yu appeared to be complying with the requirements and was receiving appropriate reviews. It is not clear if the supporting documentation is in the correct files at VAPHS; the Publication Audit itself states that, "[i]t is uncertain if the VAPHS Office of Research is in possession of all pertinent research records due to the move from the University Drive facility in July 2005."[105]

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[97] Strelec, Barbara. Publication Audit, Human Research Protection Program, VA Pittsburgh Healthcare System. September 5, 2006; p. 1. Hereafter cited as *Strelec Audit*.
[98] Committee staff interview with Barbara Strelec, *supra*.
[99] E-mail from Sonel to Jain (cc: Strelec and Squeglia). Subject: "Dr. Yu Publication Audit." September 8, 2006 (5:08 PM).
[100] E-mail from Sonel to Jain (cc:Strelec and Squeglai). Subject: "RE: Dr. Yu Publication Audit." September 11, 2006 (12:51 PM).
[101] *Ibid.*; p. 19.
[102] Interview with Strelec, supra.
[103] *Strelec Audit*; p. 17.
[104] *Publication Audit*; p. 18.
[105] *Ibid.* For the protocol entitled "Various Studies Examining Treatment, Prevalence and Eradication of *Legionella*," there is a wide gap between the "initial review" by the R&D Committee on October 1, 1998, and the "continuing review" on January 25, 2006. At that last review, the R&D Committee voted 11-0 top continue the protocol and established the next review for December 11, 2006. The protocol history only reflects by dates on the "ITEMS REVIEWED" that the study had received expedited approval on December 12, 2005." VAPHS Protocol History. "Various Studies Examining Treatment, Prevalence and Eradication of *Legionella*." Printed August 8, 2008. This document was submitted by the Department on August 22, 2008. Yet in their earlier submission of May 30, 2008, the Department submitted a Project Data Sheet for the same study. Attached there was a sheet entitled "Abstract," which shows "Last Update: 9/26/06." This sheet references "annual updates" for 2001 and 2002 that also do not appear in the protocol history. Project Data Sheet. Project Title" "Various Studies Examining Treatment, Prevalence and Eradication of *Legionella*." Apparently printed September 26, 2006. Submitted by the Department of Veterans Affairs on May 30, 2008, Book 2, Tab 6B.

Dr. Stout, too, had one protocol related to the "Exposure Assessment for Community-Acquired Legionnaires' Disease." Initiated in 2001, the protocol history demonstrates regular reviews until its closure in 2003. Indeed, it is one case where biospecimens came up for discussion, as one of the IRB members argued that informed consent forms were required for sputum samples that would be coming to Pittsburgh for analysis (even though no identifiable patient information would be included).[106] While there is not enough information to be able to tell if any of the biospecimens destroyed on December 4 were collected under the terms of these protocols, there was no attempt to make such a determination.

[106] VAPHS Protocol History. "Exposure Assessment for Community-Acquired Legionnaires' Disease." Printed August 6, 2008; p. 8.

THE STATUS OF FEDERAL BIOBANKING POLICY

The SPL's biospecimen collection was an early version of a growing trend in medical and public health studies. According to the National Cancer Institute (NCI), "Human specimens… have emerged as a critical resource for basic and translational research in cancer as they are a direct source of molecular data from which targets for therapy, detection, and prevention are identified and molecular taxonomies of cancer are derived."[107] At the SPL, Dr. Yu devoted significant effort to correlating a particular sample to the medical history of its source,[108] and that merger offered valuable new insights into how to combat infections. These so-called "biobanks"[109] are a growing trend in biomedical research, and the federal government is likely to find itself with increasing investments in such projects. The destruction of the SPL collection, however, demonstrates how quickly such investments can be lost without a strong policy framework.

Proper management of a scientific collection requires more than drawing a blood sample, writing the patient's name on the vial, and placing it in a freezer. Yet the Committee staff has not been able to find fully developed collections management policies.[110] In response to the Subcommittee's first document request to the Department for its policies,[111] the only two relevant documents dealt with assuring that donors give appropriate informed consent, not the maintenance or disposition of the collection.[112]

No mention of a policy for dealing with collection disposal emerged during staff interviews with VAPHS staff, although Dr. Sonel referred to one in his e-mails.[113] Recently, however, the Subcommittee staff found a VA document entitled "Banking of Human Research Subjects' Specimens."[114] The Directive makes it VA policy that "…human biological specimens,

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[107] *National Cancer Institute Best Practices for Biospecimen Resources*, National Cancer Institute [Bethesda, Maryland: National Institutes of Health]. June 2007, p. 1. [Hereinafter cited as *NCI Best Practices*]

[108] "Critical to the success of biorepositories is the clinical annotation of tissue and serum specimens. The annotation of these biospecimens with clinical data - disease staging, severity, progression, treatment and outcomes measures - heightens their value in translational research, particularly, in biomarker discovery." Reis, Steven E. *et al.* "Clinical and Translational Science Award Proposal." University of Pittsburgh. March 2006, p. 116. Accessed August 28, 2008 at https://www.ctnbestpractices.org/networks/nih-ctsa-awardees/university-of-pittsburgh-pittsburgh-pa/preview_popup/file.

[109] "Biobank" is the term applied to a research activity where "…data originating from microorganisms are linked with human clinical information with the ultimate aim of improving healthcare by increasing the quality of biomedical research." De Paoli, Paolo. "Future of Biobanking in Microbiology for Medical Research," *Future Microbiology* (2008) 3(1); p. 79.

[110] The Smithsonian Institution's policy considers "…the deliberate development, maintenance, preservation, documentation, use, and disposition of collections." "Collections Management," Directive 600 [Washington: Smithsonian Institution]. October 26, 2001; p. 1.

[111] Letter from Rep. Brad Miller, Chairman, Subcommittee on Investigations and Oversight; to Secretary of Veterans Affairs James Peake. May 13, 2008; p. 4.

[112] It is, of course, vital that it be carried out properly: "…[W]hen sourced bio-repositories consist of samples, which are badly collected, processed, stored or annotated, the end result of a complete experiment based on these samples can be of no better quality, despite the sophisticated techniques or analytical method chosen to perform the research." Ringman, P.H.J.; Dinjens, W.N.M and Oosterhuis, J.W.. "Biobanking for Interdisciplinary Clinical Research," *Pathobiology* (2007) 74, p. 239. Careful attention to obtaining *informed* consent is also required.

[113] Dr. Fred DeRubertis, the vice president of the medical service specialty line, stated in his interview that he did not know of Dr. Yu's collection. Committee Staff interview, July 11, 2008. See also the discussion regarding the role of the Research Compliance Committee in considering collection disposition earlier in this report.

[114] VHA Directive 2000-043. November 6, 2000. Accessed September 3, 2006, at http://www.vbri.org/Research/documents/TissueBanking.pdf. The Directive states that it was to expire on October 30, 2005. Yet the Standard Operating Procedures for the VAPHS Subcommittee on Human Studies, approved January 18, 2005 and November

as well as the linked clinical data collected as part of research projects conducted by VA investigators in VA facilities or approved off-site locations, are maintained at VA approved tissue banks."[115] Existing research protocols were to be brought into compliance during required IRB continuing reviews.[116] A later Directive that apparently replaced the 2000 statement states that research protocols and consent forms had to explicitly detail "…all potential use/disposition of collected specimens," and collection and banking activities were specifically assigned to the jurisdiction of the IRB and the R&D Committee at the hosting VA facility.[117] The staff reviewed the minutes from the VAPHS Subcommittee on Human Studies (the IRB) and protocol histories detailing the consideration of research protocols that might be associated with the biospecimens stored in the SPL. There is no indication that the IRB applied this policy. Dr. Stout told the Committee staff that she was never made aware of these requirements when her *legionella* protocol came up for its required continuing review in 2005.[118] This policy appears to fill much of the vacuum that contributed to the loss of the *legionella* collection. The Department has been asked to determine whether the Directive remains in force.

The National Institutes of Health, another agency with large biospecimen collections[119], appears to be the most advanced in developing protocols for biobanks. The Deputy Director for Intramural Research issued an interim memorandum making discussion of the expected collection strategy, use and proposed disposition a required element for any research protocol contemplating the use of biospecimens.[120] An ad hoc Science Directors Subcommittee on Biorepository Practices and Guidelines was established and charged to study the state of biospecimen management at NIH.[121] Their new "Guidelines for Human Biospecimen Storage and Tracking within the NIH Intramural Research Program" were approved by the NIH Steering Committee on June 7, 2008.[122]

NIH drew from the experience of the National Cancer Institute (NCI), which began its own evaluation in 2002. The Institute sought out best practices in biospecimen management. It published the results from this work in June 2007, seeking to "…establish and document transparent policies governing the retention of biospecimens, data, and records pertaining to informed consent and the identity of research participants…."[123] NCI's guidelines recommend open and transparent policies for biospecimen retention, establishing points during the study to review the collection, and that biospecimens be advertised for transfer to other institutions if they

---

14, 2007, both make reference to this Directive. It was not submitted to the Subcommittee by the Veterans Administration in response to Chairman Miller's request for documents.. It does not appear on the Department website publications section.

[115] *Ibid.*; p. 1.

[116] *Ibid.*; p. 2 (Section 4b).

[117] VHA Directive 1200. "Banking of Human Biological Specimens Collected From Veterans for Research." Veterans Health Administration, Department of Veterans Affairs, Washington, D.C. March 31, 2003; pp. 1-3. See Sections 2(b) and 3(h). The Directive indicates it was to be recertified at the end of March 2006.

[118] Telephone interview with Dr. Stout, September 3, 2006.

[119] Dr. Michael Gottesman, Deputy Director for Intramural Research at NIH, said that a survey of NIH biospecimen collection undertaken at the outset of the review identified some 23 million biospecimens in total. The number is expected to rise to 30 million. Telephone interview, July 31, 2008.

[120] Gottesman, Michael. Memorandum to Clinical Research Protocol Principal Investigators, Clinical Research Protocol Associate Investigators and NIH IRB Chairs. Subject: "Research Use of Stored Human Samples, Specimens or Data." June 12, 2006. Accessed September 4, 2008 from http://ohsr.od.nih.gov/info/pdf/DDIRmemorandum.pdf.

[121] Minutes of the Human Subjects Research Advisory Committee, National Institutes of Health. March 9, 2007; pp. 4-5.

[122] Attachment to E-Mail from Gemma Flamberg, Senior Legislative Analyst, National Institutes of Health, Department of Health and Human Services. Subject: "biospecimen policy." July 31, 2008 (2:38 PM).

[123] *NCI Best Practices*, Section C.1.3, p. 16.

can no longer be maintained by the original host institution or if there is no further interest in using the materials there. For biospecimens used in research, the guidelines state "...permanent storage generally is preferred...."[124]

At the Centers for Disease Control and Prevention (CDC), informal discussions regularly take place in the various laboratories to decide what to do with biospecimens left behind when a researcher retires.[125] CDC tends to retain all biospecimens it collects unless it has duplicates; that led to the decision to build a central repository for collections that would require long-term storage.[126]

How did other policies address the situation represented by the SPL collection? The NCI Best Practices include a "Principle for Responsible Custodianship," which includes advertising the availability of those biospecimens that are no longer needed for research or that a facility cannot maintain.[127] CDC's Dr. Nicholson indicated that collections identified as valuable would not be destroyed.[128] Collections in its central repository are reviewed annually; transfer to other CDC collections or other institutions must be offered before disposal.[129] Similar processes were described in policies from other scientific disciplines, such as the Smithsonian Institution's National Museum of Natural History,[130] the National Plant Germplasm System of the Department of Agriculture[131] and the United States Botanic Garden:[132] Dr. Sonel believed that this peer review should have been exercised by the Research Compliance Committee in the case of the SPL collection. But in the end, it was Dr. Melhem who made the decision.

Four years ago, the Office of Science and Technology Policy (OSTP) convened a working group on agency scientific collections. Because the group's remit covered a diverse set of collections (NASA's lunar samples, NIH's biospecimens and reagents, historical artifacts at the National Park Service), its recommendations will be broad and general.[133] The Committee staff recommends that OSTP be tasked to develop a focused policy for biospecimen collection management, building on the work that has already been done. Biobanking cannot succeed if its basic policy structure is honored more in the breach than the observance.

---

[124] NCI Best Practices; p. 16 (Sections C.1.2 and C.1.3).

[125] Telephone interview with Dr. Barry Fields, *Legionella* Lab Chief, Centers for Disease Control and Prevention, Atlanta, Georgia. August 1, 2008.

[126] Telephone interview with Dr. Janet Nicholson, Senior Advisor for Lab Science, Coordinating Center, Center for Disease Control and Prevention, Atlanta, Georgia.

[127] *Ibid.*

[128] *Ibid.*

[129] *CDC and ATSDR Specimen and Data Bank Policy.* Office of the Chief Science Officer, Office of the Director, Centers for Disease Control and Prevention. CDC-GA-1999-02. December 1999; p. 11.

[130] Smithsonian Institution Directive 600, *loc. cit.*; p. 14.

[131] *Manual of Procedures for the National Plant Germplasm System*, Agricultural Research Service, Department of Agriculture. June 2005; pp. 17-18.

[132] *Collections Management Plan and Curatorial Policies for the United States Botanic Garden*, Washington, D.C.. August 30, 2007; pp. 11-15. See Section 3.3 for policies on deaccessioning.

[133] Telephone interview with Dr. Jim Vaught, July 29, 2008. According to the co-chair, Scott Miller of the Smithsonian Institution, the group is trying to complete the draft of its report to transmit to the member agencies for review and comment. Telephone interview with Scott Miller, July 21, 2008.

CONCLUSION

The deliberate and secret destruction of a biospecimen collection that has been used to advance the detection and treatment of infectious diseases with significant mortality rates is a great loss, not only to the researchers who so carefully compiled it, but to the future patients who will not have the benefit of continuing research. It is a particular travesty because it was done by a federal health agency charged with protecting the health of our nation's veterans, and it appears to have been driven by nothing more than petty personality conflicts.

In the future, such action should never be taken again. Personality conflicts should have no role in managing federal programs, in our health care systems or in decisions to maintain biospecimen collections. Hopefully, the Veterans Affairs Department will finally take the necessary steps to make sure that it doesn't happen again.

Exhibit #1

Department of Veterans Affairs

Memorandum

Date: July 5, 1995

From: Chief, Infectious Disease Section and Microbiology Laboratory (

Subj: Laboratory Testing and Billing

To: William Boyle, Raymond Laughlin, Ron Michaels

A meeting was held on June 30, 1995 with the following individuals in attendance: V.L. Yu, M.D., Ray Laughlin, Bill Boyle, Ron Michaels, Jack Rihs, and Janet Stout. The meeting was held to finalize the mechanism for billing of microbiological testing performed at the Special Pathogens Laboratory and Clinical Microbiology Laboratory of this VAMC.

Prior to this meeting cost estimates were provided to Fiscal Services for *Legionella* testing, checkerboard antibiotic synergy testing, and mycobacteria testing. Mr. Boyle revised the costs to include VA overhead and utility costs. Mr. Boyle and Mr. Michaels provided cost figures for the proposed laboratory tests (enclosed). It was agreed that future billing would be based on these figures provided by Mr. Boyle.

Mr. Michaels and Mr. Boyle recommended that compensation for all *Legionella* testing services should be deposited in the Veterans Research Foundation of Pittsburgh corporation. Mr. Laughlin agreed. On a quarterly basis, payment will be made to the "Hospital Care Appropriation" for VA institutional costs. This amount will be calculated for each test from the Medical Center cost provided by Mr. Boyle times the number of tests performed that quarter. Dr. Yu will contact Nick Squeglia to discuss how best to set this up. The format for billing will be "fee basis" to be performed by the Infectious Disease Section. Services provided to other VA Medical Centers can be paid via "expenditure transfers" through Mr. Boyle's office or via check.

According to Mr. Laughlin, a sharing agreement is not only unnecessary, but unwieldy, given that requests for testing are usually sporadic and total funds received from "regular" users is well below $25,000 annually.

Marketing of services was also discussed. It was the understanding of the group that advertising was permissible if it was done via the VRFP Corporation and on their letterhead. However, Dr. Yu suggested that Mr. Laughlin review the advertising "flier" or letter prior to its distribution. Dr. Yu will draft the flier for *Legionella* testing and synergy testing. Jack will draft the flier for mycobacteria testing.

The Clinical Microbiology Laboratory is already a certified VA reference laboratory and Dr. Gurmukh Singh can assist us in the designation of the Special Pathogens Laboratory as a national VA reference laboratory.

VICTOR YU, M.D.

cc: Thomas Capello, Medical Center Director
Ernest Urban, M.D., Chief of Staff
Martin Sax, Ph.D., Chief, Research and Development
Jack Rihs, Supervisor, Microbiology Laboratory

VA FORM MAR 1988 2105
bill-mem

Exhibit #2

> -----Original Message-----
> From: Victor L Yu [mailto:vly+@pitt.edu]
> Sent: Friday, July 21, 2006 10:37 AM
> To: DeRubertis, Frederick R
> Cc: Jain, Rajiv VAPHS; Moreland, Michael E; janet stout; Hamerschlag,
> Arthur; Doyle; rfconley@county.allegheny.pa.us; rspanogle@legion.org;
> Santorum; Specter; Specter; Strickland
> Subject: obstacles to completion of Legionella responsibilities (fwd)
>
> Fred
>
> You promised the Special Pathogens Lab personnel 14 days to process
> clinical and lab specimens. While you have kept your promise, Moreland
> and the administration have initiated a series of actions that have
> proven extraordinarily disruptive. They are now locked out of the lab.
> The security guard is stationed there today ostensibly to prevent the
> lab personnel from entering.
>
> Yesterday, a security guard sabotaged Sue Meitzner's cultures on patient
> respiratory samples by refusing her to complete her work . The fact that
> Mr Moreland and his staff walked through the lab before the guard
> appeared suggests that they ordered the security guard to force her out
> of the lab.
>
> We insist that two patient specimens be re-processed since they have
> been ordered by VA physicians for their patients. Unfortunately we need
> the original sputum specimen and those two specimens were taken by
> Cheryl Wanzie. We also need the microscopes which were removed from the
> lab without our permssion. In addition, there are at least 200
> environmental samples that require processing. The samples are from
> Johns Hopkins University, NY Alice Hyde Hospital, Erie St Vincent
> Hospital, Bayview Medical Center, SUNY-Buffalo, Phoenix VAMC. These
> specimens must be performed for humanitarian reasons.
>
> I will not accept the suggestion that these specimens be processed in
> the clinical microbiology lab. No more disruptions. Let them finish
> their job in the lab that they have worked in for 10 years.
>
> Finally, let us both agree to assist the laboratory personnel so they
> can conclude their work. Bureaucratic politics is taking too much of
> their time and yours.
>
> ==========
> Dr. Yu,
>

> VA security removed me from the building yesterday afternoon
> without prior notice. At the time I was attempting to complete lab work
> which included surveying ongoing clinical work and verifying results of
> environmental samples. I did not realize that I had to be out of the
> lab by a specific time. Many of us have been working overtime to make
> the 14 day deadline. As a symbol of our sense of our responsibility, it
> should be emphasized that all 5 of us were working voluntarily on behalf
> of the VA and its patients. In fact, we accepted the fact that we would
> not be paid, since we were terminated. It was only in the last few days
> that we were informed we would be compensated for the extra 14 days of
> work.
>
> We understood that Dr Derubertis had given us only 14 days to fulfill
> our clinical obligations. During this period, our time has been compromised
> by numerous interruptions that, in my opinion, bordered on harrassment.
> For example, in the last couple of days:

> 1. Dr. Mona Melhem and Cheryl Wanzie from Laboratory Service
> appeared unannounced, with security guards and labor crew, to remove
> clinical specimens and clinical-specific supplies and equipment. These
> included a -70 freezer and a specimen storage refrigerator.
>
> 2. Bacterial stocks and study clinical specimens
> requirereorganization into remaining appropriate storage space due to
> the removal of equipment.
>
> 3. On Wednesday and Thursday , at least 14 different individuals
> paraded unannounced through the lab performing walk-throughs. This
> included a 5 member labor crew who removed clinical specimens,
> microscopes, all of the diagnostic test kits, and supplies during while
> the lab personnel were trying to conclude their work. When Dr Melhelm
> came, she was accompanied by 2 security guards.
>
> 4. Lab personnel were pressured to attend an interrogation conducted
> by Dr. Stephen Graham and a court recorder. This occurred in the midst
> of our work on short notice.
>
> 5. Since equipment was moved out during the workday, Dr. Singh
> required our assistance to secure her Cryptococcus and liver transplant
> study data and specimens. In addition, time was spent last week shipping
> recent study specimens to her collaborators. She had already informed
> us and Dr Melhelm that her isolates were not to be moved until after
> closing of the lab, so she could insure safety of the isolates.
>
> 6. Similarly, Dr. Muder's study coordinator required our assistance

> to secure his muropiricin study isolates that were being collected and
> frozen. During the stress and general chaos in the lab, a box of frozen
> isolates was regrettably left at room temperature. The reason that the
> isolates were not in the freeer was because the movers also came in
> unannouced and took 1 hour to move the freezer out of the lab. So,
> samples had to be moved out of the freezer. The viability of these
> isolates will need to be determined.
>
> 7. The doors at the ends of the hall were locked and our card keys
> were inactivated. We could not re-enter the building if we left during
> the day.
>
> My removal from the facility, in combination with denied access for
> other Special Pathogen Laboratory personnel, will not allow us to
> complete clinical respiratory cultures that were processed this week.
> Also, some environmental specimens suggest the possibility of legionella
> and this must be verified.
>
> Finally, the VA security guard prevented me from removing my personal
> properties such as family photos, professional books/accumulated
> reference materials, paycheck stubs, etc. Are these measures really
> necessary?
>
> Please let me know how to proceed.
>
> Sue

Exhibit #3

Sonel, Ali F

From:	Melhem, Mona F
Sent:	Tuesday, December 05, 2006 11:42 AM
To:	Sonel, Ali F; Jain, Rajiv VAPHS; Moreland, Michael E
Subject:	SPL specimens
Attachments:	SPL.doc

SPL.doc (27 KB)

TO: Rajiv Jain, MD, COS, VAPHS
Ali Sonel, MD, ACOS, Research and Development, VAPHS

Dr Jain,

Per the instructions of Mr. Moreland and Dr Graham (ACOS, R&D), assessment of the specimens was conducted according to laboratory standards and processed as follows:

A meeting with Janet Stout was held in July 2006 (minutes available), and she was instructed to label all the specimens, provide a map of the freezer and move all the clinical specimens into the clinical lab chest freezer that was available in the Special Pathogens Lab in building 2. This freezer was moved to the main building. An inventory of all the freezers, refrigerators and incubators in the special pathogens lab was conducted.

There were three types of specimens:

1- Clinical specimen of current patients were brought to the main microbiology lab, checked for results, processed according to clinical lab protocols and disposed of accordingly, after testing was completed (Approximately 10% of the specimens).
2- Specimens labeled with Dr Singh's name and "liver transplant". Those are serum specimens and are saved for future studies, if needed and are currently available and stored properly (Approximately 30% of the specimens).
3- Specimens without clear labels or accompanied by appropriate paperwork were discarded according to biohazard and infection control protocols (Approximately 60% of the specimens).

Exhibit #4

Melhem, Mona F

From: Jain, Rajiv VAPHS
Sent: Tuesday, December 05, 2006 11:18 AM
To: Sonel, Ali F
Cc: Moreland, Michael E; Melhem, Mona F
Subject: RE: SPL Samples
Signed By: rajiv.jain@va.gov

Ali:
I sent you a response on the samples on the other e mail message...basically Drs Melhem and Gutkin are preparing a memo describing the process followed to move the samples or to dispose them. The excess equipment inventory can be distributed based on standard VA process. Both Drs Yu and Janet should be referred to Dr Melhem regarding any questions about the samples....

From: Sonel, Ali F
Sent: Monday, December 04, 2006 4:36 PM
To: Jain, Rajiv VAPHS
Cc: Moreland, Michael E; Melhem, Mona F
Subject: RE: SPL Samples

Thank you for the clarification and the update. I don't think we were ever made aware of the samples being destroyed. Since the activities that generated the samples included research, albeit unauthorized, our normal process would have been to involve the Research Compliance Committee prior to destroying specimens derived from human subjects as we have done in the past. In addition, a representative of the RCC has been present in the past to observe and verify sample or data destruction processes required by the RCC. The last I had spoken to Dr. Melhem in September, they were in the freezer in her lab during my visit there and I discussed with her our prior conversations regarding potential release of samples with certain safeguards.

As far as communicating this to her and/or Dr. Yu, who should relay her the message that the samples have been destroyed and they are not to have further access to any other inventory? Also, regarding any remaining equipment from the Special Pathogens Lab, I assume we can process them as excess inventory and assign them to other investigators.

Ali

From: Jain, Rajiv VAPHS
Sent: Monday, December 04, 2006 3:40 PM
To: Moreland, Michael E; Melhem, Mona F; Sonel, Ali F
Subject: RE: SPL Samples

Ali:
Based on Mona and Mr Moreland's comments we should deny any further access to Janet and others....there are no materials left for them to review...

They have already destroyed all the computerized documents and evidence that would have supported the VA in the latest decisions concerning the Special Pathogens labs, during their last visit (Janet and Dr Yu), under the pretext of "tagging" their equipment to be transported to the university.
Since then, and as discussed with Mr. Moreland and Dr Steve Graham, then the ACOS for research, a decision

was made to get rid of all the infectious agents in that lab, in preparation for it to be demolished.

From: Moreland, Michael E
Sent: Monday, December 04, 2006 3:22 PM
To: Jain, Rajiv VAPHS; Melhem, Mona F; Sonel, Ali F
Subject: RE: SPL Samples

My understanding was that the refrigerators were reviewed, there were samples, but that the samples were from work that was not authorized and was in fact redone outside the special path lab (i.e., the company that redid samples and completed in another lab and we paid for).....so, the samples and materials from the refrigerators was disposed of and the refrigerators returned to VA inventory.

From: Jain, Rajiv VAPHS
Sent: Monday, December 04, 2006 3:17 PM
To: Melhem, Mona F; Sonel, Ali F
Cc: Moreland, Michael E
Subject: RE: SPL Samples

That's interesting...so where are they going to go to look for samples if all freezers are in the lab...?

From: Melhem, Mona F
Sent: Monday, December 04, 2006 3:09 PM
To: Jain, Rajiv VAPHS; Sonel, Ali F
Cc: Moreland, Michael E
Subject: RE: SPL Samples

Per Mr Moreland's orders, all the freezers were cleaned out.
The freezers are turned in

From: Jain, Rajiv VAPHS
Sent: Monday, December 04, 2006 3:06 PM
To: Sonel, Ali F
Cc: Melhem, Mona F
Subject: RE: SPL Samples

Ali:
I am basically in agreement...have included Dr Melhem in case she would want someone from Lab to be there also...

From: Sonel, Ali F
Sent: Monday, December 04, 2006 2:34 PM
To: Jain, Rajiv VAPHS
Subject: SPL Samples

Dr. Jain,
I wanted to check with you to confirm that it is OK for Janet Stout and Sue Mietzner to complete their inventory under police supervision tomorrow. During this process, Barbara Strelec will also review their samples they have requested and we will proceed with releasing the samples that are deidentified. We will have them sign a statement that they will not use any serial number or another key to attempt to reidentify any subjects. Please let me know if you have any concerns about this approach. Regards,

Ali

Exhibit #5

Sonel, Ali F

From: Jain, Rajiv VAPHS
Sent: Wednesday, December 06, 2006 7:50 AM
To: Sonel, Ali F
Subject: RE: SPL Samples
Signed By: There are problems with the signature. Click the signature button for details.

Sounds good....

From: Sonel, Ali F
Sent: Tuesday, December 05, 2006 4:40 PM
To: Jain, Rajiv VAPHS
Subject: RE: SPL Samples

Dr. Jain,
I appreciate your support and clarification. I am a bit disappointed that I was not given an opportunity to process this through the RCC, which I feel would have been the due process even if the end result may have been to destroy the samples. The samples and their proposed fate (to deidentify and release) was discussed in person with Dr. Melhem in September. Dr. Graham denies agreeing to destruction of the samples as well. I sincerely hope we can avoid such a confusion and I would truely appreciate being kept in the loop if data or specimen destruction is considered when it may be linked to approved or non-approved research.

Ali

From: Jain, Rajiv VAPHS
Sent: Tuesday, December 05, 2006 11:18 AM
To: Sonel, Ali F
Cc: Moreland, Michael E; Melhem, Mona F
Subject: RE: SPL Samples

Ali:
I sent you a response on the samples on the other e mail message...basically Drs Melhem and Gutkin are preparing a memo describing the process followed to move the samples or to dispose them. The excess equipment inventory can be distributed based on standard VA process. Both Drs Yu and Janet should be referred to Dr Melhem regarding any questions about the samples....

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Cc: Moreland, Michael E; Melhem, Mona F
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Thank you for the clarification and the update. I don't think we were ever made aware of the samples being destroyed. Since the activities that generated the samples included research, albeit unauthorized, our normal process would have been to involve the Research Compliance Committee prior to destroying specimens derived from human subjects as we have done in the past. In addition, a representative of the RCC has been present in the past to observe and verify sample or data destruction processes required by the RCC. The last I had spoken to Dr. Melhem in September, they were in the freezer in her lab during my visit there and I discussed with her our prior conversations regarding potential release of samples with certain safeguards.

As far as communicating this to her and/or Dr. Yu, who should relay her the message that the samples have been destroyed and they are not to have further access to any other inventory? Also, regarding any remaining equipment from the Special Pathogens Lab, I assume we can process them as excess inventory and assign them to other investigators.

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To: Moreland, Michael E; Melhem, Mona F; Sonel, Ali F
Subject: RE: SPL Samples

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They have already destroyed all the computerized documents and evidence that would have supported the VA in the latest decisions concerning the Special Pathogens labs, during their last visit (Janet and Dr Yu), under the pretext of "tagging" their equipment to be transported to the university.
Since then, and as discussed with Mr. Moreland and Dr Steve Graham, then the ACOS for research, a decision was made to get rid of all the infectious agents in that lab, in preparation for it to be demolished.

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To: Jain, Rajiv VAPHS; Melhem, Mona F; Sonel, Ali F
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Cc: Moreland, Michael E
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Cc: Moreland, Michael E
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To: Sonel, Ali F
Cc: Melhem, Mona F
Subject: RE: SPL Samples

Ali:
I am basically in agreement...have included Dr Melhem in case she would want someone from Lab to be there also...

From: Sonel, Ali F
Sent: Monday, December 04, 2006 2:34 PM
To: Jain, Rajiv VAPHS
Subject: SPL Samples

Dr. Jain,
I wanted to check with you to confirm that it is OK for Janet Stout and Sue Mietzner to complete their inventory under police supervision tomorrow. During this process, Barbara Strelec will also review their samples they have requested and we will proceed with releasing the samples that are deidentified. We will have them sign a statement that they will not use any serial number or another key to attempt to reidentify any subjects. Please let me know if you have any concerns about this approach. Regards,

Ali

Exhibit #6

Holleman, Edith

From: Melhem, Mona F [Mona.Melhem@va.gov]
Sent: Thursday, July 17, 2008 1:49 PM
To: Holleman, Edith
Cc: Prudhomme, Angela M. (009)
Subject: RE: 12/5/06 e-mail
Signed By: mona.melhem@va.gov

I truly do not remember when the memo was written, but it had to be before Dr Sonel's time (It mentions Dr Graham, who was Dr Sonel's predecessor).

I must have attached the memo to the e-mail to Dr Sonel, in reply to his inquiry about the specimens in December.

The process of examining the specimens and tallying what is labeled (to be kept) and what is NOT labeled (to be discarded) took place in July 2006 after extensive efforts to get Ms Stout's cooperation in identifying what was there.

Hope this helps.

From: Holleman, Edith [mailto:Edith.Holleman@mail.house.gov]
Sent: Wednesday, July 16, 2008 11:01 AM
To: Melhem, Mona F
Cc: Prudhomme, Angela M. (009)
Subject: 12/5/06 e-mail

Dr. Melhem:

After James and I spoke to you last Thursday, Dr. Sonel provided us with a copy of an e-mail from you dated 12/05/06 and an attached unsigned memo addressed to Dr. Jain. It is attached.

Can you tell us when the memo was written, and whether you were the author?

Thank you.

Edith Holleman

Exhibit #7

Special Pathogens Laboratory
SPL
The Legionella Experts - Pittsburgh, PA
1401 Forbes Ave, Suite 209
Pittsburgh, PA 15219
Toll Free: 1-877-SPL-PATH
Phone:412-281-5335
Fax: 412-281-7445

www.specialpathogenslab.com

To: James Paul
Fax number: 202-225-7815

From: Janet Stout, Ph.D.
Fax number: 412-281-7445

Date: 4-9-08

Regarding: E-mails regarding transfer of isolates

Phone number for follow-up:

Total pages faxed including this cover sheet: 35

Comments:

James – Thank you for your time today. As requested – I have attached the e-mail communication regarding the transfer of our collection.

Jst

Dates of Inquiries for Transfer of Isolates from the Special Pathogens Laboratory to the University of Pittsburgh

Date	From	To	Cc
8-12-06	Janet E. Stout, Ph.D.	Victor L. Yu, M.D.	---
8-12-06	Victor L. Yu, M.D.	Steven H. Graham, M.D.	F. DeRubertis, M.D. Robert Muder, M.D.
*8-15-06	Steven H. Graham, M.D.	Victor L. Yu, M.D.	
8-15-06	Victor L. Yu, M.D.	Janet E. Stout, Ph.D.	Robert Muder, M.D.
8-17-06	Janet E. Stout, Ph.D.	Victor L. Yu, M.D.	Tim Mietzner, Ph.D.
8-21-06	Victor L. Yu, M.D.	Steven H. Graham, M.D	Janet E. Stout, Ph.D.
10-1-06	Janet E. Stout, Ph.D.	Ali Sonel, M.D.	------
10-5-06	Ali Sonel, M.D.	Janet E. Stout, Ph.D.	------
10-5-06	Janet E. Stout, Ph.D.	Ali Sonel, M.D.	------
**10-5-06	Ali Sonel, M.D.	Janet E. Stout, Ph.D.	N. Squeglia, M. Melhem, M.D. R. Jain, M.D.
10-5-06	Janet E. Stout, Ph.D.	Tim Mietzner	-----
10-9-06	Tim Mietzner, Ph.D.	Janet E. Stout, Ph.D.	-------
11-7-06	Barbara Strelec	Janet E. Stout, Ph.D.	A. Sonel, M.D.
11-9-06	Janet E. Stout, Ph.D.	Barbara Strelec	A. Sonel, M.D.
11-10-06	Barbara Strelec	Janet E. Stout, Ph.D.	------
11-15-06	Janet E. Stout, Ph.D.	Barbara Strelec	-------
11-20-06	Barbara Strelec	Janet E. Stout, Ph.D.	-------
11-21-06	Janet E. Stout, Ph.D.	Barbara Strelec	-------
11-26-06	Janet E. Stout, Ph.D.	Barbara Strelec	------

11-28-06	Barbara Strelec	Janet E. Stout, Ph.D.	-------
11-29-06	Janet E. Stout, Ph.D.	Barbara Strelec	-------
12-4-06	Barbara Strelec	Janet E. Stout, Ph.D.	-------
12-4-06	Janet E. Stout, Ph.D.	Ali Sonel, M.D.	------
***12-4-06	Ali Sonel, M.D.	Janet E. Stout, Ph.D.	N. Squeglia, B. Strelec

*Dr. Graham states "Of course I don't want to see valuable specimens destroyed…"

** Dr. Sonel states "We will work with you to facilitate the transfer"

*** Dr. Sonel states " I was asked by the front office to put this process on hold".

Filename: SpecialPathogensLabIsolateTransferRequests

From: "Victor L Yu" <vly+@pitt.edu>
Subject: RE: Invaluable isolates for research (fwd)
Date: Tue, August 15, 2006 12:56 pm
To: "janet stout" <jes20@pitt.edu>,jes20ebsol@gmail.com
Cc: "muder robert" <rmuder1@aol.com>

JES

What do you suggest???

Victor L Yu MD (111E-U)
Infectious Disease Section
VA Medical Center
University Drive C
Pittsburgh, PA 15240

Direct: 412-688-6643
Secretary: 412-688-6179
Direct Fax: 412-688-6507
Cell ph: 412-901-7707
Home: 412-343-7429

---------- Forwarded message ----------
Date: Tue, 15 Aug 2006 13:53:41 -0400
From: "Graham, Steven H" <Steven.Graham@va.gov>
To: Victor L Yu <vly@pitt.edu>
Subject: RE: Invaluable isolates for research

Of course I don't want to see valuable specimens destroyed, but these specimens are biohazards so we must follow accepted proceedures in order to transfer them. We recently went through this process in regards to VonKammens samples at HD.

In order to move such specimens, they must be moved to an institution approved to handle biohazards. They must sign a materials transfer agreement and have an approved biosafety program.

Any transfers of equipment of samples will have to be approved by the board.

-----Original Message-----
From: Victor L Yu [mailto:vly+@pitt.edu]
Sent: Saturday, August 12, 2006 3:58 PM
To: Graham, Steven H
Cc: DeRubertis, Frederick R; muder robert
Subject: Invaluable isolates for research

Steven

Included in the freezers is a treasure trove of isolates including Pseudmonias aeruginosa, Staph aureus, Klebsiella pneumoniae, Enterobacter species, Candida species, Streptococcus pneumoniae and Cryptococcus species collected by collborative research teams over the past 30 years.

The legionella isolates are the most ocmplete set of isolates of not omly Legionella pneumophila but also of 8 other rare legionella speices taken from patients throughout the world. They are now the basis of for devising the new molecular tests for legionella diagnosis.
Moreover, hundreds of hospitals with legionella outbreaks are relying on us for storage of these isolates. For example one hospital in southwestern Us had a repeat outbreal of Legionnaires' disease. Because the clinical isolates and environmental isolates had been svaed since the 1990's, we wer eable to demonstrate that this was a recurrent outbreak in which the original isolates had emerged resistant to the disinfectant used for the wqater supply.

I fear the vindictiveness of the administration especially Mona Melhelm may imperil this irreplaceable collection.

The administration in such haste to close down this lab of excellence and the movement of our equipment and freezers has now endangered this extraordinary collection.

Steve and Fred, you are the only MDs and scientists who have the ability to ensure the safety of these isolates. The administration is now acting recklessly without conscience. How can you safeguard these isolates?

Victor L. Yu , MD
Professor of Medicine
University of Pittsburgh
Chief, Infectious Disease Section
VA Medical Center
Pittsburgh, PA

Victor L Yu MD (111E-U) Direct: 412-688-6643
Infectious Disease Section Secretary: 412-688-6179
VA Medical Center Direct Fax: 412-688-6507
University Drive C Cell ph: 412-901-7707
Pittsburgh, PA 15240 Home: 412-343-7429

---------- Forwarded message ----------
Date: Sat, 12 Aug 2006 10:24:36 -0400
From: Janet E Stout <jes20ebsol@gmail.com>
To: Victor L Yu <vly@pitt.edu>
Subject: Re: My research equipment

Dr. Yu;
I am deeply concerned about the safe keeping of our stock cultures in the -70 freezer in building 2: This repository of isolates represents 30 years of work and includes isolates that were collected for study over many years. In addition to our own research, we have assisted other investigators over the years by providing these unique and well characterized isolates to them for their investigations.
If the freezer were to be unplugged or the proper operation of this freezer not monitored, these irreplaceable scientific materials would be lost.
Can we get some assurance from Dr. Graham that our work will be safeguarded until these issues are resolved?

Janet

On 8/10/06, Victor L Yu <vly+@pitt.edu> wrote:
> Steve
> As we discussed, now thatthe VA Special Pathogens lab has been
> destroyed, the research projects underway, and the services that we
> provide to other hospitals including VAMCs needs to be continued.
> I request assistance in moving equipment and supplies purchased
> through my VRF funds elsewhere.
> Please acknowledge receipt of this email.
> Victor L. Yu , MD
> Professor of Medicine
> University of Pittsburgh
> Chief, Infectious Disease Section
> VA Medical Center
> Pittsburgh, PA
> Victor L Yu MD (111E-U) Direct: 412-688-6643

> Infectious Disease Section Secretary: 412-688-6179
> VA Medical Center Direct Fax: 412-688-6507
> University Drive C Cell ph: 412-901-7707
> Pittsburgh, PA 15240 Home: 412-343-7429
>

Download this as a file

From: "Victor L Yu" <vly+@pitt.edu>
Subject: Safeguarding our research isolates
Date: Mon, August 21, 2006 10:58 am
To: steve.graham@va.gov
Cc: "janet stout" <jes20@pitt.edu>

Dear Steve

We wish to proceed with the transfer of isolates to the University of Pittsburgh. Please send us the proper forms and we will fill them out. Please proceed with obtaining approval from the "board".

This is a legitimate scientific matter, and we are hopeful that the political and bureaucratic issues which have so dominated the unfortunate closing of the Special Pthgoens Lab will not be a problem.

Regards, Victor Yu

Forwarded message ---------- > Date: Tue, 15 Aug 2006 13:53:41 -0400
> From: "Graham, Steven H" <Steven.Graham@va.gov>
> To: Victor L Yu <vly@pitt.edu>
> Subject: RE: Invaluable isolates for research
>
> Of course I don't want to see valuable specimens destroyed, but these specimens are biohazards so we must follow accepted procedures in order to transfer them. We recently went through this process in regards to VonKammens samples at HD.
>
In order to move such specimens, they must be moved to an institution approved to handle biohazards. They must sign a materials transfer agreement and have an approved biosafety program.
>
> Any transfers of equipment of samples will have to be approved by the board.
>
>
> -----Original Message-----
> From: Victor L Yu [mailto:vly+@pitt.edu]
> Sent: Saturday, August 12, 2006 3:58 PM
> To: Graham, Steven H
> Cc: DeRubertis, Frederick R; muder robert
> Subject: Invaluable isolates for research
>
> Steven
>
> Included in the freezers is a treasure trove of isolates including Pseudmonias aeruginosa, Staph aureus, Klebsiella pneumoniae,
> Enterobacter species, Candida species, Streptococcus pneumoniae and Cryptococcus species collected by collborative research teams over the past 30 years,
>
> The legionella isolates are the most ocmplete set of isolates of not only Legionella pneumophila but also of 8 other rare legionella speices taken from patients throughout the world. They are now the basis of for devising the new molecular tests for legionella diagnosis.
> Moreover, hundreds of hospitals with legionella outbreaks are relying on us for storage of these isolates. For example one hospital in
> southwestern Us had a repeat outbreal of Legionnaires' disease. Because the clinical isolates and environmental isolates had been saved since the 1990's, we wer eable to demonstrate that this was a recurrent outbreak in which the original isolates had emerged resistant to the disinfectant used for the water supply.
>
> I fear the vindictiveness of the administration especially Mona Melhelm

may imperil this irreplaceable collection.
>
> The administration in such haste to close down this lab of excellence
and the movement of our equipment and freezers has now endangered this
extraordinary collection.
>
> Steve and Fred, you are the only MDs and scientists who have the
ability to ensure the safety of these isolates. The administration is now
acting recklessly without conscience. How can you safeguard these
isolates?
>
> Victor L. Yu , MD
> Professor of Medicine
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> Pittsburgh, PA
>
> Victor L Yu MD (111E-U) Direct: 412-688-6643
> Infectious Disease Section Secretary: 412-688-6179
> VA Medical Center Direct Fax: 412-688-6507
> University Drive C Cell ph: 412-901-7707
> Pittsburgh, PA 15240 Home: 412-343-7429

>
> ---------- Forwarded message ----------
> Date: Sat, 12 Aug 2006 10:24:36 -0400
> From: Janet E Stout <jes20ebsol@gmail.com>
> To: Victor L Yu <vly@pitt.edu>
> Subject: Re: My research equipment
>
> Dr. Yu;
> I am deeply concerned about the safe keeping of our stock cultures
> in the -70 freezer in building 2. This repository of isolates
> represents 30 years of work and includes isolates that were collected
for study over many years. In addition to our own research, we have
assisted other investigators over the years by providing these unique and
well characterized isolates to them for their investigations.
> If the freezer were to be unplugged or the proper operation of
> this freezer not monitored, these irreplaceable scientific materials
would be lost.
> Can we get some assurance from Dr. Graham that our work will be
> safeguarded until these issues are resolved?
>
> Janet
>
>
>
> On 8/10/06, Victor L Yu <vly+@pitt.edu> wrote:
>> Steve
>> As we discussed, now thatthe VA Special Pathogens lab has been
>> destroyed, the research projects underway, and the services that we
provide to other hospitals including VAMCs needs to be continued. I
request assistance in moving equipment and supplies purchased through my
VRF funds elsewhere.
>> Please acknowledge receipt of this email.
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>> Infectious Disease Section Secretary: 412-688-6179
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>> University Drive C Cell ph: 412-901-7707
>> Pittsburgh, PA 15240 Home: 412-343-7429

From: "Mietzner, Timothy" <rmietzner@mgb.pitt.edu>
Subject: RE: Invaluable isolates for research (fwd)
Date: Mon, August 21, 2006 9:42 pm
To: jes20@pitt.edu

J,

Let me know the space that you need and I will ensure that this will happen post MTA. I can give you the Pitt MTA if you like.

I still think you should consider a two-month sabaticle into the Mietzner/Montelaro lab until the special pathogens issue is resolved. This probably would help in the transfer of materials. It would not cost you or us a thing. The major advantage that you would gain is the MGB infastructure which involves internet help, internet space, telephone, office support and access to wet lab space. I use my office about 10% of my time; you could be there at your leisure.

Anyway, these are my thoughts.

Call me on my cell phone (412-215-6700) after your meeting with Rinaldo if you want.

T

From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
Sent: Mon 8/21/2006 9:34 AM
To: Mietzner, Timothy
Cc: jes20@pitt.edu; drd7@pitt.edu; smmietzner@yahoo.com
Subject: RE: Invaluable isolates for research (fwd)

Hi Tim;
I would feel better knowing our Legionella isolates were in a safe place. There are no class 3 pathogens. I guess I will have to get the materials transfer agreement form from the research office. I'll ask Dr. Graham to send to me. A week lead time is no problem.
I am glad to hear that Sue is in Mississippi visiting her Mom. A very good use of her time right now!
My meeting with Rinaldo is set for tomorrow at 4:30pm. I'll keep you posted.

Thanks again for all your help!

Janet

Janet,
>
> Two issues with regard to freezer space in MGB, which is no problem, but
> we should resolve these if you choose to advance on this:
>
> 1. I will need about a week lead time to get all the paperwork through,
> as long as we are not transferring class any class 3 pathogens (e.g.,
> anthrax, yersineae, etc), this should not be a problem.
>
> 2.. Sue estimates that you will need about two shelves of a standard
> upright -70 freezer. We can accomidate this in my personal freezer with
> Dilhari's help and a little cleaning. We do have transient common room
> space for a -70 freezer if you coan procure your entire freezer from the
> VA.
>

> Let me know your thoughts on this and the outcome of your meeting with Dr.
> Rinaldo.
>
> Sue is in Mississippi and happy tonight. She is picking up her email if
> you have any questions.
>
> T
>
> _____
>
> From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
> Sent: Thu 8/17/2006 12:30 PM
> To: Victor L Yu
> Cc: Mietzner, Timothy
> Subject: RE: Invaluable isolates for research (fwd)
>
>
>
> -
>
> Dr. Yu ;
> Tim Mietzner at the University Molecular Genetics and Biology Dept. has
> offered to accept our isolates. This department is approved to handle
> biohazards and has an approved biosafety program. I'm sure Tim would
> sign a materials transfer agreement. I have copied Tim on this message
>
> Janet
> _____
> JES
>>
>> What do you suggest???
>>
>> Victor L Yu MD (111E-U) Direct: 412-688-6643
>> Infectious Disease Section Secretary: 412-688-6179
>> VA Medical Center Direct Fax: 412-688-6507
>> University Drive C Cell ph: 412-901-7707
>> Pittsburgh, PA 15240 Home: 412-343-7429
>>
>> ---------- Forwarded message ----------
>> Date: Tue, 15 Aug 2006 13:53:41 -0400
>> From: "Graham, Steven H" <Steven.Graham@va.gov>
>> To: Victor L Yu <vly@pitt.edu>
>> Subject: RE: Invaluable isolates for research
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>> -----Original Message-----
>> From: Victor L Yu [mailto:vly+@pitt.edu]
>> Sent: Saturday, August 12, 2006 3:58 PM
>> To: Graham, Steven H
>> Cc: DeRubertis, Frederick R; muder robert
>> Subject: Invaluable isolates for research
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> Pseudmonias aeruginosa, Staph aureus, Klebsiella pneumoniae,
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> acting recklessly without conscience. How can you safeguard these
> isolates?
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>> Victor L. Yu , MD
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>> Pittsburgh, PA 15240 Home: 412-343-7429
>>
>> ---------- Forwarded message ----------
>> Date: Sat, 12 Aug 2006 10:24:36 -0400
>> From: Janet E Stout <jes20ebsol@gmail.com>
>> To: Victor L Yu <vly@pitt.edu>
>> Subject: Re: My research equipment
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>> Janet
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>>> Steve

>>> As we discussed, now thatthe VA Special Pathogens lab has been
>>> destroyed, the research projects underway, and the services that we
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>>> Pittsburgh, PA 15240 Home: 412-343-7429
>>
>
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Download this as a file

From: "Sonel, Ali F" <Ali.Sonel@va.gov>
Subject: RE: Material Transfer Agreement- Special Pathogens Lab isolates
Date: Mon, October 2, 2006 7:58 am
To: jes20@pitt.edu
Cc: "Squeglia, Nicholas L" <Nicholas.Squeglia@va.gov>

Dr. Stout,
Do any of the isolates contain any reference numbers that could link it to human subjects? We could only consider releasing isolates that do not contain such identifiers.

If they are only isolates without any direct or indirect linkage to human subjects, we could schedule a time for you to visit and identify what you would like to remove.

AFS

-----Original Message-----
From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
Sent: Sunday, October 01, 2006 11:26 PM
To: Sonel, Ali F
Subject: Material Transfer Agreement- Special Pathogens Lab isolates

Dr. Sonel;
I had some discussion with Dr. Graham regarding the transfer of our frozen collection of isolates to the University. Now that he has stepped down and you have taken over as ACOS for research, I would like to move this request forward.

Would you please tell me where I can obtain the material transfer forms and what other steps are necessary to accomplish this?

Sincerely,

Janet E. Stout, Ph.D.

Download this as a file

From: "Sonel, Ali F" <Ali.Sonel@va.gov>
Subject: RE: Yu equipment purchased through VRF
Date: Thu, October 5, 2006 9:15 am
To: "Victor L Yu" <vly@pitt.edu>
Cc: "Squeglia, Nicholas L" <Nicholas.Squeglia@va.gov>,"Jain, Rajiv VAPHS" <Rajiv.Jain@va.gov>,"Graham, Steven H" <Steven.Graham@va.gov>,"DeRubertis, Frederick R" <Frederick.DeRubertis@va.gov>,shirley.brinker@gmail.com,"janet stout" <jes20@pitt.edu>,"Crawford, John Jack" <John.Crawford@va.gov>

Dr. Yu,
Please report to the office of the VA Police in Building 1 at 11 AM tomorrow and an officer will assist you in identifying and tagging the equipment in question in building 2.

AFS

-----Original Message-----
From: Victor L Yu [mailto:vly+@pitt.edu]
Sent: Wednesday, October 04, 2006 10:01 PM
To: Sonel, Ali F
Cc: Squeglia, Nicholas L; Jain, Rajiv VAPHS; Graham, Steven H; DeRubertis, Frederick R; shirley.brinker@gmail.com; janet stout
Subject: Yu equipment purchased through VRF

Fri Oct 6 at 11:00 am or later would be fine.

I also need to pick up personal files and mail at my ID office.

Victor L. Yu , MD
Professor of Medicine
University of Pittsburgh
Chief, Infectious Disease Section
VA Medical Center
Pittsburgh, PA

Victor L Yu MD
Secretary: 412-688-6179
Fax: 412-688-6507
Cell ph: 412-901-7707
Home: 412-343-7429

On Wed, 20 Sep 2006, Sonel, Ali F wrote:

> Dr. Yu,
> Thanks for your email. You are correct in that on certain occasions,
> VA equipment can be transferred from one VA facility to another. but
> it still remains VA property. For that process, a request must come
> from the Director of the VA facility that is making the request to
> transfer, to Mr. Moreland. At that point, the actual transfer would be

> at the discretion of Mr. Moreland.
>
> What I would propose is to set up a day for you to visit the Special
> Pathogens Lab and identify the equipment that you have purchased with
> your research funds. Once you have tagged that equipment, we can then
> review the invoices for those equipment and identify those that may be

> eligible for such a transfer, if requested. Please note that we would
> not be able to release any equipment on the day of your visit. Would
> you please provide me with 2-3 dates that would work for you so that
> we can arrange a visit?
>
> AFS
>

> -----Original Message-----
> From: Victor L Yu [mailto:vly+@pitt.edu]
> Sent: Tuesday, September 19, 2006 7:58 AM
> To: Sonel, Ali F
> Cc: Squeglia, Nicholas L; Jain, Rajiv VAPHS; Graham, Steven H
> Subject: RE: VRF inforamtion
>
> Dear Dr Sonel
>
> Your statement is incorrect. I have the option to send my equipment to

> another VA collaborator. Regardless, it is appropriate that you send
> me an inventory of mu equipment. Please do so.
>
> Multiple requests for this equipment have been documented.
> And, it is inappropriate that you withhold this information from me.
>
> Victor L. Yu , MD
> Professor of Medicine
> University of Pittsburgh
> Chief, Infectious Disease Section
> VA Medical Center
> Pittsburgh, PA
>
> Victor L Yu MD
> Secretary: 412-688-6179
> Fax: 412-688-6507
> Cell ph: 412-901-7707
> Home: 412-343-7429
>
> On Thu, 7 Sep 2006, Sonel, Ali F wrote:
>
>> Dr. Yu,
>> Nick Squeglia, AO/R&D, will be sending you the balances for your VRFP

>> accounts. In terms of the inventory of the equipment purchased
>> through
>
>> VRFP, all such equipment is considered property of the VA and not the

>> respective investigator's property. As such, I am not authorized at
>> this time to provide you with that information. Regards,
>>
>> AFS
>>
>> -----Original Message-----
>> From: Graham, Steven H
>> Sent: Thursday, September 07, 2006 2:52 PM
>> To: Victor L Yu
>> Cc: Sonel, Ali F
>> Subject: RE: VRF inforamtion
>>
>> As of 9/1/06 I am no longer ACOS for Research. Dr. Ali Sonel has
>> been
>
>> appointed as acting ACOS. I will forward this message to him.
>>
>> -----Original Message-----
>> From: Victor L Yu [mailto:vly+@pitt.edu]
>> Sent: Thursday, September 07, 2006 2:45 PM
>> To: Graham, Steven H
>> Cc: Squeglia, Nicholas L; glovelaw@adelphia.net
>> Subject: VRF inforamtion
>>
>> Steve
>>
>> As you know, I have made multiple requests for the status of my VRF

```
>> account and an inventory of my equipment.  I have never received a
>> reply.
>>
>> This seems unreasonable and inappropriate.
>>
>> Please respond by Monday.
>>
>> Victor L. Yu  , MD
>> Professor of Medicine
>> University of Pittsburgh
>> Chief, Infectious Disease Section
>> VA Medical Center
>> Pittsburgh, PA
>
```

Download this as a file

From: "Sonel, Ali F" <Ali.Sonel@va.gov>
Subject: RE: Material Transfer Agreement- Special Pathogens Lab isolates
Date: Thu, October 5, 2006 10:16 am
To: jes20@pitt.edu
Cc: "Squeglia, Nicholas L" <Nicholas.Squeglia@va.gov>,"Melhem, Mona F" <Mona.Melhem@va.gov>,"Jain, Rajiv VAPHS" <Rajiv.Jain@va.gov>

We will work with you to facilitate the transfer. However more definitive deidentification would be needed than taping over identifiers.

In terms of the paperwork, please check with the laboratory that will be receiving them in terms of what documentation they would need from us in order to accept the transfer. While we would assist in any providing information needed from us, ultimately you would be responsible to complete the required paperwork.

-----Original Message-----
From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
Sent: Thursday, October 05, 2006 11:03 AM
To: Sonel, Ali F
Subject: RE: Material Transfer Agreement- Special Pathogens Lab isolates

Dr. Sonel;
The majority of the isolates are environmental in origin. Among any clinical isolates, the majority have been deidentified. I would be willing to over label any that would need to be further deidentified. Obviously my future research depends on this collection and I would appreciate every professional courtesy in facilitating this transfer.

It is my understanding that some documentation will be needed from the institution/laboratory that will house the isolates. Please provide whatever information we need to accomplish this.

Thanks.

Janet

Dr. Stout,
> Do any of the isolates contain any reference numbers that could link
> it to human subjects? We could only consider releasing isolates that
> do not contain such identifiers.
>
> If they are only isolates without any direct or indirect linkage to
> human subjects, we could schedule a time for you to visit and identify

> what you would like to remove.
>
> AFS
>
> -----Original Message-----
> From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
> Sent: Sunday, October 01, 2006 11:26 PM
> To: Sonel, Ali F
> Subject: Material Transfer Agreement- Special Pathogens Lab isolates
>
>
> Dr Sonel;
> I had some discussion with Dr. Graham regarding the transfer of
> our frozen collection of isolates to the University. Now that he has
> stepped down and you have taken over as ACOS for research, I would

> like to move this request forward.
>
> Would you please tell me where I can obtain the material transfer
> forms and what other steps are necessary to accomplish this?
>
> Sincerely,
>
> Janet E. Stout, Ph.D.
>

Download this as a file

From: "Mietzner, Timothy" <mietzner@mgb.pitt.edu>
Subject: RE: [Fwd: RE: Material Transfer Agreement- Special Pathogens Lab isolates]
Date: Mon, October 9, 2006 9:25 am
To: jes20@pitt.edu

Janet,

Attached is the incoming MTA that I need to fill out from Pitts end. If you fill out as much info as possible and send it back to me, I will complete.

Let me know a good day this week to get the boxes of tagged material, preferably this week (Friday would be best).

My lab can submit material to autoclave for you, however one of our two autoclaves are down and you would have to let me know the number of items that you intend to submit for me to confirm that we can do this.

T

From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
Sent: Thu 10/5/2006 12:05 PM
To: Mietzner, Timothy
Subject: [Fwd: RE: Material Transfer Agreement- Special Pathogens Lab isolates]

Hi Tim;
I'd like to move ahead with this transfer. Dr. Sonel says that the receiving lab would have the burden of telling us what documentation is needed to make the transfer. I don't know if this is a run around, but can you update me on this?

Also Sue said that the stuff we marked for taking can be removed. Can we schedule that for a time that is convenient for you?

One last request- if needed, can we use your autoclave for media prep and sterilization of filters?

JAnet

---------- Original Message ----------
Subject: RE: Material Transfer Agreement- Special Pathogens Lab isolates
From: "Sonel, Ali F" <Ali.Sonel@va.gov>
Date: Thu, October 5, 2006 11:16 am
To: jes20@pitt.edu
Cc: "Squeglia, Nicholas L" <Nicholas.Squeglia@va.gov>
"Melhem, Mona F" <Mona.Melhem@va.gov>
"Jain, Rajiv VAPHS" <Rajiv.Jain@va.gov>

We will work with you to facilitate the transfer. However more definitive deidentification would be needed than taping over identifiers.

In terms of the paperwork, please check with the laboratory that will be receiving them in terms of what documentation they would need from us in order to accept the transfer. While we would assist in any providing information needed from us, ultimately you would be responsible to complete the required paperwork.

-----Original Message-----

From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
Sent: Thursday, October 05, 2006 11:03 AM
To: Sonel, Ali F
Subject: RE: Material Transfer Agreement- Special Pathogens Lab isolates

Dr. Sonel;
The majority of the isolates are environmental in origin. Among any clinical isolates, the majority have been deidentified. I would be willing to over label any that would need to be further deidentified. Obviously my future research depends on this collection and I would appreciate every professional courtesy in facilitating this transfer.

It is my understanding that some documentation will be needed from the institution/laboratory that will house the isolates. Please provide whatever information we need to accomplish this

Thanks.

Janet

Dr. Stout,
> Do any of the isolates contain any reference numbers that could link it to human subjects? We could only consider releasing isolates that do not contain such identifiers.
>
> If they are only isolates without any direct or indirect linkage to human subjects, we could schedule a time for you to visit and identify

> what you would like to remove.
>
> AFS
>
> -----Original Message-----
> From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
> Sent: Sunday, October 01, 2006 11:26 PM
> To: Sonel, Ali F
> Subject: Material Transfer Agreement- Special Pathogens Lab isolates
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> Would you please tell me where I can obtain the material transfer
> forms and what other steps are necessary to accomplish this?
>
> Sincerely,
>
> Janet E. Stout, Ph.D.
>

Download this as a file

From: "Strelec, Barbara A" <Barbara.Strelec@va.gov>
Subject: Transfer of Isolates
Date: Tue, November 7, 2006 10:43 am
To: jes20@pitt.edu
Cc: "Sonel, Ali F" <Ali.Sonel@va.gov>

Good Morning Dr. Stout,

I am writing at the request of Dr. Sonel to help facilitate the transfer of your frozen collection of isolates from the Special Pathogens Lab to the University. As mentioned previously, the release is contingent upon the complete de-identification of the specimens. OHRP considers private information or specimens not to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. I understand that the majority of your specimens are de-identified and you agree to the complete de-identification of the remainder. Could you please forward information regarding how the identifiable specimens are labeled? It is necessary to establish a mutually agreed upon method of de-identification prior to the transfer. In addition, please forward a copy of the Materials Transfer Agreement and any other paperwork required for the transfer.

Thank you for your cooperation.

Sincerely,

Barbara Strelec
VA Pittsburgh Healthcare System
Research Education and Compliance Coordinator
7180 Highland Drive
Pittsburgh, PA 15206-1297
Phone (412) 365-4266
FAX (412) 365-4281

Download this as a file

From: "Strelec, Barbara A" <Barbara.Strelec@va.gov>
Subject: RE: Transfer of Isolates
Date: Fri, November 10, 2006 8:42 am
To: jes20@pitt.edu

Sounds good, I am working on things at this end. I hope we can resolve this for you soon.

Barbara

Barbara Strelec
VA Pittsburgh Healthcare System
Research Education and Compliance Coordinator
7180 Highland Drive
Pittsburgh, PA 15206-1297
Phone (412) 365-4266
FAX (412) 365-4281

-----Original Message-----
From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
Sent: Thursday, November 09, 2006 11:08 PM
To: Strelec, Barbara A
Cc: Sonel, Ali F
Subject: Re: Transfer of Isolates

Barbara;
I just got your message. I'll get this information to you next week.

Janet

> Good Morning Dr. Stout,
>
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> transfer of your frozen collection of isolates from the Special
> Pathogens Lab to the University. As mentioned previously, the
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> a copy of the Materials Transfer Agreement and any other paperwork
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> Research Education and Compliance Coordinator 7180 Highland Drive
> Pittsburgh, PA 15206-1297 Phone (412) 365-4266 FAX (412) 365-4281
>

>
>

Download this as a file

From: "Strelec, Barbara A" <Barbara.Strelec@va.gov>
Subject: RE: Transfer of Isolates
Date: Mon, November 20, 2006 9:06 am
To: jes20@pitt.edu

Hi Janet,

I was off for a few days, sorry for the delay. Yes, I think it would be good to meet. This is also a short week, I am off Wednesday and Friday. Next week I am attending a conference. Anytime the week of December 4th would be good for me. I understand you are anxious to get the specimens and will do what I can to expedite the process.

Thanks,

Barb

-----Original Message-----
From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
Sent: Wednesday, November 15, 2006 4:25 PM
To: Strelec, Barbara A
Subject: RE: Transfer of Isolates

Hi Barbara;
Do you want me to meet with you about the deidentification process or should I write something and have you review it? If you wish to meet with me, please give me a couple of days & times so that we can find a time that works for both of us. Thanks.

Janet

Sounds good, I am working on things at this end. I hope we can resolve
> this for you soon.
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> Barbara
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> Barbara Strelec
> VA Pittsburgh Healthcare System
> Research Education and Compliance Coordinator 7180 Highland Drive
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> From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
> Sent: Thursday, November 09, 2006 11:08 PM
> To: Strelec, Barbara A
> Cc: Sonel, Ali F
> Subject: Re: Transfer of Isolates
>
> Barbara;
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> Janet
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>> Research Education and Compliance Coordinator 7180 Highland Drive
>> Pittsburgh, PA 15206-1297 Phone (412) 365-4266 FAX (412) 365-4281
>>
>>
>>
>

Download this as a file

From: "Strelec, Barbara A" <Barbara.Strelec@va.gov>
Subject: RE: Transfer of Isolates
Date: Tue, November 28, 2006 8:46 am
To: jes20@pitt.edu

Good Morning Janet,

Yes, Tuesday the 5th at 10:00 AM still works for me. Please see the previous e-mail I sent. I will be out of the office until Friday and will check in with you then,

Thanks,

Barb

-----Original Message-----
From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
Sent: Sunday, November 26, 2006 3:46 PM
To: Strelec, Barbara A
Subject: RE: Transfer of Isolates

Barbara;
I have not received a response regarding a meeting for the 5th of December. Please let me know your availability or you can suggest an alternative day/time. Thanks.

Janet

Hi Barb;
> Can we meet on Tuesday the 5th at 10:00am? Please tell me again where
> you are located and your tel. no. In preparation for the meeting,
> please have your specific instructions for me in writing to facilitate

> our discussion. Thanks.
>
> Janet
>
> P.S. If you needd to reach me, my number is 412-719-0488
>
>
> ---
>
>
> Hi Janet,
>>
>> I was off for a few days, sorry for the delay. Yes, I think it would

>> be good to meet. This is also a short week, I am off Wednesday and Friday.
>> Next week I am attending a conference. Anytime the week of December
>> 4th would be good for me. I understand you are anxious to get the
>> specimens and will do what I can to expedite the process.
>>
>> Thanks,
>>
>> Barb
>>
>>
>>
>> -----Original Message-----
>> From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]

>> Sent: Wednesday, November 15, 2006 4:25 PM
>> To: Strelec, Barbara A
>> Subject: RE: Transfer of Isolates
>>
>> Hi Barbara;
>> Do you want me to meet with you about the deidentification process

>> or should I write something and have you review it? If you wish to
>> meet with me, please give me a couple of days & times so that we can
>> find a time that works for both of us. Thanks.
>>
>> Janet
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>>
>> _____
>>
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>> Sounds good, I am working on things at this end. I hope we can
>> resolve
>>> this for you soon.
>>>
>>> Barbara
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>>> Barbara Strelec
>>> VA Pittsburgh Healthcare System
>>> Research Education and Compliance Coordinator 7180 Highland Drive
>>> Pittsburgh, PA 15206-1297 Phone (412) 365-4266 FAX (412) 365-4281
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>>> From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
>>> Sent: Thursday, November 09, 2006 11:08 PM
>>> To: Strelec, Barbara A
>>> Cc: Sonel, Ali F
>>> Subject: Re: Transfer of Isolates
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>>>> you agree to the complete de-identification of the remainder.
>>>> Could you please forward information regarding how the identifiable

>>>> specimens are labeled? It is necessary to establish a mutually
>>>> agreed
>>> upon method of

From: "Strelec, Barbara A" <Barbara.Strelec@va.gov>
Subject: RE: Transfer of Isolates
Date: Mon, December 4, 2006 9:04 am
To: jes20@pitt.edu

Hi Janet,

I was away for a few days, sorry for the delay. I thought it would be best to actually take a look at the specimens to see how they are identified. I think it would make the day of the transfer easier. We can get access to the lab through security. Is that OK with you? I could meet you there at 10 AM tomorrow.

Thanks,
Barb

-----Original Message-----
From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
Sent: Wednesday, November 29, 2006 11:54 PM
To: Strelec, Barbara A
Subject: RE: Transfer of Isolates

Barbara;
Getting into the lab would require that you make a request to the laboratory to gain access to the lab. I do not have access.

Alternatively we can just meet in your office to discuss the specifics/requirements. Let me know how you want to proceed.

Janet

Good Morning Janet,
>
> Yes, October 5th at 10:00 AM will be fine. It might be a good idea to

> meet in the lab to identify exactly what specimens you would like to
> transfer and also to determine how we will de-identify them.
>
> Thanks,
>
> Barb
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> Barbara Strelec
> VA Pittsburgh Healthcare System
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> Pittsburgh, PA 15206-1297 Phone (412) 365-4266 FAX (412) 365-4281
>
>
>
> -----Original Message-----
> From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
> Sent: Tuesday, November 21, 2006 11:59 AM
> To: Strelec, Barbara A
> Subject: RE: Transfer of Isolates
>
> Hi Barb;
> Can we meet on Tuesday the 5th at 10:00am? Please tell me again
> where
> you are located and your tel. no. In preparation for the meeting,
> please have your specific instructions for me in writing to facilitate

> our discussion. Thanks.
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> Friday.
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>> From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
>> Sent: Wednesday, November 15, 2006 4:25 PM
>> To: Strelec, Barbara A
>> Subject: RE: Transfer of Isolates
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>> Hi Barbara;
>> Do you want me to meet with you about the deidentification process

>> or should I write something and have you review it? If you wish to
>> meet with me, please give me a couple of days & times so that we can
>> find a time that works for both of us. Thanks.
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From: jes20+@pitt.edu
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To: "Strelec, Barbara A" <Barbara.Strelec@va.gov>

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>>>>
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Download this as a file

From: "Sonel, Ali F" <Ali.Sonel@va.gov>
Subject: RE: Material Transfer Meeting Cancelled?
Date: Mon, December 4, 2006 6:34 pm
To: jes20@pitt.edu
Cc: "Squeglia, Nicholas L" <Nicholas.Squeglia@va.gov>,"Strelec, Barbara A" <Barbara.Strelec@va.gov>

Dr. Stout,
I was asked by the front office to put this process on hold. I or someone from the front office will be updating you soon regarding this request. I apologize for any inconvenience that this may have caused. Regards,

AFS

-----Original Message-----
From: jes20+@pitt.edu [mailto:jes20+@pitt.edu]
Sent: Monday, December 04, 2006 5:44 PM
To: Sonel, Ali F
Subject: Re: Material Transfer Meeting Cancelled?

Dr. Sonel;
Barbara Strelec requested that I meet her in the lab in building 2 to go over the process for the material transfer of our frozen stock collection. She called me late today to tell me that you instructed her to cancel the meeting. Would you please tell me why you told her not to proceed with this process?

Janet E. Stout, Ph.D.

> Good Morning Dr. Stout,
>
> I am writing at the request of Dr. Sonel to help facilitate the
> transfer of your frozen collection of isolates from the Special
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> Research Education and Compliance Coordinator 7180 Highland Drive
> Pittsburgh, PA 15206-1297 Phone (412) 365-4266 FAX (412) 365-4281
>
>
>

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Exhibit #8

Gmail +talk BETA

Janet Stout <jes20micro@gmail.com>

FW: Transfrer agreement from the VA to Pitt

Strelec, Barbara A <Barbara.Strelec@va.gov> **Mon, Nov 13, 2006 at 2:20 PM**
To: Janet Stout <jes20micro@gmail.com>

Dr. Stout,

We have not received a copy of the University's "incoming transfer" form referred to below. Could you please FAX it again to 412-365-4281? This comes directly into my office. We do have a copy of the VA Material Transfer Agreement. Can you please provide a FAX number to which I can send it? Also, we need to agree on how the specimens will be de-identified.

Thank you,

Barbara

Barbara Strelec
VA Pittsburgh Healthcare System
Research Education and Compliance Coordinator
7180 Highland Drive
Pittsburgh, PA 15206-1297
Phone (412) 365-4266
FAX (412) 365-4281
[Quoted text hidden]

Exhibit #9

From: "Herbers, Jerome (OIG)" <Jerome.Herbers@va.gov>
Subject: VA Legionnaire's Disease survey
Date: Tue, May 8, 2007 10:31 am
To: jes20@pitt.edu

Dr. Stout -

Thanks for your phone message. I pick up e-mail messages quickly, but sometimes miss voice messages for a while. I look forward to speaking with you and Dr. Yu about our survey results. I acknowledge that our efforts at moving VA healthcare facilities forward in LD prevention would not be possible without the advice you've generously given and, of course, without your pioneering work over the years.

Our report is now with VHA, which has another 2-3 weeks to develop a formal response and action plan. The report and response will subsequently be published for public access via the internet. Aside from this Friday, I have plenty of times available to speak by phone. Perhaps you could offer a time or two.

Yours,

Jerry Herbers

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Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 2008-010

February 11, 2008

PREVENTION OF *LEGIONELLA* DISEASE

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes guidelines for the annual evaluation of *Legionella* risk at VHA inpatient facilities.

2. BACKGROUND

a. The Gram-negative bacterium, *Legionella*, causes respiratory diseases including *Legionella* pneumonia (traditionally known as Legionnaires' disease), hereafter abbreviated as "LD" for "*Legionella* disease." Disease is primarily caused by *Legionella pneumophila*; however other species of *Legionella* can be pathogenic, particularly in transplant and other immunocompromised patients. The bacteria, found naturally in water, have been associated with man-made reservoirs, such as building water distribution systems and cooling towers. Disease occurs after inhalation or aspiration of contaminated water, followed by an average incubation period of 2 to 10 days. The disease is not transmitted from person-to-person.

b. Health care facilities have been connected with the transmission of *Legionella* to patients. Such cases, often termed health care-associated (HCA) LD, frequently arise due to the presence of *Legionella* bacteria in hospital hot water distribution systems. However, HCA LD has also been associated with respiratory care equipment, ice machines, decorative fountains, hot tubs, and cooling towers. The Centers for Disease Control and Prevention (CDC) considers laboratory-confirmed cases to be "definite" HCA LD if continuous inpatient stay is equal to or greater than 10 days prior to onset of LD, or "possible" HCA LD if inpatient stay is 2 to 9 days prior to onset of LD.

c. Bone marrow and solid organ transplant patients are at increased risk for contracting HCA LD. Other at-risk patients include the immunocompromised (due to, for example, malignancy, renal disease, or diabetes), those over 65 years of age, those with chronic lung disease, and smokers.

d. Prevention of HCA LD depends on minimizing the exposure of patients to *Legionella* in facility water systems. A number of preventive measures are available including maintenance of appropriate hospital hot water temperatures to limit the growth of *Legionella*. Current evidence indicates that treatment of water with monochloramine or the addition of a copper-silver ionization system can reduce the amount of *Legionella* in facility water systems. Monitoring hospital water systems for *Legionella* and implementation of mitigation efforts, if necessary, can be an important component of a prevention plan to reduce HCA LD.

e. A multidisciplinary VHA Expert Working Group has developed guidance for the prevention of HCA LD at VHA inpatient facilities in response to the recommendations of the Department of Veterans Affairs Office of Inspector General in the 2007 Report, "Assessment of Legionnaire's Disease Risk in Veterans Health Administration Inpatient Facilities." The VHA

Expert Working Group consisted of experts from transplant facilities, infectious diseases, pulmonary and critical care medicine, pathology and laboratory medicine, infection prevention and control, engineering, public health, occupational health, and operations.

3. POLICY: It is VHA Policy that all inpatient facilities implement an annual evaluation for LD prevention in accordance with a facility written plan.

4. ACTION

a. **Network Director.** The Network Director is responsible for ensuring that all inpatient facilities in the network jurisdiction perform an annual evaluation for prevention of LD.

b. **Facility Director.** The facility Director is responsible for ensuring that:

(1) The facility has a written plan for the annual evaluation of LD prevention using the guidance noted below and provided in Attachment A.

(a) Transplant facilities and facilities where at least five post-transplant patients per year are cared for within 3 months of the transplant procedure need to have the facility plan written not later than March 14, 2008.

(2) Completion of the first facility evaluation occurs not later than May 1, 2008.

(3) The facility reviews and implements the *Legionella* evaluation plan annually.

(4) The evaluation is reported to the facility Infection Control Committee (ICC), or equivalent, and other appropriate staff.

c. **Chief of Staff.** The Chief of Staff is responsible for ensuring that clinical care staff is knowledgeable in the diagnosis and treatment of all pneumonias, including pneumonia due to *Legionella* species.

d. **Chief of Pathology and Laboratory Medicine Service.** The facility Chief of Pathology and Laboratory Medicine is responsible for:

(1) Ensuring that the facility laboratory has access to *Legionella pneumophila* serogroup 1 urinary antigen testing. Transplant Centers and those facilities that care for at least five post-transplant patients per year within the first 3 months of the transplant surgery need to consider on-site availability of *L. pneumophila* serogroup 1 urinary antigen testing.

(2) Ensuring that, if the facility is a Transplant Center or cares for at least five post-transplant patients per year within the first 3 months of the transplant surgery, the facility has access to a clinical laboratory that can perform cultures on respiratory secretions for pathogenic species of *Legionella* other than *L. pneumophila*, including at least those non-*pneumophila*

species that are most frequently linked to HCA LD in immunosuppressed patients (*L. micdadei*, *L. bozemanii*, *L. dumofii* and *L. sainthelensis*).

(3) Ensuring that clinical cultures for *Legionella* and/or antigen tests are performed in accordance with current VHA policy on laboratory testing.

(4) Ensuring that results from laboratory tests and clinical cultures are entered into the Computerized Patient Record System (CPRS) in a clinically relevant timeframe.

(5) Ensuring that, if the facility collects environmental samples for *Legionella* testing, the facility has access to a laboratory that can perform cultures for *Legionella pneumophila* (see Att. D for considerations when selecting an environmental testing laboratory). If the facility is a Transplant Center or cares for at least five post-transplant patients per year within the first 3 months of the transplant surgery, the facility needs to have access to a laboratory that can culture environmental samples for *L. pneumophila* and at least the other pathogenic *Legionella* species listed in paragraph 4d(2) of this Directive.

(6) Ensuring that any environmental samples collected for *Legionella* testing are appropriately transferred to the environmental testing laboratory. ***NOTE:*** *It may be prudent to consult with the environmental testing laboratory for recommendations and requirements regarding sample shipping.*

(7) Annually providing the facility ICC with the:

(a) Total number of urinary antigen tests and clinical cultures for *Legionella* ordered,

(b) Total number of persons with positive results for *Legionella*, and

(c) Results of any environmental testing for *Legionella*.

e. **Chief Engineer or Facility Manager.** The Chief Engineer or Facility Manager is responsible for:

(1) Regular monitoring, maintenance and cleaning of the facility water distribution system(s) and cooling towers, and documenting these activities.

(2) Maintenance of appropriate water temperatures in the hot water distribution system(s) in accordance with current VHA policy.

(3) Routinely ensuring that any extra measures implemented in the facility water treatment system for the prevention of *Legionella* are functioning according to the manufacturer's specifications and at recommended capacity for *Legionella* inhibition.

(4) Routinely confirming with appropriate municipal officials that the monochloramine treatment system is functioning properly, if a municipal water source treated with monochloramine is used at the facility.

(5) Planning, directing, overseeing, and documenting post-construction commissioning activities that minimize risk of exposure to *Legionella*, in accordance with current VHA policy. Commissioning needs to take into consideration the impact that the construction had on piped plumbing systems (alteration, disturbance, stagnation) and the past history of HCA LD or system contamination with *Legionella*. For example, flushing of all outlets as a pre-occupancy precaution may be sufficient if there is no history of the organism in the system's water or of prior cases of HCA LD; however, if a history of contamination or HCA LD exists, it may be prudent to take more aggressive measures (such as hyper-chlorination or thermal eradication) followed by culturing the water for the presence of *Legionella* to assure effectiveness of mitigation activity. ***NOTE:*** *Consider similar activities before inactive portions of the water distribution system (e.g., unused showers) are reused.*

(6) Providing the facility ICC with an annual report of the water system maintenance and monitoring, and any *Legionella* mitigation actions taken.

f. **Facility Infection Control Committee (ICC) or Equivalent.** The facility ICC is responsible for:

(1) Developing an Action Plan for mitigation of *Legionella* in facility water systems (see Att. E for guidelines).

(2) Recording in the ICC's minutes the collection of annual summaries from Pathology and Laboratory Medicine Service and Engineering Service or Facilities Management, along with annual *Legionella* evaluation and risk assessment reports.

5. REFERENCES

a. American Society for Heating, Refrigerating and Air-conditioning Engineers (ASHRAE). Guideline 12-2000. Minimizing the Risk of Legionellosis Associated with Building Water Systems; 2000.

b. CDC. Guidelines for Environmental Infection Control in Health-care Facilities. Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Morbidity and Mortality Weekly Reports (MMWR) 52 (RR10):1-42; 2003. www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a1.htm

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d. Department of Veterans Affairs Office of Inspector General. Assessment of Legionnaire's Disease Risk in Veterans Health Administration Inpatient Facilities. Report No. 07-00029-151; June 20, 2007.

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l. World Health Organization (WHO). *Legionella* and the Prevention of Legionellosis. WHO Press; 2007 http://www.who.int/water_sanitation_health/emerging/legionella.pdf

6. FOLLOW-UP RESPONSIBILITY: The Chief Officer, Patient Care Services (11) is responsible for the contents of this Directive. Questions relating to the technical aspects of this Directive and to LD may be referred to the Infectious Diseases Program Office at (513) 475-6398. Questions relating to the Laboratory aspects of this Directive may be referred to the Pathology and Laboratory Medicine Service Line Director at (202) 273-8332. Questions regarding Engineering aspects of this Directive may be referred to the Director, Healthcare Engineering (10NB) at (202) 266-4604.

7. RECISSIONS: None. This VHA Directive expires February 28, 2013.

Michael J. Kussman, MD, MS, MACP
Under Secretary for Health

Attachments

DISTRIBUTION: CO: E-mailed 2/14/08
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 2/14/08

ATTACHMENT A

GUIDELINES FOR INPATIENT FACILITY *LEGIONELLA* EVALUATION PLANS

1. Definitions. The following definitions apply for the purpose of this Directive:

a. ***Legionella* Evaluation Plan.** The *Legionella* Evaluation Plan is the written document that calls for the annual appraisal of the considerations and activities a facility needs to implement to prevent HCA LD.

b. ***Legionella* Risk Assessment.** The *Legionella* Risk Assessment is a component of the facility *Legionella* evaluation plan that calls for the collection of environmental or clinical samples for *Legionella* testing to determine if mitigation is necessary.

c. **Transplant Center.** A Transplant Center is a facility that is designated by Veterans Health Administration (VHA) to conduct bone marrow or solid organ transplants.

d. **Immediate post-tranplant care facility.** An immediate post-transplant care facility is one that, in the past year, has cared for at least five patients within 3 months of the transplant procedure.

2. Appropriate *Legionella* evaluation plans need to be in place for each of the following specific types of facilities: an inpatient facility that is an Acute Care (non-transplant) facility; a Nursing Home Care Unit (NHCU), including what some may call "Long Term Care Units", not physically housed within an Acute Care building; or a Transplant Center or immediate post-transplant care facility. This status needs to be reviewed annually and the facility evaluation plan amended if necessary.

a. Based on the facility classification, algorithms have been developed for the annual *Legionella* evaluation plan. These algorithms are described in detail in this Attachment (Att. A), and are summarized as flowcharts in Attachment B (Non-transplant Acute Care facilities and NHCU facilities) and Attachment C (Transplant Centers/immediate post-transplant care facilities). ***NOTE:*** *Facilities that care for less than five transplant patients in a year within the three months of the transplant procedure need to be cognizant of the increased susceptibility of these patients to LD. Consider the implementation of measures to prevent* Legionella *transmission to these patients, such as sequestration to a particular section of the building to facilitate* Legionella *control.*

b. For facilities with multiple campuses, each campus needs to be considered as a separate location, and each campus with inpatient facilities needs to have a separate and appropriate *Legionella* evaluation plan(s).

3. If the facility is a VHA Acute Care (non-transplant) facility, or a NHCU not physically housed within an Acute Care building, then a facility *Legionella* evaluation plan needs to be written for implementation that includes the following considerations (see Att. B for summary flowchart):

NOTE: *If the NHCU is housed within an Acute Care facility, then a separate Unit* Legionella *evaluation plan is not required; instead, the* Legionella *evaluation plan needs to be developed at the Acute Care facility level that includes consideration of the NHCU.*

a. Determine if there is a history of epidemiologically-linked HCA LD ever at the facility.

(1) "Epidemiologically-linked" refers to the association of a suspected HCA LD case in the facility to exposure of the patient to *Legionella* at the facility. The ICC determines the criteria for epidemiological linkage of LD cases to the facility. Examples of criteria to consider for epidemiological linkage of suspected HCA LD include, but are not limited to:

(a) Temporal association (e.g., any LD patient with 10 or more days of continuous inpatient care prior to onset of LD),

(b) Environmental association (e.g., isolation of *L. pneumophila* serogroup 1 from the facility water system);

(c) Outbreak association (e.g., more than one HCA LD case at the facility within a defined time period),

(d) Molecular association (e.g., genetically-identical strains of *L. pneumophila* serogroup 1 isolated from clinical and environmental samples).

NOTE: *For case investigations, the facility may need to consider appropriate sub-culturing and storage of clinical and environmental* Legionella *isolates depending on the criteria used for epidemiological linkage.*

(2) If there has been a history of epidemiologically-linked HCA LD, then the facility needs to implement an Action Plan, determined by the facility ICC, for ongoing mitigation of *Legionella* in the water distribution system, and monitoring and evaluation of the mitigation effort (see Att. E). ***NOTE:*** *Any existing water treatment systems present for the prevention of waterborne pathogens, such as copper-silver ionization or monochloramine, can be included as part of the mitigation protocol of the Action Plan; water treatment systems need to be regularly monitored and evaluated.*

(3) Acute care (non-transplant) facilities and NHCU facilities not housed within an acute care facility that do not have a history of epidemiologically-linked HCA LD need to proceed to the following actions depending on whether or not the facility water source (e.g., municipal water) is treated with monochloramine:

(a) If the water is treated with monochloramine, then no routine environmental or clinical testing for *Legionella* or LD is required. Facilities need to, however, maintain a high index of suspicion for LD in patients. If a case of LD is diagnosed, determine if there is epidemiological linkage of the case to the facility (see subpar. 3a(1) of Att. A). ***NOTE:*** *Proper functioning of the monochloramine treatment system needs to be routinely verified (see subpar. 4e(4) of Directive).*

If the monochloramine treatment system is not functioning properly then the evaluation continues as if no such system is present.

(b) If the water is not treated with monochloramine, then the facility needs to implement an annual *Legionella* Risk Assessment plan. This plan has the option of including either environmental testing for *Legionella pneumophila* serogroup 1, or clinical screening of patients for LD.

1. Environmental Testing. Testing of select distal water sites (e.g., faucets and showers) of the facility hot water distribution system(s) needs to be done at least annually. The facility is responsible for determining the frequency of environmental testing, and the number and location of distal water sites. See Att. D for guidelines on distal site selection, and sample collection and processing. Remedial action for *Legionella*-positive environmental samples occurs if the percentage of positive distal sites is above a "threshold level" determined by the facility. This threshold level needs to be explicitly stated in the written *Legionella* evaluation plan. ***NOTE:*** *It is recommended that the threshold level for positive distal sites be set at 30 percent. For example: if a facility tests water from ten distal sites and four sites are positive for* L. pneumophila *serogroup1, then remedial action is implemented because the percentage of positive distal sites (40 percent) is above the threshold level for action (30 percent). If the threshold level for action is set higher than 30 percent, then the written plan needs to provide the rationale for this decision.* If remedial action is needed, the facility implements an Action Plan, determined by the facility ICC, to reduce *Legionella* in the water distribution system (see Att. E). If the percentage of *Legionella*-positive distal sites is less than the threshold level for action, then the Action Plan does not need to be implemented.

2. Clinical Screening. Alternatively, a subset of the facility patient population with HCA pneumonia needs to be screened annually for *L. pneumophila* serogroup 1 using urinary antigen testing. The facility determines the number of patients to be tested in a year. This number must be a minimum of ten patients or 10 percent of annual HCA pneumonia cases (if whole-house surveillance is done and the annual number of HCA pneumonia cases is known), whichever number is greater. For example, a facility with 150 HCA pneumonia cases annually would need to test at least 15 cases for LD; however, a facility with 20 HCA pneumonia cases annually would need to test at least ten cases (not two cases). A facility that does not know the number of HCA pneumonia cases per year would need to test at least ten cases. If a laboratory-confirmed case of HCA LD is identified, then the case needs to be examined for epidemiological linkage to the facility (see subpar 3a(1) of Att. A). Positive epidemiological linkage prompts implementation of the facility Action Plan, determined by the facility ICC (see Att. E).

b. A written report must be reviewed by the facility ICC annually on the implementation of the LD evaluation plan and on whether there was LD risk identified for the facility. If risk was identified, a summation of the Action Plan needs to be included in the report.

4. If the facility is a VHA-designated Transplant Center, or an immediate post-transplant care facility, then a facility *Legionella* evaluation plan needs to be written for implementation that includes the following considerations (see Att. C for summary flowchart):

a. Determine if there is a history of epidemiologically-linked HCA LD ever at the facility.

(1) "Epidemiologically-linked" refers to the association of an HCA LD case in the facility to exposure of the patient to pathogenic *Legionella* species at the facility (see subpar. 4d(2) of the Directive for a list of species). The ICC determines the criteria for epidemiological linkage of LD cases to the facility. Examples of criteria to consider for epidemiological linkage of suspected HCA LD include, but are not limited to:

(a) Temporal association (e.g. any LD patient with 10 or more days of continuous inpatient care prior to onset of LD),

(b) Environmental association (e.g., isolation of pathogenic *Legionella* from the facility water system),

(c) Outbreak association (e.g., more than one HCA LD case at the facility within a defined time period),

(d) Molecular association (e.g., genetically identical strains of pathogenic *Legionella* isolated from clinical and environmental samples).

NOTE: *For case investigations, the facility may need to consider appropriate sub-culturing and storage of clinical and environmental* Legionella *isolates depending on the criteria used for epidemiological linkage.*

(2) If there has been a history of epidemiologically-linked HCA LD, the facility needs to:

(a) Implement an Action Plan, determined by the facility ICC, for ongoing mitigation of *Legionella* in the water distribution system, and monitoring and evaluation of the mitigation effort (see Att. E).

1. The Action Plan environmental monitoring must not be less frequent than two times per year.

2. Any existing water treatment systems present for the prevention of waterborne pathogens, such as copper-silver ionization or monochloramine, can be included as part of the mitigation protocol of the Action Plan. Water treatment systems need to be regularly monitored and evaluated.

(b) Routinely test all patients at the facility (not just transplant patients) with HCA pneumonia for LD. Any laboratory-confirmed positive results for HCA LD need to be assessed for epidemiological linkage to the facility (see subpar. 4a(1) of Att. A) and reported to the facility ICC.

(3) If the facility does not have a history of epidemiologically-linked HCA LD, then the facility needs to implement biannual environmental testing of facility water distribution system distal sites (e.g. faucets and showers) for *Legionella pneumophila* and the other pathogenic *Legionella* species listed in subpar. 4d(2) of the Directive (see Att. D for sampling guidelines).

(a) For each round of biannual testing, at least ten distal sites need to be tested for the presence of pathogenic *Legionella* species. Any positive results need to be reported to the facility ICC. Remedial action is implemented if the percent of positive distal water sites is above the "threshold level" determined by the facility. ***NOTE:*** *It is recommended that the threshold level be set at 30 percent. For example: if a facility tests water from ten distal sites and four sites are positive for* Legionella, *then remedial action is implemented since the percentage of positive distal sites (40 percent) is above the threshold level for action (30 percent). If the threshold level for action is set higher than 30 percent, then the written plan needs to provide the rationale for this decision.* Remedial action needs to include both:

1. Implementation of an Action Plan, determined by the facility ICC, for mitigation of the *Legionella* hazard in the water distribution system, and monitoring and evaluation of the mitigation effort (see Att. E), and

2. If the environmental samples are positive for *Legionella pneumophila* serogroup 1, then all patients at the facility (not just transplant patients) with HCA pneumonia need to be tested for LD by urinary antigen testing. If the environmental samples are positive with another pathogenic *Legionella* species, then the facility needs to perform cultures of respiratory secretions on all transplant patients with HCA pneumonia. Any laboratory-confirmed positive results for HCA LD need to be assessed for epidemiological linkage to the facility (see subpar. 4a(1) of Att. A) and reported to the facility ICC.

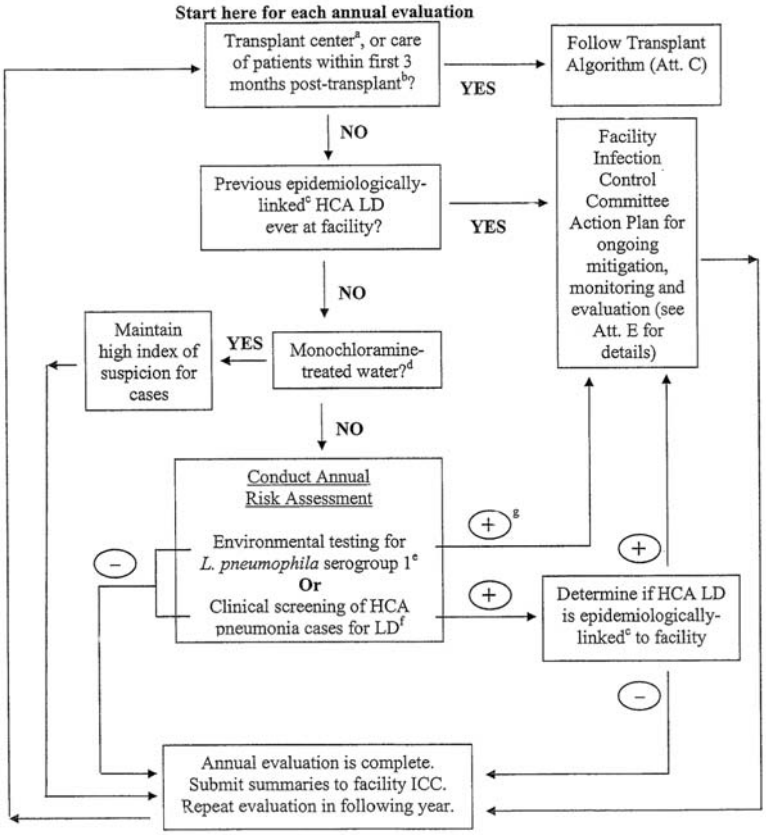
(b) If both sets of the biannual environmental testing yield negative results (i.e., the percentage of positive distal sites is below the threshold level for action), then the annual facility *Legionella* evaluation is complete.

1. For the first year only that the evaluation plan is implemented, if a facility had not performed environmental testing for *Legionella* within the past 2 years (i.e., prior unknown environmental risk), then the facility needs to test all transplant patients with suspected HCA pneumonia for LD until initiation of the next annual evaluation. If there are no diagnoses of HCA LD, then the annual evaluation is complete. If cases of HCA LD are diagnosed, then the facility needs to determine if the cases are epidemiologically-linked to the facility (see subpar. 4a(1) of Att. A). If the cases are epidemiologically-linked, then proceed to implementing the facility Action Plan (see Att. E) and clinical testing of all HCA pneumonia cases for LD. If the cases are not epidemiologically-linked to the facility, then the annual evaluation is complete.

b. A written report must be reviewed by the facility ICC annually on the implementation of the *Legionella* evaluation plan and on whether there was *Legionella* risk identified for the facility. If risk was identified, a summation of the Action Plan needs to be included in the report.

ATTACHMENT B

ANNUAL *LEGIONELLA* FACILITY EVALUATION ALGORITHM FOR ACUTE CARE (NON-TRANSPLANT) FACILITIES, AND FOR NHCU NOT PHYSICALLY HOUSED WITHIN AN ACUTE CARE FACILITY ***NOTE:*** *See page B-2 for the legend of the diagram.*



1. Legend for Acute Care (non-transplant) and Nursing Home Care Unit (NHCU) algorithm:

a. VHA-designated facilities that conduct bone marrow and/or solid organ transplants.

b. Facilities that, in the past year, cared for at least five patients in the 3 months following the transplant procedure.

c. "Epidemiologically-linked" refers to the association of a health care-associated (HCA) *Legionella* Disease (LD) case in the facility to exposure of the patient to *Legionella pneumophila* serogroup 1 at the facility. The ICC determines the criteria for epidemiological linkage of LD cases to the facility. Examples of criteria to consider for epidemiological linkage of suspected HCA LD include, but are not limited to: temporal association (e.g. any LD patient with 10 or more days of continuous inpatient care prior to onset of LD), environmental association (e.g. isolation of *L. pneumophila* serogroup 1 from the facility water system), outbreak association (e.g. more than one HCA LD case at the facility within a defined time period), or molecular association (e.g., genetically identical strains of *L. pneumophila* serogroup 1 isolated from clinical and environmental samples).

d. For each annual implementation of the LD evaluation plan, the Engineering Service or Facilities Management is responsible for routinely verifying with water source officials that the monochloramine treatment system is functioning properly. If the monochloramine treatment system is not functioning properly, then the facility needs to proceed to the Annual Risk Assessment.

e. See Attachment D for guidelines on environmental sampling procedures.

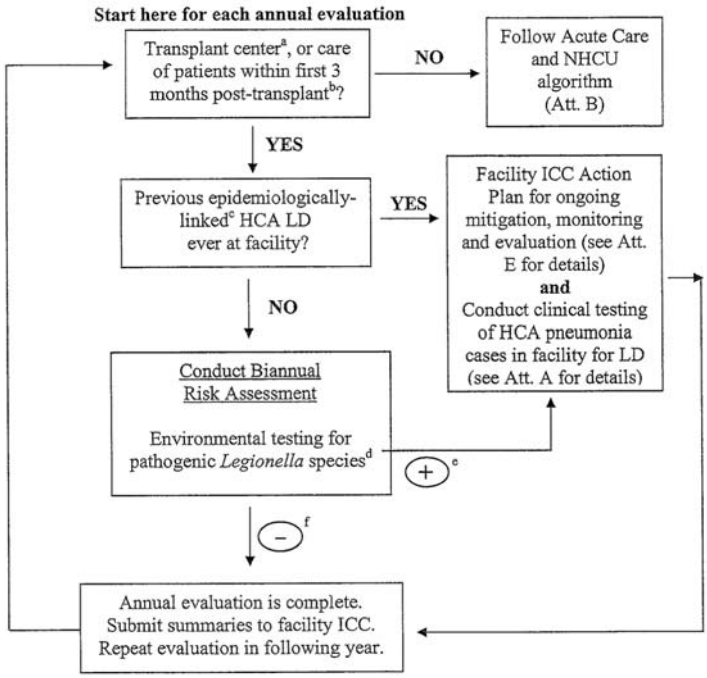
f. A subset of the facility patient population with HCA pneumonia needs to be screened annually for *L. pneumophila* serogroup 1 using urinary antigen testing. The facility determines the number of patients to be tested in a year. This number must be a minimum of ten patients or 10 percent of annual HCA pneumonia cases (if whole-house surveillance is done and the annual number of HCA pneumonia cases is known), whichever number is greater. For example, a facility with 150 HCA pneumonia cases annually would need to test at least fifteen cases for LD; however, a facility with twenty HCA pneumonia cases annually would need to test at least 10 cases (not two cases). A facility that does not know the number of HCA pneumonia cases per year would need to test at least ten cases.

g. Remedial action for *Legionella* positive environmental samples occurs if the percentage of positive distal sites is above a "threshold level" determined by the facility. It is recommended that the threshold level be set at 30 percent. For example: if a facility tests water from ten distal sites and four sites are positive for *Legionella*, then remedial action is implemented since the percentage of positive distal sites (40 percent) is above the threshold level for action (30 percent).

ATTACHMENT C

ANNUAL *LEGIONELLA* FACILITY EVALUATION ALGORITHM FOR TRANSPLANT CENTERS[a] AND FACILITIES THAT CARE FOR POST-TRANSPLANT PATIENTS[b]

NOTE: *See page C-2 for the legend of the diagram.*



1. Legend for transplant center and post-transplant care algorithm:

a. Veterans Health Administration (VHA) designated facilities that conduct bone marrow and/or solid organ transplants.

b. Facilities that, in the past year, cared for at least five patients in the 3 months following the transplant procedure.

c. "Epidemiologically-linked" refers to the association of a health care associated (HCA) *Legionella* Disease (LD) case in the facility to exposure of the patient to a pathogenic *Legionella* species (listed below in subpar. 1d) at the facility. The ICC determines the criteria for epidemiological linkage of LD cases to the facility. Examples of criteria to consider for epidemiological linkage of suspected HCA LD include, but are not limited to: temporal association (e.g., any LD patient with 10 or more days of continuous inpatient care prior to onset of LD), environmental association (e.g., isolation of pathogenic *Legionella* from the facility water system), outbreak association (e.g., more than one HCA LD case at the facility within a defined time period), or molecular association (e.g., genetically identical strains of pathogenic *Legionella* isolated from clinical and environmental samples).

d. The pathogenic *Legionella* species that environmental samples at least need to be tested for are *L. pneumophila*, *L. micdadei*, *L. bozemanii*, *L. dumofii* and *L. sainthelensis* (see Att. D for guidelines on environmental sampling procedures).

e. Remedial action for *Legionella* positive environmental samples occurs if the percentage of positive distal sites is above a "threshold level" determined by the facility. It is recommended that the threshold level be set at 30 percent. For example: if a facility tests water from 10 distal sites and four sites are positive for *Legionella*, then remedial action is implemented because the percentage of positive distal sites (40 percent) is above the threshold level for action (30 percent).

f. For the <u>first year only</u> that the evaluation plan is implemented, if a facility had not performed environmental testing for *Legionella* within the past 2 years (i.e., prior unknown environmental risk), then the facility should test all transplant patients with suspected HCA pneumonia for LD until initiation of the next annual evaluation. If there are no diagnoses of HCA LD, then the annual evaluation is complete. If cases of HCA LD are diagnosed, then the facility needs to determine if the cases are epidemiologically-linked to the facility (see subpar. 4a(1) of Att. A). If the cases are epidemiologically-linked, then proceed to implementing the facility Action Plan (see Att. E) and clinical testing of all HCA pneumonia cases for LD. If the cases are not epidemiologically-linked to the facility, then the annual evaluation is complete.

ATTACHMENT D

ENVIRONMENTAL WATER SAMPLING PROTOCOL

1. The facility determines when environmental samples are to be collected based upon the need for routine environmental risk assessment or mitigation.

2. Determination of who is responsible for the collection of the environmental samples needs to be agreed upon by the facility Infection Control Committee (ICC), Engineering Service or Facilities Management, and Pathology and Laboratory Medicine Service.

3. Once collected, samples are to be processed by a testing laboratory with experience in microbial testing of potable water. ***NOTE:*** *It is recommended that the facility Pathology and Laboratory Medicine Service be involved in selection of the testing laboratory.*

a. Considerations when selecting an environmental testing laboratory include:

(1) Use of an environmental testing laboratory that meets, at least, the minimal requirements for state-certified competency of microbial testing of potable water.

(2) Selection of a laboratory that is proficient at performing the culture of *Legionella* species from environmental samples. ***NOTE:*** *Rapid testing methods, such as polymerase chain reaction (PCR) and direct fluorescent antibody (DFA), are not recommended for the detection of Legionella in environmental water samples.*

(a) Samples from Acute Care (non-transplant) facilities and Nursing Home Care Unit (NHCU) need to be cultured for *Legionella pneumophila*.

(b) Samples from Transplant Centers and facilities where at least five patients per year are cared for within the first 3 months of the transplant procedure need to have cultures performed for at least the following *Legionella* species: *L. pneumophila, L. micdadei*, *L. bozemanii*, *L. dumofii,* and *L. sainthelensis*.

(3) Selection of a laboratory capable concentrating water samples prior to plating the samples on selective media to increase the sensitivity of the assay (see subpar. 5k of the Directive). A limit of detection of ten colony forming units per milliliter is recommended for the culture of *Legionella* from water samples.

(4) If there is a possibility that the facility will need molecular characterization of environmental *Legionella* isolates, consider selection of a laboratory that can, at least, temporarily store the isolates appropriately.

b. The facility Pathology and Laboratory Medicine Service is responsible for ensuring that the samples are transferred to the environmental testing laboratory and recording the results from the testing. Any positive results are to be reported to the facility ICC. ***NOTE:*** *It would*

be prudent to confirm with the testing laboratory any requirements and/or recommendations for the transfer of environmental samples.

4. Location of water samples in the water distribution system.

a. **Distal water sites.** Distal water sites are the points in the water distribution system where the end user (e.g., patient) comes in contact with the water (e.g., faucets and showers).

(1) Distal water sites are sampled any time environmental sampling is needed in the course of implementing the facility *Legionella* evaluation plan (e.g., for routine environmental surveillance, or for monitoring of an Action Plan mitigation effort).

(2) Consider sampling at least ten distal water sites at the facility. Transplant centers and facilities that provide immediate post-transplant care need to consider the sampling of more than ten distal sites.

(3) Considerations when selecting site numbers and locations include:

(a) If a facility has greater than 500 beds, increase the sample size by two distal sites per 100 beds over 500. For example, a facility with 700 beds would test 14 distal sites (first 500 beds = 10 sites, then add 4 sites for the additional 200 beds over 500).

(b) If environmental testing is initiated due to a suspected HCA LD case, samples from distal sites in the immediate vicinity of the case should be included in the samples collected.

(c) Sampling includes sites from high risk areas (e.g., hematology-oncology, transplant units, medical-surgical units).

(d) Some facilities may have more than one water distribution system; therefore, it is important to ensure that all systems are included in the distal sites sampled.

b. **Hot Water Tanks (HWT).** If the facility needs to implement environmental water testing to monitor an Action Plan mitigation effort (e.g., due to a prior history of epidemiologically-linked HCA LD or positive environmental screening results), then it is recommended that two samples are taken from each HWT in addition to testing at least ten distal water sites.

5. Collecting samples from distal sites.

a. Options for sample collection methods include collecting a volume of water at each distal site or collecting swab samples at each distal site.

b. The facility needs to determine if it is appropriate to collect water and/or swab samples. Considerations include whether the samples are for routine environmental screening or for a case investigation, ability to collect the samples, and the transport of the samples to the testing laboratory. Prior to sampling, it would be prudent to consult with the environmental testing

laboratory for requirements and/or recommendations on sample collection and shipping.
NOTE: *Optimal sensitivity is desirable in the context of a case investigation (e.g., that results from clinical screening). Therefore, consideration needs to be given to collecting both water and swab samples from the water outlets in the immediate environment of a suspected case.*

c. The following procedure is recommended for distal site water sampling:

(1) Turn on the hot water faucet.

(2) Immediately fill a specimen container with a minimum of 100 milliliters (ml) of water.
NOTE: *If the testing laboratory requires a larger sample volume, follow their recommendations.*

(3) Label container with location and "immediate sample".

(4) Refrigerate samples at 2-8°Celsius (C) until processing.

d. The following procedure is recommended for distal site swab sampling:

(1) Remove aerator, if present.

(2). Moisten the distal site outlet by allowing water to trickle through the opening.

(3) Remove a sterile swab from its transport container. Insert the swab into the outlet and rotate four times around the inner circumference and moving up the faucet as far as the swab will reach.

(4) For showerheads, rotate the swab over the entire surface of the showerhead four times.

(5) Replace the swab into the container.

(6) If no liquid media is in the swab container, add a few mls of water from the sample source.

(7) Label the swab container with the sample location.

6. Collecting water samples from HWTs. It is recommended that two samples be taken from each HWT as follows:

a. Open the drain valve and immediately fill one specimen container with 100 ml of water. Label the container with the sample location and "HWT 1st sample"

b. Allow the water to flow for approximately 30 seconds to 1 minute. Fill a second specimen container with 100 ml of water. Label the container with the sample location and "HWT 2nd sample"

NOTE: *These samples represent both the tank contents and the residual water within the drain pipe.* L. pneumophila *is often recovered from samples which contain sediment (scale); however, thick rusty sediment can actually inhibit* Legionella *growth.*

c. Refrigerate samples at 2-8°C until processing.

ATTACHMENT E

ACTION PLAN FOR THE MITIGATION OF *LEGIONELLA* IN FACILITY WATER DISTRIBUTION SYSTEMS

1. The facility Infection Control Committee (ICC) needs to develop an Action Plan after the need for remedial action for environmental control of *Legionella* is identified. If Engineering Service or Facilities Management is not regularly represented on the facility ICC, then, for purposes of this Action Plan, the ICC needs to work with this office.

2. Considerations for the Action Plan include the following:

a. **Mitigation Protocol**

(1) The mitigation protocol needs to be implemented in the following situations:

(a) If the facility has positive environmental risk assessment results, the mitigation protocol needs to be implemented to reduce the percentage of *Legionella*-positive distal sites below the threshold level. For example, if a facility determines that the threshold percentage of *Legionella*-positive distal sites is 30 percent (e.g., three positive sites out of ten distal sites tested), then mitigation efforts need to reduce the percent of positive distal sites to below 30 percent.

(b) If the facility has a history of epidemiologically-linked health care associated (HCA) *Legionella* disease (LD) or if the facility identified epidemiologically-linked HCA LD from clinical screening, then the mitigation protocol needs to be implemented to reduce the risk of exposure of patients to *Legionella* from the facility water distribution system.

(2) Mitigation protocol options. There are a number of options for mitigation protocols to reduce *Legionella* in water systems. Facilities may consider the implementation of more than one mitigation option in the Action Plan. Options for mitigation include, but are not limited to:

(a) Thermal Eradication. This method, also referred to as superheat and flush, uses high water temperature to kill *Legionella* present in the water system. The procedure involves the temporary resetting of the hot water temperature to 160 degrees Fahrenheit (°F) - 170°F (71 degrees Celsius [°C] - 77°C) and the flushing of the system by selectively opening all valves for at least 30 minutes. Thermal eradication is temporary; *Legionella* species typically reappear in 1 to 3 months after the procedure. ***NOTE:*** *Since there is* ***significant risk for scalding*** *at the water temperatures used for thermal eradication, extreme care must be taken to protect end users of the water distribution system.*

(b) Hyperchlorination. This method involves increasing the chlorine level such that a free chlorine residual of at least 2 milligrams (mg) per liter (L) is maintained throughout the system for at least 2 hours (but not exceeding 24 hours). Chlorination of the water heater or tank to a concentration of 20 to 50 mg/L may be required to achieve this level of free chlorine residual. After the hyperchlorination procedure is complete, the system needs to be thoroughly flushed. Hyperchlorination results in temporary eradication of *Legionella*.

(c) Copper-silver ionization. Consider addition of a copper-silver ionization system to the facility water system for *Legionella* control. Studies have shown that use of a copper-silver ionization system can reduce *Legionella* in hospital water systems and HCA LD. ***NOTE:*** *Proper use, monitoring and maintenance documentation of the system are necessary to ensure appropriate activity for inhibition of* Legionella.

(d) Point-of-use filters. Filters are attached at distal water sites, such as faucets and showers, to prevent exposure of patients to even low levels of *Legionella* in the water. This mitigation method may be of particular use in areas that treat high-risk patients.

(e) Chlorine dioxide. The use of chlorine dioxide gas is approved by the Environmental Protection Agency (EPA) for disinfection of water systems. There is some evidence to suggest that chlorine dioxide can reduce *Legionella* in hospital water systems.

NOTE: *Any existing water treatment systems already present for the prevention of waterborne pathogens, such as copper-silver ionization or monochloramine, can be included as part of the mitigation protocol of the Action Plan; existing water treatment systems need to be regularly monitored and evaluated.*

b. **Monitor the Mitigation Effort**

(1) Monitoring of the mitigation protocol involves the culture of water in hot water tanks and distal water sites for *Legionella*. The frequency of the testing, determined by the facility ICC, needs to be at appropriate intervals to ensure that the mitigation protocol is successful at reducing the risk of exposure to *Legionella*. This testing needs to occur a minimum of two times per year in Transplant Centers and in facilities that care for at least five transplant patients per year within the 3 months after the transplant procedure, or one time per year for other Acute Care facilities or Nursing Home Care Units (NHCU) (see Att. D for guidelines on environmental testing procedures).

(2) For Veterans Health Administration (VHA) designated Transplant Centers and facilities where at least five post-transplant patients per year are cared for within the first 3 months of the transplant procedure, if the environmental samples are positive for *L. pneumophila* serogroup 1, then all patients at the facility (not just transplant patients) with HCA pneumonia need to be tested for LD by urinary antigen testing. If the environmental samples are positive with another pathogenic LD species (subpar. 4d(2) of the Directive), then the facility needs to perform cultures of respiratory secretions on all transplant patients with HCA pneumonia.

(3) Acute Care (non-transplant) facilities and NHCU facilities not physically housed within an Acute Care facility need to maintain a high index of suspicion for LD in HCA pneumonia cases.

c. **Evaluate the Mitigation Effort**

(1) Use the results from the mitigation monitoring to determine if the mitigation effort has reduced or maintained the percent of *Legionella* positive distal water sites to below the threshold limit.

(a) If post-mitigation evaluation indicates that the mitigation was not effective, the ICC needs to reassess the mitigation plan, modify the Action Plan to include revised mitigation protocols, and implement the revised mitigation protocols. Monitoring of the new mitigation efforts needs to occur.

(b) If the post-mitigation evaluation indicates that the mitigation was successful, the annual facility evaluation for *Legionella* risk is complete. ***NOTE:*** *If the Action Plan was implemented due to a history of LD at a facility, then ongoing mitigation, monitoring and evaluation needs to occur on a routine basis.*

3. A written summation of Action Plan activities and findings is to be submitted to the facility ICC.

Increasing Incidence of Legionellosis in the United States, 1990–2005: Changing Epidemiologic Trends

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(See the editorial commentary by Ng et al. on pages 600–2)

Background. An abrupt increase in the incidence of legionellosis in the United States has been noted since 2003. Whether the recent increase is associated with shifting epidemiologic trends has not been well characterized.

Methods. We analyzed all cases of legionellosis reported to the Centers for Disease Control and Prevention through the National Notifiable Disease Surveillance System from 1990 through 2005.

Results. A total of 23,076 cases of legionellosis were reported to the Centers for Disease Control and Prevention from 1990 through 2005. The number of reported cases increased by 70% from 1310 cases in 2002 to 2223 cases in 2003, with a sustained increase to >2000 cases per year from 2003 through 2005. The eastern United States showed most of the increases in age-adjusted incidence rates after 2002, with the mean rate in the Middle Atlantic states during 2003–2005 exceeding that during 1990–2002 by 96%. During 2000–2005, legionellosis cases were most commonly reported in persons aged 45–64 years. Persons aged <65 years comprised 63% of total cases in 2000–2005. Age-adjusted incidence rates in males exceeded those in females for all age groups and years. Legionellosis incidence showed marked seasonality in eastern states, with most cases reported in the summer or fall.

Conclusions. Reported legionellosis cases have increased substantially in recent years, particularly in the eastern United States and among middle-aged adults. *Legionella* infection should be considered in the differential diagnosis of any patient with pneumonia. Public health professionals should focus increased attention on detection and prevention of this important and increasing public health problem.

More than 30 years have passed since the recognition of *Legionella* species as the cause of a severe pneumonia outbreak in Philadelphia in 1976 [1]. Since then, we have made great progress in understanding this disease and its environmental sources. Despite this, an abrupt increase in the incidence of legionellosis has been noted since 2003 [2], with recent increases in the Bronx prompting the New York City Department of Health to issue a press release in July 2007 [3]. This trend has also been noted internationally, as evidenced by a press release issued in August 2007 by the Health Protection Agency in England [4].

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Legionella species are weakly gram-negative bacteria found primarily around fresh water environments, such as lakes and streams, where the bacteria use free-living amoeba as hosts for intracellular survival and multiplication [5]. More than 45 species of *Legionella* have been identified. However, *Legionella pneumophila* is associated with ~90% of reported cases in the United States, with *L. pneumophila* serogroup 1 causing ~80% of these cases [5]. Disease is usually associated with man-made environments, such as cooling towers, whirlpools, and building water systems, where warm water (25°C–42°C) and biofilms support growth and survival of *Legionella* species [5]. Disease caused by *Legionella longbeachae* has been associated with use of potting soil and gardening [5].

Legionella species are implicated in 2 clinical syndromes: legionnaires disease and Pontiac fever, collectively known as legionellosis. Pontiac fever is generally a self-limited, influenza-like illness, whereas legionnaires disease is a common cause of serious bacterial pneumonia. Risk factors for legionnaires disease include older age, smoking, male sex, and underlying

diseases (immunosuppression, diabetes, chronic lung disease, and renal failure) [6]. Cases have been reported in otherwise healthy individuals [7–9] and in all age groups, including infants [8]. Although <20% of legionnaires disease cases are outbreak related [5, 6], outbreaks have been associated with whirlpool spas, cooling towers, decorative fountains, hotels, hospitals, nursing homes, and cruise ships [10–12]. To investigate whether the recent increase in legionellosis in the United States is associated with shifting epidemiologic trends, we analyzed data on cases reported to the Centers for Disease Control and Prevention (CDC) from 1990 through 2005.

METHODS

The CDC collects data on voluntarily nationally notifiable diseases through the National Notifiable Diseases Surveillance System. Legionellosis has been a nationally notifiable disease since 1980 [13]. Because only summary data are available before 1990, we analyzed legionellosis cases reported from 1990 through 2005, which is the last year for which finalized data were available.

DATA SET AND CASE DEFINITION

Subsequent to a data-use agreement, the CDC provided data on cases reported in states where legionellosis was designated as notifiable from 1990 through 2005 [14]. The 1990–2003 data included all reported legionellosis cases, whereas the 2004–2005 data were limited to "confirmed" cases of legionellosis with the exception of data from California [15]. Data set variables were year, event month (based on the report month), state, sex, race, ethnicity, and age, categorized as <1 year, 1–4 years, 5-year groups from 5 to 74 years, and ≥75 years.

Three case definitions were used by the CDC from 1990 through 2005 [16–18]. For "confirmed" legionellosis, all 3 require a clinically compatible case plus either culture isolation of any *Legionella* organism from respiratory secretions, lung tissue, pleural fluid, or other normally sterile fluid; detection of *L. pneumophila* serogroup 1 antigen in urine; or at least a 4-fold increase in serum antibody titer for *L. pneumophila* serogroup 1 [17, 18]. Before 2005, criteria also included detection of *L. pneumophila* serogroup 1 by direct fluorescent antibody staining. Before 1996, a "probable" status based on a single convalescent-phase serum antibody titer of ≥256 was included [17, 18].

DATA ANALYSIS

Data were analyzed using SAS statistical software, version 9.1 (SAS Institute). Analysis was limited to the 50 states and the District of Columbia. Broader age categories and US Census Bureau regions and divisions were coded. Event months were combined into seasons: spring was defined as March, April, and May; summer as June, July, and August; fall as September, October, and November; and winter as December, January, and February. Pediatric cases were defined as cases that occurred in individuals aged ≤19 years.

Sex distribution was compared with the 2000 US Census population [19]. Crude and age-specific incidence rates were calculated using the case count and the corresponding yearly population estimate [20]. Populations of states where legionellosis was not notifiable in a given year were excluded in the denominator for affected rate calculations. Rates for periods >1 year were obtained by averaging annual rates. Age-adjusted rates were calculated using the 2000 US standard population [21].

RESULTS

A total of 23,076 cases of legionellosis were reported to the CDC from 1990 through 2005. The annual number ranged from 1094 to 2291 cases (figure 1). The number of reported cases increased by 70%, from 1310 cases in 2002 to 2223 cases in 2003, with a sustained increase to >2000 cases per year from 2003 through 2005. During 1990–2002, the mean (±SD) annual legionellosis case count was 1268 ± 139.40 cases (range, 1094–1610 cases), whereas from 2003 through 2005, the yearly mean was 2198 ± 107.15 cases (range, 2081–2291 cases). The age-adjusted incidence rate for legionellosis in the United States paralleled this rise, increasing 65%, from 0.45 cases per 100,000 residents in 2002 to 0.75 cases per 100,000 in 2003.

DEMOGRAPHIC DISTRIBUTION

Age. Age was known in 22,604 (98%) of the reported legionellosis cases. Mean age-specific incidence rates for the 1990–2005 period generally increased with increasing age group (figure 2). Legionellosis cases are now most commonly reported in persons aged 45–64 years (figure 3). From 1990 through 1999, the 65–74-year-old age group had the highest mean (±SD) number of reported cases annually (275 ± 38.48 cases per year). In contrast, from 2000 through 2005, the 55–64-year-old age group had the highest mean annual case count (388 ± 154.22 cases per year), followed by the 45–54-year-old age group. Persons aged <65 years comprised 63% of total cases in 2000–2005.

From 1990 through 2005, 375 cases (1.7%) were reported in pediatric age groups; 209 cases (0.93%) were reported in children aged ≤14 years. Most pediatric cases were reported in children 15–19 years old (44.3%), followed by infants aged <1 year (18.1%).

Sex. Males comprised 61% of the 22,763 case patients for whom sex was known, compared with 49% of the 2000 US Census population. Rates in males exceeded those in females for all age groups and years. The gap between male and female incidence rates steadily widened in adults as the age group

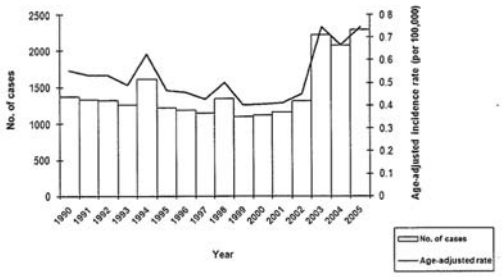

Figure 1. Annual number of legionellosis cases reported through the Centers for Disease Control and Prevention National Notifiable Disease Surveillance System and the corresponding annual age-adjusted incidence rate per 100,000 for 1990–2005.

increased. The male rate exceeded the female rate by 11% in the 15–24-year-old age group (0.073 vs. 0.066 cases per 100,000 residents). This sex difference increased to 116% in those aged ≥75 years (2.62 vs. 1.21 cases per 100,000). The sex difference in annual incidence rates for legionellosis was highest in recent years. Yearly age-adjusted rates in males were >2 times higher than those in females from 2003 through 2005.

Geographic distribution. During 1990 through 2005, cases were reported from the District of Columbia and every state except Alaska. The Northeast region reported the largest percentage of cases (31.5%), followed by the Midwest (30.6%), the South (26.7%), and the West (11.2%). Most reported cases (69%) were concentrated in 3 contiguous eastern divisions: Middle Atlantic (26%), East North Central (25%), and South Atlantic (19%). The states with the highest reported case counts were Pennsylvania (11.5% of total cases), New York (11.0%), and Ohio (10.3%). Age-adjusted incidence rates were highest in Delaware (1.8 cases per 100,000 residents). Lowest age-adjusted rates were in North Dakota (0.04 cases per 100,000) and Oregon (0.07 cases per 100,000).

The increase in reported legionellosis cases after 2002 is mainly reflective of increased incidence in the states east of the Mississippi River (figure 4). The Northeast and South regions showed the greatest change in the mean annual number of cases from 1990–2002 to 2003–2005, increasing by 104% in the Northeast and 113% in the South. Regional mean age-adjusted incidence rates reveal similar findings. The mean rate (per 100,000) for 2003–2005 exceeded that for 1990–2002 by 82% in the Northeast (1.30 vs. 0.72), 76% in the South (0.60 vs. 0.34), 22% in the Midwest (0.81 vs. 0.66), and 4% in the West (0.30 vs. 0.29). By US Census Bureau division, the highest mean annual case counts for both the 1990–2002 and 2003–2005 periods were seen in the Middle Atlantic, East North Central, and South Atlantic divisions. The Middle Atlantic states showed the greatest increases in mean age-adjusted incidence rates, with the 2003–2005 rate exceeding the 1990–2002 rate by 96% (1.47 vs. 0.75), followed by the South Atlantic division (85%; 0.80 vs. 0.43). Divisional changes in age-adjusted incidence rates between these periods are shown in figure 5.

From 1990 through 2005, legionellosis cases were most frequently reported to the CDC in the fall and summer: 30% of the cases were reported in the fall, 29% in the summer, 23% in the winter, and 18% in the spring. Cases were reported most frequently in August (11.2%) and least frequently in February (5.6%). The West region had the least monthly variation in reported cases during this time (figure 6).

DISCUSSION

The number of reported legionellosis cases in the United States has increased substantially in recent years, particularly in the eastern United States. The number of reported legionellosis cases increased abruptly, from a mean of 1268 yearly cases before 2003 to >2000 cases per year from 2003 through 2005, with a brief spike in 1994, which appears to primarily reflect a few outbreaks in the South that year [22]. Final data from 2006 show a sustained increase: 2834 legionellosis cases were reported [23], which is the greatest number reported since legionellosis surveillance began.

The passive nature of the notifiable disease system likely leads to underreporting of cases: 1 population-based study estimated that *Legionella* species cause 8000–18,000 pneumonia cases annually [24], suggesting that more than three-quarters of cases are currently undiagnosed or unreported. Whether the recent increase in reported legionellosis cases and the predilection for cases in the eastern states reflect true changes in the incidence

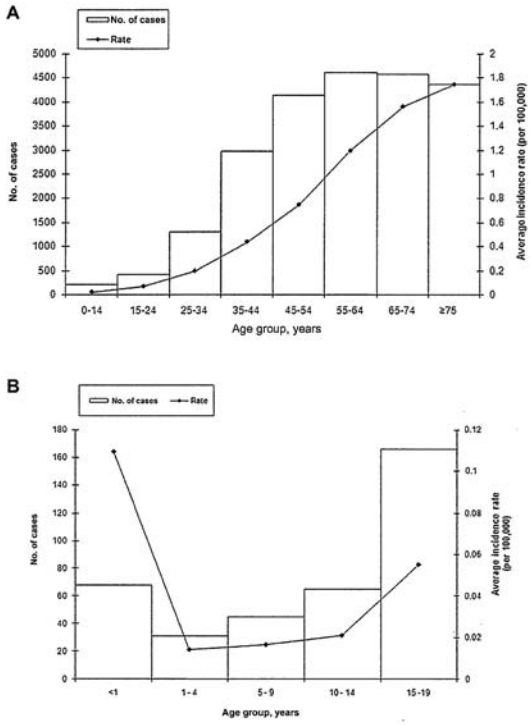

Figure 2. Total number of legionellosis cases reported for 1990–2005 and mean age group–specific incidence rates (per 100,000) for this period by all age groups *(A)* and pediatric age groups *(B)*.

of legionellosis, rather than artifact due to changes in legionellosis testing or reporting practices over time is unclear. We found no evidence that changes in diagnostic testing were responsible for the increase after 2000. Increased use of urine antigen testing had already occurred in the 1990s, when diagnosis by this test increased from 0% to 69% [13]. Currently, there is no commercially available PCR approved for clinical diagnostic use in the United States, making widespread routine use of PCR for diagnosis of legionellosis less likely. An increase due to introduction of other new diagnostic methods or changes in reimbursement in ~2003 is also unlikely (V. Baselski, personal communication).

Although completeness of notifiable disease reporting is difficult to assess, we found no evidence that variations in case-reporting procedures or completeness contributed to the increased incidence over time. Although physicians in states with

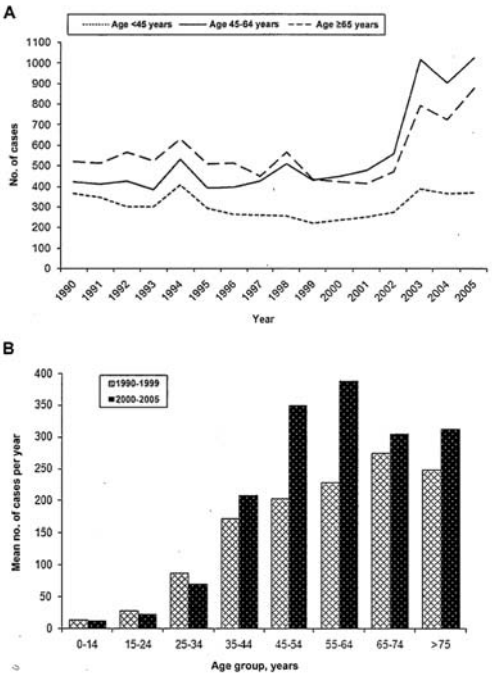

Figure 3. Trends in age distribution of reported legionellosis cases. *A*, Annual number of reported legionellosis cases by 0–45 years of age, 45–64 years of age, and ≥65 years of age during 1990–2005. *B*, Comparison of the mean number of legionellosis cases per year for the 1990–1999 versus 2000–2005 periods among different age groups. Note that cases in the 45–64-year-old age group surpassed those in the ≥65-year-old age group in ~2000.

historically higher legionellosis rates or recent outbreaks may have increased awareness and may be more likely to test for and report *Legionella* species, evaluation of the Middle Atlantic, East North Central, and South Atlantic divisions on a state-by-state basis reveals that the number of case reports increased across almost all these states after 2002, rather than being limited to a few states. This makes the geographic variation and post-2002 increase less suggestive of state-specific reporting artifacts. We also found no changes in national water-quality standards that would promote increased of risk of proliferation of *Legionella* species in water sources.

Past research has suggested a link between weather and legionellosis. A 1990–2003 study by Hicks et al. [25] analyzing the 2003 increase in the incidence of legionellosis in several Middle Atlantic states correlated the 2003 increase in legionellosis with increased total monthly rainfall. Because legionellosis occurrence has continued to increase after 2003 despite decreased rainfall in some areas—for example, case reports increased in South Atlantic states through 2006 despite a drought in that area [23, 26]—the correlation to total rainfall is less certain. A separate study by Fisman et al. [27] that evaluated the association of weather patterns and legionellosis

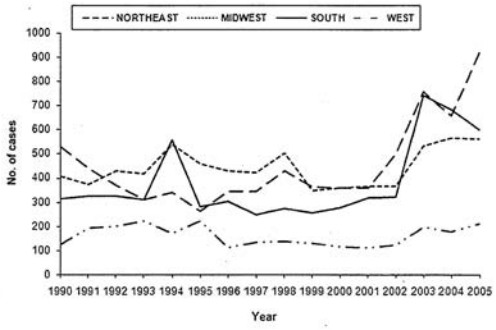

Figure 4. Annual number of reported legionellosis cases by US Census Bureau region, 1990–2005

in Philadelphia from 1995 through 2003 alludes to a more complex weather pattern than just increased monthly rainfall. Although this study did not find an association between monthly incidence of legionellosis and total monthly precipitation after controlling for other meteorologic variables, it identified a short-term association between legionellosis and the presence of precipitation and increased humidity at 6–10 days before disease [27]. Given that climate trends predict continued precipitation increases in northeastern states [28], more detailed analyses are needed to clarify the association among climate, weather, and temporal and geographic variations in legionellosis occurrence.

In our analysis, as in previous studies [6, 13], annual reported incidence rates for legionellosis increased with age across all age groups older than 1 year. However, we noted a trend toward younger ages in recent years. Despite the common perception that legionnaires disease is a disease primarily of elderly people, since the year 2000 the highest number of legionellosis cases has been reported in persons 45–64 years old, rather than the ≥65-year-old age group as seen before 2000.

This study highlights the importance of considering *Legionella* species as a cause of pneumonia in all age groups. A continued misperception that legionnaires disease is a disease of elderly people may lead to preferential testing of older patients and missed cases in children and young adults if legionellosis is not considered in the differential diagnosis. For example, McDonough et al. [9] recently reported 5 cases of legionnaires disease in military recruits aged 18–28 years in the same training company that were identified only retrospectively through PCR analysis of throat swabs as part of a pneumonia surveillance study. Pediatric cases comprise ~1% of the cases reported from 1990 through 2005, yet evidence-based pediatric management guidelines for community-acquired pneumonia [29, 30] do not discuss legionnaires disease in the differential diagnosis or as part of the testing recommendations, potentially leading to misdiagnosis and underreporting of cases.

Legionella species are arguably the most important waterborne organisms in the United States with regard to serious morbidity and mortality. Legionnaires disease has been identified as a significant cause of community-acquired pneumonia leading to hospitalization, identified in 2%–8% of cases in North American and European studies [24, 31–33]. In several studies of severe community-acquired pneumonia, *Legionella* species have been the second most commonly identified organism, after pneumococcus [34, 35]. It is also a significant cause of waterborne-disease outbreaks. In the most recent Waterborne-Disease Outbreak Surveillance System summary [11], *Legionella* species were the most commonly identified infectious organisms in waterborne outbreaks associated with drinking water and with water not intended for drinking (excluding recreational water). *Legionella* species were also linked to all the deaths associated with these outbreaks [11].

Given the significant morbidity associated with legionnaires disease and its apparent rising incidence in recent years, legionnaires disease is increasingly important as a public health threat. Approximately 20%–25% of legionellosis cases are travel related [13, 36]. Because pneumonia caused by *Legionella* species is clinically indistinguishable from other bacterial pneumonias [5, 31], clinicians should consider *Legionella* species in the differential diagnosis of any patient with pneumonia, regardless of age, especially for patients with immunosuppression; a recent history of travel, especially if it included stays in hotels or on cruiseships; or exposure to environmental water sources, such as whirlpool spas or decorative fountains. Current guide-

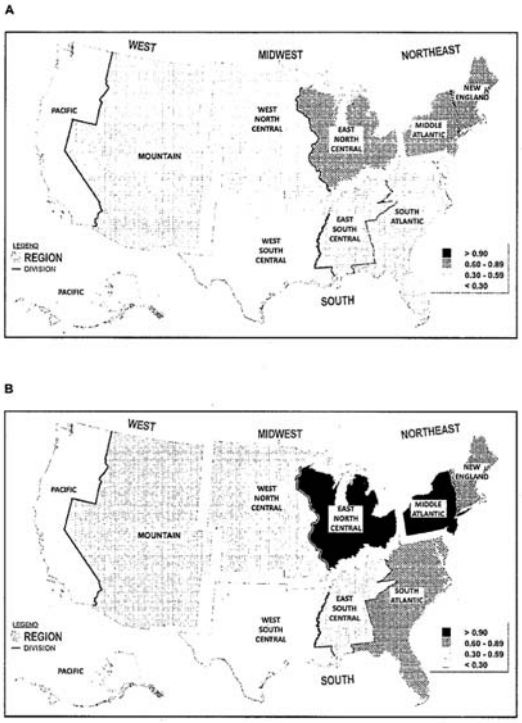

Figure 5. Mean age-adjusted incidence rates for legionellosis (cases per 100,000) by US Census Bureau division during 2 periods: 1990–2002 *(A)* and 2003–2005 *(B)*. Maps have been modified from the Census Regions and Divisions of the United States map prepared by the Geography Division, US Census Bureau (http://www.census.gov/geo/www/maps/CP_MapProducts.htm).

lines for management of community-acquired pneumonia in adults [37] recommend *Legionella* testing in patients with a history of travel within 2 weeks before the onset of symptoms, community-acquired pneumonia requiring admission to the intensive care unit, failure of outpatient antibiotic therapy or other nonresponding pneumonia, history of active alcohol abuse, presence of a pleural effusion, or exposure as part of a legionellosis outbreak or suspected outbreak. Current health care–associated pneumonia guidelines [38] recommend that clinicians maintain a high index of suspicion for legionnaires disease in patients with health care–associated pneumonia, especially in those who have recently undergone transplantation, who have immunosuppression, who have chronic underlying diseases, or who are aged ≥65 years. Clinical guidelines for *Legionella* testing in pediatric pneumonia are lacking and should be developed.

Further research is required to explain the recent increases in legionellosis. Routine collection and dissemination to researchers of more-comprehensive patient risk factor, laboratory diagnostic testing, and other epidemiologic information by na-

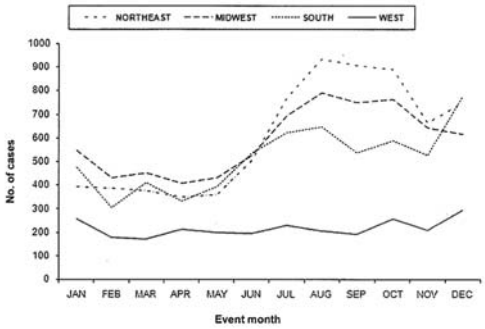

Figure 6. Monthly number of reported legionellosis cases by US Census Bureau region, 1990–2005

tional surveillance systems would aid these efforts. Programs of routine environmental water monitoring for *Legionella* species with reduction or elimination of the bacteria from water systems when detected, are increasingly being implemented as a prevention strategy [39, 40], and the impact of these programs requires further assessment. In addition, more research is needed on the effectiveness of various water disinfection systems for reduction of *Legionella* species in water systems.

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