DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 201-212 and 37 CFR Part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Nucleic Acid-based Compositions and Methods for the Detection of Pathogenic Candida Fungi

Description of Technology: This invention pertains to the development of oligonucleotides for the rapid nucleic acid-based identification of the Candida fungi species C. haemulonii, C. kefyr, C. lamberca, C. lusitaniae, C. norvegicensis, C. norvegica, C. rugosa, C. utilis, C. viswanathii, C. zeylanoides, C. dubliniensis, and C. pelliculosa within biological samples. This identification is accomplished by targeting the internally transcribed spacer-2 (ITS2) region that is specific for each species. The assay is sensitive, specific and rapid.

Implementation of the technology will facilitate earlier specific diagnoses, and lead to better antifungal therapy implementation for infected patients. Potential Commercial Applications:

- Directing antifungal drug therapy for improved patient outcomes
- Detection, discrimination of Candida species from biological samples
- Addressing secondary infections of immunosuppressed individuals

Competitive Advantages:

- Easily adapted for use in kits
- High-throughput capable
- Rapid and cost-effective

Development Stage: In vitro data available

Inventors: Christine J. Morrison, Errol Reiss, Brian Holloway, Jong Hee Shin (all of CDC)


- US Patent No. 6,235,890 issued 22 May 2001
- Various international issued patents

Related Technologies:
- HHS Reference No. E–293–2013/0
- HHS Reference No. E–332–2013/0
- HHS Reference No. E–322–2013/0
- HHS Reference No. E–335–2013/0
- Licensing Contact: Whitney Blair, J.D. M.P.H.; 301–435–4937; whitney.blair@nih.gov

Nucleic Acid-based Compositions and Methods for the Detection of Pathogenic Candida or Aspergillus Fungi Species within Biological Samples

Description of Technology: This invention relates to assays for the detection and species-specific identification of Aspergillus fungi. Accurate clinical diagnosis of Aspergillus species has become increasingly important as certain species, such as A. terreus and A. fumigatus, are resistant to specific commonly employed antifungal compounds. Most contemporary fungal diagnostic methods are time-consuming and inaccurate. This invention directly addresses those inadequacies by providing a method to rapidly and accurately differentiate all medically important species of Aspergillus based on differences in the DNA sequences of the internal transcribed spacer 1 region of ribosomal DNA.

Potential Commercial Applications:

- Directing antifungal drug therapy for improved patient outcomes
- Detection, discrimination of Aspergillus species from biological samples
- Addressing secondary infections of immunosuppressed individuals or asthmatics

Competitive Advantages:
Nucleic Acid-based Differentiation and Identification of Medically Important Fungi

Description of Technology: This invention entails nucleic acid-based assays for detecting the presence of pathogenic fungi such as Histoplasma capsulatum, Blastomyces dermatitidis, Coccidioides immitis, Pneumocystis carinii, Histoplasma capsulatum, Blastomyces dermatitidis, and/or Penicillium marneffei within a sample. Within a healthcare setting, this particular approach can greatly reduce pathogen identification time, better direct treatments and ultimately improve patient outcomes. Further, this technology provides improved diagnostic specificity compared to serologic tests for circulating antibodies using patient serum samples— an approach that may give particularly aberrant results for immunosuppressed individuals, and who are frequently afflicted with opportunistic fungi. This technology is readily adaptable as kits used for species-specific identification of fungal pathogen infections and environmental contamination.

Potential Commercial Applications:
• Directing antifungal drug therapy for improved patient outcomes
• Detection, discrimination of fungal pathogens
• Addressing secondary infections of immunosuppressed individuals or asthmatics

Competitive Advantages:
• Rapid, sensitive, simple and specific
• Potential for automation and high-throughput screening
• Easily adaptable to kit form

Development Stage: In vitro data available

Inventors: Christine J. Morrison and Hans Peter Hinrikson (CDC)

Publications:
2. CDC Fact Sheet: Aspergillosis [http://www.cdc.gov/fungal/aspergillosis/]

• PCT Application No. PCT/US2003/016076 filed 16 May 2003, which was published as WO 2003/097815 on 27 Nov 2003

Various international patents issued or pending

Related Technologies:
• HHS Reference No. E–293–2013/0
• HHS Reference No. E–332–2013/0
• HHS Reference No. E–232–2013/0

Licensing Contact: Whitney Blair, J.D. M.P.H.; 301–435–4937; whitney.blair@nih.gov

Nucleic Acid Detection of the Fungal Pathogen Histoplasma capsulatum from Clinical and Environmental Samples

Description of Technology: This invention relates to detecting Histoplasma capsulatum by PCR using oligonucleotide probes specific for the fungus. Histoplasmosis is a mycotic infection of varying severity, usually localized in the lungs. Caused by H. capsulatum, infections are usually symptomatic but can develop into chronic disease, especially in immunocompromised individuals. Test samples may originate from the environment (soil, for example), where H. capsulatum spores are found or from clinical samples obtained from patients. Furthermore, the invention also provides for methods that detect the presence of H. capsulatum in a sample using a nested, or two-stage, PCR assay.

Potential Commercial Applications:
• Directing antifungal drug therapy for improved patient outcomes
• Vocational health and safety screening for workers who may encounter bird or bat waste
• Screening biological or soil samples for the presence of fungal pathogens
• Environment testing for immunocompromised patients

Competitive Advantages:
• Rapid and precise
• Cost-effective
• Easily adapted for H. capsulatum detection kits
• Can positively identify small sample sizes of as few as 10 spores

High-throughput capable

Development Stage: In vitro data available

Inventors: Millie Schafer and Thomas Reid (CDC)

Publications:
2. CDC Fact Sheet: Histoplasmosis [http://www.cdc.gov/fungal/histoplasmosis/]


Related Technologies:
• HHS Reference No. E–293–2013/0
• HHS Reference No. E–332–2013/0
• HHS Reference No. E–232–2013/0
• HHS Reference No. E–335–2013/0

Licensing Contact: Whitney Blair, J.D. M.P.H.; 301–435–4937; whitney.blair@nih.gov

Multiplexed Immunoassay for Rapid Serological Diagnosis of a Specific Viral Infection in Clinical Samples

Description of Technology: CDC researchers have developed a multiplexed diagnostic assay for sensitive detection and distinction between viral group members based on the presence/absence of infection-generated antibodies within a clinical serum sample. For example, this assay can be used for rapid discrimination of a clinical unknown as specifically a West Nile or St. Louis encephalitis viral infection. This is particularly beneficial as these two viruses are typically difficult to distinguish by standard serological assays.

This new technique uses microsphere/microbead-based flow-analysis as a platform. Because of a basis in a pre-existing technology, the technique can be easily incorporated into current state and health department diagnostic testing protocols. The method is particularly unique because the assay-generated data can be standardized and then classified via discriminant analysis to determine the presence or absence of antibodies of interest within the clinical sample tested.
Furthermore, along with allowances for single-result generation, data manipulation and classification algorithms allow for assay output comparisons to the original large data set references used in development. In this way, results from different laboratories can now be directly compared to one another, provided that the same controls are used.

**Potential Commercial Applications:**
- Clinical diagnostics for specific identification and discrimination of viral infections
- Research tool for evaluation of vaccine candidates
- Assay standardization and quality control
- Public health and viral outbreak surveillance programs

**Competitive Advantages:**
- Increased efficiency compared to single-antibody diagnostic approaches
- Easily implemented and integrated into present protocols and techniques, as this technology is based on current, widely used flow-analysis platforms
- Can be formatted as customizable kits for detection of viral group antibodies
- Rapid and precise
- Ideal for high-throughput analyses

**Development Stage:** In vitro data available

**Inventors:** Alison J. Basile and Bradley J. Biggerstaff (CDC)

**Publications:**

**Intellectual Property:** HHS Reference No. E–302–2013/0—
- US Patent No. 8,433,523 issued 30 Apr 2013

**Various international patent applications pending or issued**

**Licensing Contact:** Whitney Blair, J.D., M.P.H.; 301–435–4927; whitney.blair@nih.gov

**Detection and Differentiation of Pathogenic Fungi in Clinical Samples Using a Multi-Analyte Profiling System**

**Description of Technology:** This invention provides a rapid, sensitive and specific diagnostic tool for the detection of pathogenic fungi and subsequent species-specific discrimination. CDC scientists have developed nucleic acid probes to identify the six most medically important *Candida* species and endemic mycoses, and to differentiate them from other medically important fungi in a multi-analyte profiling system. *Candida* fungi are one of the leading causes of clinically-acquired bloodstream infections and, although improved antifungal compounds have been recently introduced, they have unique, species-specific treatment responses.

This multi-analyte approach has the potential to simultaneously identify up to 100 different fungi in one assay. Additionally, the assay is quite cost effective in terms of resource input, time invested and technician labor. Used in conjunction with contemporary antifungal medications, this assay provides a very rapid and specific diagnosis allowing for the selective administration of appropriate compounds and ultimately improved patient outcomes.

**Potential Commercial Applications:**
- Directing antifungal drug therapy for improved patient outcomes
- Detection, discrimination of *Candida* species from biological samples
- High-throughput screening
- Liquid or solid phase microarray development to detect medically important fungi

**Competitive Advantages:**
- Rapid, sensitive, simple and specific
- Multi-analyte nature provides cost-efficiency
- Easily adaptable to kit form
- Permits the multiplexing of up to 100 different hybridization reactions in a single sample

**Development Stage:**
- Early-stage
- In vitro data available

**Inventors:** Christine J. Morrison, Sanchita Das, Teresa Brown, Brian F. Holloway (all of CDC)

**Publication:** Das, S. et al. DNA probes for the rapid identification of medically important *Candida* species using a multianalyte profiling system. FEMS Immunol Med Microbiol. 2006 Mar;46(2):244–50. [PMID 16487306]

**Intellectual Property:** HHS Reference No. E–293–2013/0—
- PCT Application No. PCT/US2006/037640 filed 26 Sep 2006, which published as WO 2007/038578 on 05 Apr 2007
- Several international filings issued or pending

**Related Technologies:**
- HHS Reference No. E–232–2013/0
- HHS Reference No. E–332–2013/0
- HHS Reference No. E–335–2013/0
- HHS Reference No. E–339–2013/0

**Licensing Contact:** Whitney Blair, J.D., M.P.H.; 301–435–4937; whitney.blair@nih.gov

**Novel Primate T-cell Lymphotropic Viruses (HTLV, STLV) for Development of Diagnostics, Therapeutics, Research Tools, and Vaccines**

**Description of Technology:** CDC researchers have isolated and characterized the novel primate T-lymphotropic viruses denoted human T-lymphotropic viruses 3 and 4 (HTLV–3 and HTLV4), that are believed to have resulted from cross-species transmission at some point in the past. It has been previously established that HTLV–1 causes adult T cell leukemia and other inflammatory diseases; HTLV–2 is considered less pathogenic than HTLV–1 and has been associated with a neurologic disease similar to HTLV–1-associated myelopathy. At present, the human pathologies of HTLV–3 and HTLV–4 are yet uncharacterized, but have been identified as infecting rural Central African hunters who have much greater risk of contact with non-human primates, sometimes infected with simian T-lymphotropic viruses (STLVs). As HTLV infected individuals from rural, isolated populations have increasing contact with their urban brethren, there is increased potential for the rapid spread of new viral zoonotic-originating pathogens, much like the theorized “bushmeat” origins of HIV. There is a present and unmet need for increased surveillance, study, and preventative therapeutics directed towards mitigating the public health impact of these viruses. This CDC developed technology provides methods and tools to that end.

**Potential Commercial Applications:**
- Development of HTLV diagnostics
- Simian/human T-cell lymphotropic virus research
- Zoonosis surveillance
- Vaccine design and development

**Competitive Advantages:**
- Provides tremendous opportunity for phylogenetic, clinical and epidemiological investigations of HTLV and STLV
- Facilitates monitoring of viral diversity and study of zoonotic disease transmission

**Development Stage:**
- Early-stage
- In vitro data available

**Inventors:** Donald S. Burke (Johns Hopkins Univ), Thomas M. Folks (CDC), Walid Heneine (CDC), Eitel Mpoudi
Ngole (CDC), William M. Switzer (CDC), Nathan D. Wolfe (Johns Hopkins Univ)

**Publications:**


**Intellectual Property:**
- HHS Reference No. E–281–2013/0—
- PCT Application No. PCT/US2006/005869 filed 21 Feb 2006, which published as WO 2006/091511 on 31 Aug 2006—Various international patents granted and pending
- HHS Reference No. E–281–2013/1—

**Related Technologies:** HHS Reference No. E–303–2013/2—

**Licensees:**

- Licensing Contact: Whitney Blair, J.D., M.P.H.; 301–435–4937; whitney.blair@nih.gov

**Method for Finding Usable Portion of Sigmoid Curve (the Taylor Method), Improved Assay Readouts, and Enhanced Quality Control/Assurance:**

**Description of Technology:** CDC researchers have developed algorithmic methods for determining sigmoid curve optimaums and calculating component concentrations. Sigmoid curves are commonly generated in bioassays and used to calculate results. Various techniques have been used to define the curve, analyze the observations, and calculate a concentration. This technology is an algorithmic approach to identifying the usable portion of a sigmoid curve. This approach is more objective than other methods, reducing the variability introduced by individuals and/or by repetition and allows substantially higher throughput in a situation where a lot of samples are being analyzed using the same assay.

**Potential Commercial Applications:**
- Observation and data analysis
- Determining concentrations
- Improving calculations and estimations
- Enhancing consistency and reproducibility of outcomes for bio and chem assays

**Competitive Advantages:**
- Less output-data subjectivity than alternate methods
- Rapid, accurate and simple to implement
- Quality control and assurance for a number of assays such as PCR, ELISA, toxin neutralization assays (TNA), flow cytometry, cell death assays, titrations, etc.
- Reduces data variability due to errant input
- Easily adapted to high-throughput analyses
- Demonstrated efficacy quantifying anthrax lethal toxin neutralization activity

**Development Stage:** In vitro data available
**Inventors:** Thomas H. Taylor (CDC)


**Intellectual Property:** HHS Reference No. E–270–2013/0—

**Licenseing Contact:** Whitney Blair, J.D., M.P.H.; 301–435–4937; whitney.blair@nih.gov

**Real-time PCR and High Resolution Melt Analysis for Genotyping of Chlamydia psittaci**

**Description of Technology:** This nucleic acid assay employs Light Upon Extension (LUX) chemistry and High Resolution Melt (HRM) analysis to detect and distinguish the different genotypes of *Chlamydia psittaci*. *C. psittaci* is an atypical pathogen which may result in severe pneumonia upon infection of birds, mammals and humans (depending on inter-relationships between host and pathogen genotypes). Presently, *C. psittaci* clinical identification is achieved by a cumbersome and time-intensive mix of ompA gene sequencing, microarray analysis, RFLP and/or serological testing. Accurate and timely molecular *C. psittaci* diagnosis techniques are not generally available in most clinical facilities, leading to improper treatment of patients.

To that end, this robust CDC developed assay should be useful for epidemiological studies and may provide valuable information for best implementing public health measures in the event of outbreaks. This tool may also offer greater insight into the heterogeneity and dissemination of *C. psittaci* genotypes. Additionally, the assay can serve as a veterinary diagnostic and/or pre-screening tool for companion birds. Such applications would provide further benefit by resulting in reduced transmission of the disease to humans.

**Potential Commercial Applications:**
- Validation studies, proficiency testing
- Public health and veterinary/ zoonotic disease monitoring programs
- Diagnostic testing, especially within the poultry industry
- Disease screening of companion birds

**Competitive Advantages:**
- Rapid and simple
- Simultaneous detection and discrimination of *C. psittaci* genotypes
- Improved efficiency in time and cost
- Easily adapted for use in kits

**Development Stage:** In vitro data available
**Inventors:** Stephanie L. Mitchell and Jonas M. Winchell (CDC)


**Licenseing Contact:** Whitney Blair, J.D., M.P.H.; 301–435–4937; whitney.blair@nih.gov

**Universal Diagnostic Assay for Detection and Identification of Poxviruses in Clinical Samples**

**Description of Technology:** CDC researchers have developed an assay for detection and diagnosis of poxviruses within clinical samples or from lab culture-systems. The assay specifically targets chordopoxviruses (except avipoxviruses) for PCR-based identification; an improvement upon the current standard of cell culturing methodologies. Individual chordopoxvirus species can cause disease in humans (e.g., vaccinia, cowpox, monkeypox/Molluscum contagiosum) and animals (e.g., sheeppox, myxoma, swinepox, mule...
Novel Rift Valley Fever Virus Vaccines

**Description of Technology:** This invention relates to recombinant Rift Valley fever (RVF) viruses containing deletions in one or more virulence genes. The recombinant RVF viruses, generated using a plasmid-based reverse genetics system, can be used as vaccines to prevent RVF infection in livestock and humans. The recombinant RVF viruses grow to high titers, provide protective immunity following a single injection, and allow for the differentiation between vaccinated animals and animals infected with wild-type RVF virus. Additionally, this technology relates to a method of using reverse genetics to generate recombinant RVF viruses.

**Potential Commercial Applications:**
- Rift Valley fever (RVF) virus vaccine development or improvement
- Prevention of RVF virus infection in livestock and humans
- Biodefense, biosecurity

**Competitive Advantages:**
- Allows for discrimination between vaccinated and naturally-infected subjects
- Useful for controlled screening of therapeutic compounds

**Development Stage:** In vivo data available

**Inventors:** Yu Li, Inger K. Damon, Hui Zhao (all of CDC)


**Intellectual Property:** HHS Reference No. E–256–2013/0—
- PCT Application No. PCT/US2010/055061 filed 02 Nov 2010, which was published as WO 2011/056771 on 12 May 2011
- Various international patent applications pending

**Licensing Contact:** Whitney Blair, J.D., M.P.H.; 301–435–4937; whitney.blair@nih.gov

**Personal Air Sampler for Collecting Airborne Aerosol Particulates for Molecular Analysis**

**Description of Technology:** This invention consists of a sampling apparatus that utilizes one or more cyclone separators to collect airborne particles from the atmosphere. The apparatus not only separates out aerosols from the atmosphere, but also serves as a collection tube for aerosol particles. Through its unique design, this CDC-developed apparatus is able to use the centrifugal force of the air flow on aerosolized particles forcing them to separate. Since the sample is collected directly in a microcentrifuge tube, in situ analysis of the ambient particulates can be performed. Analysis may include, but is not limited to, PCR, immunoassay analysis, microscopic spore counting, and counting colony-forming units. The device should also have many additional uses for environmental surveillance and occupational health applications.

**Potential Commercial Applications:**
- Analysis of ambient air particulates
- Environmental surveillance
- Occupational safety monitoring
- Biodefense
- Long-term exposure assessment

**Competitive Advantages:**
- Rapid, on-site sampling and analysis
- Alternative to surface-sampling and culturing for aerosolized biological agents
- Superior extraction efficiency compared to filters, impingers, and impactors
- Real-world testing demonstrated device’s ability to collect airborne mold and mycotoxins, pollen and pollen fragments, airborne dust particulates, as well as airborne influenza virus in a hospital environment.

**Development Stage:** In situ data available (on-site)

**Prototype Inventors:** Teh-Hsun R. Chen, Gregory Feature, Jyoti Keswani, Herbert D. Edgell (all of CDC)

**Publications:**
2. CDC Fact Sheet: Rift Valley Fever [http://www.cdc.gov/vhf/rvf/]
3. CDC: Rift Valley Fever: An Overview (http://www.cdc.gov/vhf/rvf/)

**Intellectual Property:** HHS Reference No. E–254–2013/2—
- PCT Application No. PCT/US2008/087023 filed 16 Dec 2008, which was published as WO 2009/082647 on 02 Jul 2009
- Additional applications granted and pending

**Licensing Contact:** Whitney Blair, J.D., M.P.H.; 301–435–4937; whitney.blair@nih.gov

**Personal Air Sampler for Collecting Airborne Aerosol Particulates for Molecular Analysis**

**Description of Technology:** This invention relates to recombinant Rift Valley fever (RVF) viruses containing deletions in one or more virulence genes. The recombinant RVF viruses, generated using a plasmid-based reverse genetics system, can be used as vaccines to prevent RVF infection in livestock and humans. The recombinant RVF viruses grow to high titers, provide protective immunity following a single injection, and allow for the differentiation between vaccinated animals and animals infected with wild-type RVF virus. Additionally, this technology relates to a method of using reverse genetics to generate recombinant RVF viruses.

**Potential Commercial Applications:**
- Rift Valley fever (RVF) virus vaccine development or improvement
- Prevention of RVF virus infection in livestock and humans
- Biodefense, biosecurity

**Competitive Advantages:**
- Allows for discrimination between vaccinated and naturally-infected subjects
- Useful for controlled screening of therapeutic compounds

**Development Stage:** In vitro data available

**Inventors:** Yu Li, Inger K. Damon, Hui Zhao (all of CDC)

Warning System for Mobile Machinery Hazardous Zones

Description of Technology: This invention relates to a warning system designed to protect individuals working near hazardous machinery. The system consists of a proximity-warning transmitter mounted to hazardous machinery and a receiver, worn by a worker, capable of detecting the transmitter signal. This worker-safety system can incorporate visual alerts and audible alerts. It also allows automatic shutdown of machinery upon receiver activation and may be particularly useful in the mining industry.

Potential Commercial Applications:
- Auxiliary safety equipment for heavy machinery
- Occupational health and safety
- Mining worker safety

Competitive Advantages:
- Easy transmitter installation
- Signal can be adjusted for an audio or visual “warning zone alert” and a proximal “imminent danger zone alert”

Development Stage:
- In situ data available (on-site)
- Prototype

Inventors: William H. Schiffbauer and Carl W. Gano (CDC)


Related Technologies:
- HHIS Reference No. E–293–2013/0
- HHIS Reference No. E–323–2013/0
- HHIS Reference No. E–386–2013/0
- Licensing Contact: Whitney Blair, J.D., M.P.H.; 301–435–4937; whitney.blair@nih.gov

Improved Protein Quantification Process and Vaccine Quality Control Production

Description of Technology: This CDC invention is a method for identifying and quantifying a group of proteins in a complex mixture by a liquid chromatography-tandem mass spectrometry assay. The technology was developed for influenza although it can be used for a wide variety of protein quantification applications. As specifically developed, conserved peptides from the proteins of influenza (hemagglutinin, neuraminidase, matrix 1 and 2, and nucleoprotein) have been synthesized and labeled to be used as internal standards for the quantification of those proteins in a complex (biological or manufactured) matrix. One or more of these peptides can be used to simultaneously detect and quantify the target proteins by establishing mass ratios and calibration curve comparison. This method for quantifying influenza proteins and peptides in samples has potential for improving vaccine production quality control and therefore, the effectiveness and overall cost-efficiency of influenza vaccines.

Potential Commercial Applications:
- Improved vaccine cost and production efficiency
- Development Stage:
  - Early-stage
  - In vitro data available

Inventors: Tracie L. Williams, John R. Barr, Zhu Guo, Leah G. Luna, Ruben O. Donis, James L. Pirkle (all of CDC)

Publications:

Novel Epitopes of Bacillus anthracis Lethal Factor for Development of Diagnostics and Therapeutics

Description of Technology: CDC researchers have characterized epitopes of Bacillus anthracis Lethal Factor (LF), a critical component of the B. anthracis lethal toxin. These epitopes may allow for development of therapeutics for the treatment or prevention of B. anthracis infection. They may also allow screening for B. anthracis LF in a sample and development of a peptide anthrax vaccine.

Potential Commercial Applications:
- Improved vaccine cost and production efficiency
- Development Stage:
  - Early-stage
  - In vitro data available

Inventors: Tracie L. Williams, John R. Barr, Zhu Guo, Leah G. Luna, Ruben O. Donis, James L. Pirkle (all of CDC)

Publications:
Respiratory Syncytial Virus (RSV) is a major cause of acute lower respiratory tract infection in children, and a significant cause of mortality and hospitalization in this age group. The virus is a common cause of bronchiolitis and pneumonia, and is a significant cause of hospitalization in young infants. Infants and young children are particularly vulnerable due to their immature respiratory system.

### Disease Description
- **Clinical Manifestations:** Infections range from mild to severe, with the most severe cases occurring in young infants and children. Severe disease can lead to hospitalization and occasionally death, particularly in premature infants and children with underlying conditions.
- **Transmission:** RSV is transmitted through respiratory droplets, primarily from person to person through coughing, sneezing, and direct contact.
- **Prevalence:** Worldwide, RSV is estimated to cause 3–5 million hospitalizations and 200,000–500,000 deaths in children under 5 years of age annually.

### Vaccines and Therapeutics
Vaccines for RSV are widely used in the United States to prevent severe disease, particularly in young infants. However, the current vaccines are not highly effective and do not protect against infection. RSV therapeutics include monoclonal antibodies and small molecule inhibitors, which are under development to improve efficacy and safety.

### CDC-Developed Technology
- **Title:** Controlled Expression and Assembly of Human Group-C Rotavirus-like Particles for Creation of Rotavirus Diagnostic Assays and Improved Vaccine Formulations
- **Description:** CDC researchers have developed methods of producing unlimited quantities of Group-C (GpC) rotavirus antigens. GpC rotaviruses are a major, worldwide cause of acute gastroenteritis in children and adults that is distinct from Group-A rotavirus. However, GpC rotavirus cannot be grown in culture, resulting in a lack of tools for detection and treatment of GpC rotavirus disease.
- **Competitive Advantages:**
  - Increased safety, effectiveness compared to current vaccines
  - Findings suggest likely prevention or mitigation of RSV-related pulmonary disease for previously established infections
  - In vitro data available
  - In vivo data available (animal)

### Licensing Information
- **Licensing Contact:** Whitney Blair, J.D., whitney.blair@nih.gov
- **Publications:**

### Related Technologies
- **Description:** CDC and collaborative researchers have demonstrated that a vaccine based on amino acid sequences corresponding to group-specific regions of the RSV G-protein can effectively induce antibodies, facilitate virus clearance, and reduce the virus-induced inflammatory response to RSV challenge. This composition may be used alone as a vaccine to safely protect infants, children, and adults from RSV, or with inactivated virus as a vaccine to ensure that it can be given safely and effectively improve protection from RSV.
- **Potential Commercial Applications:**
  - Development or improvement of rotavirus vaccines
  - Rotavirus vaccine composition research
  - Potential Commercial Applications:
    - Childhood illness vaccination programs and rotavirus monitoring endeavors
    - Development of novel rotavirus diagnostic tools

### Intellectual Property
- **HHS Reference No.:** E–210–2013/0—
  - PCT Application No. PCT/US2013/059179 filed 11 Sep 2012
  - US Provisional Application No. 61/699,738 filed 11 Sep 2012

### Contacts
- **Inventors:** Jason Goldstein, Conrad Quinn, Dennis Bagarozzi, Anne Boyer (all of CDC)
- **Inventors:** Larry J. Anderson (CDC), Lia M. Haynes (CDC), Ralph A. Tripp (University of Georgia)
- **Publications:**

### Controlled Expression and Assembly of Human Group-C Rotavirus-like Particles
This technology allows for the expression of the three major capsid proteins (VP2, VP6 and VP7) of GpC rotavirus by recombinant baculovirus and assembly of virus-like particles (2–6–7 and/or 6–7) within insect cells. Further, this CDC generated technology allows for the large-scale access to GpC rotavirus antigens, previously infeasible, and will permit use of these novel virus-like particles for the development of rotavirus diagnostic assays and improved vaccine formulations.

### Potential Commercial Applications
- Development or improvement of rotavirus vaccines
- Potential for advanced vaccine composition research

### Licensing Contact
- **Licensing Contact:** Whitney Blair, J.D., whitney.blair@nih.gov
- **Publications:**

### Controlled Expression and Assembly of Human Group-C Rotavirus-like Particles
This technology allows for the expression of the three major capsid proteins (VP2, VP6 and VP7) of GpC rotavirus by recombinant baculovirus and assembly of virus-like particles (2–6–7 and/or 6–7) within insect cells. Further, this CDC generated technology allows for the large-scale access to GpC rotavirus antigens, previously infeasible, and will permit use of these novel virus-like particles for the development of rotavirus diagnostic assays and improved vaccine formulations.

### Potential Commercial Applications
- Development or improvement of rotavirus vaccines
- Potential for advanced vaccine composition research

### Licensing Contact
- **Licensing Contact:** Whitney Blair, J.D., whitney.blair@nih.gov
- **Publications:**
Diisocyanate Specific Monoclonal Antibodies for Occupational and Environmental Monitoring of Polyurethane Production Exposure-related Asthma and Allergy and Clinical Diagnosis

Description of Technology: CDC researchers have developed monoclonal antibodies useful as diagnostics for diisocyanate (dNCO) exposure and for toxicity characterization of specific dNCOs. Currently, dNCOs are used in the production of all polyurethane products and are the most commonly reported cause of occupational-induced asthma and also linked to allergic contact dermatitis. Presumptive diagnosis of dNCO asthma is presently dependent on criteria such as work history, report of work-related asthma-like symptoms and nonspecific airway reactivity to methacholine challenge.

This invention is a cost-effective, objective alternative for clinical assessment of occupational/environmental dNCO exposure in patient samples. These antibodies may also provide for passive-immunization and prevention of allergic contact dermatitis and/or asthma that can result from extended dermal exposure to dNCO-contaminated surfaces and vapors. Further, the present technology allows for high-throughput testing of workplace dNCO air, fabric and working-surface contamination.

Potential Commercial Applications:
- Occupational/environmental safety biomonitoring of polyurethane-worker/user exposure to diisocyanates (dNCOs)
- Clinical diagnostic use
- dNCO-induced allergy/asthma prevention by passive immunization

Competitive Advantages:
- Ready for use in high-throughput immuno-histochemistry biomarker detection assays and kits
- Two sandwich ELISAs have been developed and validated using human samples
- Monitoring is currently performed by laborious analytical chemical assays; this technology is more rapid and cost effective for dNCO exposure/contamination assessment

Development Stage:
- Early-stage
- In vitro data available

Inventors:
- Paul D. Siegel, Donald H. Beezhold, Tinashe Blessing Ruwona, Detlef Schmechel, Victor Johnson (all of CDC)

Publications:

Intellectual Property:
- HHS Reference No. E–153–2013/0
- HHS Reference No. E–223–2013/0

Licensing Contact: Whitney Blair, J.D., M.P.H.; 301–435–4937; whitney.blair@nih.gov

Entangling/Entrapping Synthetic Setae for Control of Insects and Other Pests

Description of Technology: In nature, some beetle larvae possess specialized barbed hasteate setae that serve as an entanglement defense mechanism and incapacitate other insects. CDC researchers have developed synthetic setae for control and entrapment of insects and other pests. While smaller synthetic setae can trap mosquitoes and small insects, larger “macro” setae can be used for entrapment of bats, rodents, etc. Once used, the setae can be “reset” by a vigorous shaking of the fabric. This solution to pest control would be long-lasting and non-toxic, with the additional benefit of avoiding the evolutionary selection of pesticide resistant organisms.

Potential Commercial Applications:
- Insect and pest control agents
- Population sampling and monitoring

Competitive Advantages:
- Fine entanglement setae can be used anywhere insects congregate, including mosquito bed netting, resting boxes, curtains, or bedding
- Mosquitoes and other pests trapped in the setae will quickly desiccate
- Easy reuse of setae by shaking
- Long-lasting, non-toxic (no insecticide) alternative to insect control

Development Stage: Prototype

Inventor: Brian H. Bird and Stuart T. Nichol (CDC)

Publications:


Licensing Contact: Whitney Blair, J.D., M.P.H.; 301–435–4937; whitney.blair@nih.gov
Sensitivity Method for Detection and Quantification of Anthrax, Bordetella pertussis, Clostridium difficile, Clostridium botulinum and Other Pathogen-Derived Toxins in Human and Animal Plasma

Description of Technology: CDC research scientists have developed a method to identify and quantify the activity of pathogenic bacterial adenylate cyclase toxins by liquid chromatography tandem mass spectrometry (LC–MS/MS). Bacterial protein toxins are among the most potent natural poisons known, causing paralysis, immune system collapse, hemorrhaging and death in some cases. A useful tool for quantitative detection of specific toxin activity in clinical samples will provide insights into the kinetics of intoxication, stage of infection and present stage of pathogenesis. This rapid, high-throughput analysis method will provide measurements that quantify the efficacy of toxin-based therapeutics and support patient management decisions during treatment. This technology is specific, ultrasensitive and can be implemented to detect toxins from a wide range of pathogenic bacteria. This method could be fabricated into a kit format to deliver to state or research laboratories for use during an anthrax emergency or for research purposes, i.e., animal studies evaluating anthrax therapeutics. This technology may be easily applied to detection/diagnosis of additional pathogenic bacterial species infections as well.

Potential Commercial Applications:
- Detect toxins from a wide range of pathogenic bacteria
- Biodefense, biosecurity diagnostics

Competitive Advantages:
- Presently no individual patient screening assay for anthrax-exposure is widely available. Exposure is determined by public health investigation and environmental-sampling tests
- Current tests lack sensitivity and evidence of effectiveness
- Relatively rapid and exquisitely sensitive method for the detection and quantification of bacterial toxin activity from very small blood samples, accurately assessing exposure and infection

Development Stage:
- In vitro data available
- In vivo data available (animal)

Inventors: Anne E. Boyer, Renata C. Lins, Zsuzsanna Kuklenyik, Maribel Gallegos-Candela, Conrad P. Quinn, John R. Barr (all of CDC)

Publications:

- Various international filings pending

Related Technologies:
- HHS Reference No. E–157–2013/0
- HHS Reference No. E–158–2013/2
- HHS Reference No. E–196–2013/0
- HHS Reference No. E–203–2013/0
- HHS Reference No. E–210–2013/0
- HHS Reference No. E–474–2013/0
- Licensing Contact: Whitney Blair, J.D., M.P.H.; 301–435–4937; whitney.blair@nih.gov

A Simple Colorimetric Assay for Anti-malarial Drugs Quality Assurance and Rapid, On-site Counterfeit Detection

Description of Technology: This CDC assay aims to lessen the anti-malarial drug counterfeiting epidemic by testing for the artemisinin-type drugs (the active compound), through the use of a simple, inexpensive colorimetric test. Poor quality and counterfeit drugs pose an immediate threat to public health and undermine malaria control efforts, resulting in resistant-parasites and invalidates effective compounds, i.e. the artemisinins.

In response to this threat, CDC researchers have developed a simple, inexpensive, field-adapted colorimetric test to determine artemisinin-derivative authenticity in anti-malarial tablets. This assay exploits a chemical reaction in which the active element in question readily reacts under mild conditions with diazonium salts producing a visually distinct green-colored product. The resultant product delineates a positive correlation between color intensity and the drug’s concentration of active-compound; counterfeit drugs will have no or little change in color.

Development Stage:
- In vitro data available
- In situ data available (on-site)

Inventor: Michael D. Green (CDC)

Publications:

- US Patent 8,435,794 issued 07 May 2013

Licensing Contact: Whitney Blair, J.D., M.P.H.; 301–435–4937; whitney.blair@nih.gov

Use of Detector Response Curves to Optimize Settings for Mass Spectrometry

Description of Technology: This CDC developed optimization technology allows one to characterize the behavior of the coefficient of variation (CV) for a range of mass spectrometer machine settings. Surface-enhanced laser desorption/ionization (SELDI) and matrix-assisted laser desorption/ionization (MALDI) are used for the early detection of numerous diseases, for example cervical cancer. A critical step in the analytical process is the optimization of experiment and machine settings to ensure the best possible reproducibility of results, as measured by the CV. The high cost of this procedure includes man hours spent optimizing the machine, opportunity cost, materials used, and spent biological samples used in the optimization process.

This technology can be used to optimize the CV with the following advantages over conventional methods:
- (1) No need to use biological samples,
E virus (HEV) antigenic polypeptides. HEV causes epidemic and sporadic cases of hepatitis outbreaks with a mortality rate as high as 20% for pregnant women. In order to address this problem, CDC scientists carried out thorough HEV antigen screenings and subsequently developed recombinant proteins that efficiently model major HEV neutralization epitope(s). These recombinant proteins may be considered as candidates for the development of an HEV subunit vaccine, as well as for the development of highly sensitive and specific diagnostic tests.

**Potential Commercial Applications:**
- Development of a peptide subunit-based vaccine for hepatitis E virus (HEV).
- Development of HEV sero-diagnostic tools and reagents.
- Blood transfusion screening.
- Pregnancy screening safety precautions.
- Hepatitis monitoring programs.
- Basic research into hepatitis pathogenicity and immune response.

**Competitive Advantages:**
- Generated antibodies were cross-reactive with a number of geographically distinct HEV strains.
- Useful for development of highly sensitive and specific diagnostic tests.
- Could be useful for improving efficacy and HEV-strain immunity provided by current vaccine(s).

**Development Stage:** In vitro data available.

**Inventors:** Vincent A. Emanuele and Brian M. Gurbaxani (CDC)

**Publications:**

**Intellectual Property:** HHS Reference No. E–157–2013/0—

**Related Technologies:**
- HHS Reference No. E–119–2013/0—
- PCT Application No. PCT/US2013/021546 filed 01 Dec 2013, which published as WO 2014/067109 on 06 May 2014.

**Licensing Contact:** Whitney Blair, J.D., M.P.H.; 301–435–4937; whitney.blair@nih.gov

**New Human Rotavirus Vaccine Strains**

**Description of Technology:** This invention relates to rotavirus vaccine compositions and methods of vaccination. The vaccine strains include Rotavirus A CDC–9 and CDC–66. These strains represent common rotavirus serotypes and may serve as improvements or alternatives to current live, oral rotavirus vaccine strains.

**Potential Commercial Applications:**
- Novel rotavirus vaccines.
- Childhood vaccination initiatives.
- Rotavirus surveillance programs.

**Competitive Advantages:**
- Isolated strains are representative of those involved in community-acquired infection.
- Suitable for the development of improved, broadly effective rotavirus vaccines.
- Can be developed for injection and/or oral vaccine administration.
- Derived vaccines may be administered alone or in combination with other vaccines.

**Development Stage:** In vitro data available.

**Inventors:** Howard Fields, Yury Khudyakov, Jihong Meng (all of CDC)

**Publications:**

**Intellectual Property:** HHS Reference No. E–150–2013/0—
- Various international filings pending or deferred.

**Related Technologies:**
- HHS Reference No. E–122–2013/0—
- HHS Reference No. E–153–2013/0—
- HHS Reference No. E–521–2013/0—

**Licensing Contact:** Whitney Blair, J.D., M.P.H.; 301–435–4937; whitney.blair@nih.gov

**Non-radioactive, Miniature Bipolar Aerosol Particle Charger for Personal, Portable Instrumentation**

**Description of Technology:** This CDC developed invention is a novel device for a miniature, nonradioactive bipolar charger to electrically charge aerosol particles for use in personal and portable aerosol instrumentation. Such devices are an integral component of aerosol instruments employing electrical mobility-based techniques. Current, commercial state-of-the-art mobility instruments employ aerosol chargers using radioactivity to achieve bipolar particle charging and, therefore, are not suitable for field-portable instruments. Due to strict regulatory restrictions on use of radioactive materials, these radioactive chargers also tend to be too bulky for use in compact aerosolization instruments.
This invention circumvents these two critical drawbacks by eliminating radioactivity and miniaturizing overall unit size (1.0x0.75 x 0.5 inch). Other unique aspects of the invention entail elimination of the need for additional air flows (other than the aerosol sample flow), minimal power consumption, a low per-unit cost, and simplicity of operation. In all, excellent transmission efficiency, steady-state charging characteristics and the miniature size make this bipolar particle charger well-suited for integration with portable or personal aerosol instrumentation.

**Potential Commercial Applications:**
- Personal and portable aerosol instrumentation
- Component of field-use device for determining workplace/environmental exposure to ultrafine aerosols and airborne nanoparticles
- Tool for environmental/occupational health, toxicology, workplace control evaluations and hazard identification involving aerosol exposure

**Competitive Advantages:**
- Non-radioactive: no associated regulatory or transportation issues
- Low-cost and requires very little power to operate
- Additional air flows other than sample airflow are unnecessary
- Unit is small (1x0.75x0.5 in; 2.54x1.91x1.27 cm) and highly portable
- Eliminates a major barrier for reliable aerosol sampling using “bipolar charger + differential mobility analyzer + condensation particle detector” scheme in a compact device

**Development Stage:** In situ data available

**Inventors:** Prarnod Kulkarni and Chaolong Qi (CDC)

**Intellectual Property:**
- Various international patents issued
- US Patent No. 6,787,126 issued 07 Sep 2004
- Various international patents issued
- HHS Reference No. E–129–2013/0

**Description of Technology:**
This invention will enhance clinical monitoring of individual patient antiretroviral therapy
- HIV/AIDS public health programs
- Surveillance of retroviral drug resistance

**Competitive Advantages:**
- Rapid diagnostic which greatly reduces time and labor for improved clinical monitoring of HIV treatment
- Ready for commercialization
- Easily adapted to kit format
- Assists continued usefulness of common antiretroviral therapeutics

**Development Stage:** In vitro data available

**Inventors:** Walid M. Heneine, Gerardo Garcia-Lerma, Shinji Yamamoto, William M. Switzer, Thomas M. Folks (all of CDC)


**Intellectual Property:**
- HHS Reference No. E–129–2013/0

**Description of Technology:**
This invention covers the breadth of S. pneumoniae infection
- Pneumococcal disease vaccine development or refinement
- Easily adapted to a high-throughput assay for mass screening purposes
- Can be formatted as an on-site, lateral-flow diagnostic; both PfpA antigen and anti-PfpA mAb are available

**Development Stage:** In vitro data available

**Inventors:** Harold Russell, Jacqueyn Sampson, Steven P. O’Connor (all of CDC)

**Publications:**

**Intellectual Property:**

**Related Technologies:**
- HHS Reference No. E–030–2010/0
- HHS Reference No. E–250–2013/0
- HHS Reference No. E–325–2013/0
- HHS Reference No. E–660–2013/0
- HHS Reference No. E–661–2013/0

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01).

Date: February 26, 2014.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Susana Mendez, Ph.D., DVM, Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–496–2550, mendezs@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)


David Clary,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–02253 Filed 2–3–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2013–0066]


AGENCY: Department of Homeland Security, Privacy Office.

ACTION: Notice of Privacy Act System of Records.

SUMMARY: Pursuant to the Privacy Act of 1974 (5 U.S.C. 552a), the Department of Homeland Security (“Department” or “DHS”) proposes to modify the current Department of Homeland Security system of records notice titled, “Department of Homeland Security/ALL—001 Freedom of Information Act and Privacy Act Records System of Records,” last published October 28, 2009. This system of records allows the Department of Homeland Security to collect and maintain records about Freedom of Information Act (FOIA) and Privacy Act requests and appeals submitted to the Department, including any litigation that may result therefrom, information on Mandatory Declassification Reviews, and information that is created and used in the Department’s management of the FOIA and Privacy Act programs. As a result of the biennial review of this system, (1) the location of certain records has been updated, (2) categories of records has been updated to clarify that responses are included, (3) five routine uses have been added, and (4) six routine uses have been modified. Additionally, this Notice includes non-substantive changes to simplify the formatting and the text of the previously published Notice. The entire notice is being republished for ease of reference. This updated system will be included in the Department of Homeland Security’s inventory of record systems.

DATES: Submit comments on or before March 6, 2014. This updated system will be effective March 6, 2014.

ADDRESSES: You may submit comments, identified by docket number DHS–2013–0066 by one of the following methods:

- Fax: 202–343–4010.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to http://www.regulations.gov, including any personal information provided.

Docket: For access to the docket to read background documents or comments received go to http://www.regulations.gov.


SUPPLEMENTARY INFORMATION:

I. Background


As part of its biennial review process, DHS is updating and reissuing this system of records notice to reflect a change in the location of records to include the use of electronic FOIA tracking systems by DHS and its components, and because routine uses are being updated to permit additional sharing. Categories of records have been updated to include responses to requests. Routine use (L) has been added to permit sharing with National Archives and Records Administration (NARA), Office of Government Information Services (OGIS) so those agencies can review administrative policies, procedures, and compliance, and to facilitate resolutions to disputes between persons making Freedom of Information Act (FOIA) requests and DHS. Routine use (M) has been added to allow information to be shared with a court, magistrate, or administrative tribunal in the course of presenting evidence, litigation, or settlement negotiations, or in response to a subpoena, or in connection with criminal law proceedings. Routine use (N) has been added to allow information to be shared with a court, grand jury, or administrative or adjudicative body, when DHS determines that the records are relevant, to the proceeding. Routine use (O) has been added to allow information to be shared with appropriate federal, state, tribal, local, or foreign governmental agencies or multilateral government organizations.