HIV–1 BED: A Simple Serological Assay for Detecting Recent Infection and Estimating Incidence of Multiple, Worldwide HIV–1 Subtypes

**Description of Technology:** This CDC developed invention is a simple enzyme immunoassay that detects increasing levels of anti-HIV-IgG after seroconversion and can be used for detection of HIV–1 infection. The assay, termed IgG-Capture BED–EIA, incorporates a branched peptide derived from 3 different subtypes to allow equivalent detection of antibodies of different subtypes. The competitive format of the assay allows detection of increasing proportion of HIV–1 IgG for almost 2 years after seroconversion. This is different from what is normally observed in a conventional EIA (with antigen coated plates) that plateaus soon after seroconversion. This assay will be important for HIV prevention activities, targeting resources, and evaluation of ongoing interventions.

**Potential Commercial Applications:**
- HIV clinical serodiagnostics
- Informing clinical decision-making
- Public health/HIV monitoring programs and incidence surveillance

**Competitive Advantages:**
- Ready for commercialization
- Simple and high-throughput capable
- Detects HIV–1 subtypes prevalent in N. America, Europe, Japan, Thailand, Australia, and also central and E. Africa

**Development Stage:** In vitro data available

**Inventors:** Bharat S. Parekh and J. Steven McDougal (CDC)

**Publications:**

**Intellectual Property:** HHS Reference No. E–555–2013/0—Research Tool. Patent protection is not being pursued for this technology. Related Technologies:

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

**Improved Botulism, Botulinum Neurotoxin Type-E Diagnostics**

**Description of Technology:** CDC researchers have improved upon a prior,
HHS patented mass spectrometry-based Endopep-MS assay that is able to rapidly detect and differentiate all seven botulinum neurotoxin (BoNT) types A to G. This current improvement comprises the addition of two optimized substrate peptides that increases the assay’s sensitivity, relative to prior substrates, for botulinum neurotoxin type-E (BoNT/E) by greater than 100 fold.

Currently, the primary method of detecting BoNT contamination entails mouse lethality bioassays. In addition to the sacrifice of numerous animals, these lethality assays are expensive and require several days to obtain results. During a suspected BoNT exposure, time is of the essence. The previously patented mass spectrometry approach can provide diagnostic results for all seven BoNT types in a matter of hours, at greater cost-efficiency and without animal toxicity studies. The specific innovation builds upon those earlier improvements by providing new substrates that allow for tremendous increases in the degree of sensitivity for BoNT/E-specific detection within clinical samples.

**Potential Commercial Applications:**
- Detection of botulinum neurotoxin type-E (BoNT/E) in clinical samples
- Basic research investigating neurotoxin activity, *Clostridium botulinum* and botulism
- Biodefense, biosecurity
- Food safety assurance

**Competitive Advantages:**
- More sensitive, greater cost-efficiency and provides results significantly faster than traditional BoNT/E mouse lethality assays
- Builds upon a previously established and patented mass spectrometry-based Endopep-MS assay, adding optimized peptides that improve current BoNT/E detection sensitivity >100 fold

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

**Inventors:** Dongxia Wang, Suzanne R. Kalb, John R. Barr (all of CDC).

**Publications:**

**Intellectual Property:** HHS Reference No. E–528–2013/0—Research Tool. Patent protection is not being pursued for this technology.

**Stable, Early-Stage Biomarker for Diagnosis of Bacillus Anthracis Infection and Anthrax Vaccine Development**

**Description of Technology:** This invention comprises monoclonal antibodies, proteins, and related nucleic acid coding sequences that identify all or part of the antigenic anthrose oligosaccharide of *Bacillus anthracis*, the causative agent of anthrax toxicity in humans. It is imperative to identify virulent *B. anthracis* with speed and specificity, however there presently is substantial difficulty in early-stage recognition and diagnosis of anthrax inhalation. Improved diagnostic assays that can reliably identify anthrax exposure in its earliest stages and distinguish anthrax from other flu-like illnesses are sorely needed.

CDC and collaborative researchers have developed this technology and confirmed the value of an anthrose biomarker assay as a potentially valuable tool in informing early-stage response decisions following potentially anthrax exposure with *in vivo* primate data. This invention may be used for development of point-of-care anthrax exposure tests, as well as therapeutics and vaccines directed against *B. anthracis*.

**Potential Commercial Applications:**
- Biodefense, biosecurity
- Point-of-care *B. anthracis*-exposure diagnostic
- Anthrax vaccine development
- Development of *B. anthracis* therapeutics

**Competitive Advantages:**
- Valuable tools for screening at-risk individuals following possible anthrax exposure
- May be developed as a rapid, lateral-flow assay for emergency point-of-care diagnosis
- In vivo primate studies validate efficacy as serologic biomarker following aerosolized spore exposure


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

Antihemorrhagic Hemostatic Gel

Description of Technology:cdc researchers have developed a fabrication process to create multifunctional microparticles displaying two distinct proteins that are spatially segregated onto a single hemispheric surface. At present, there is no described way of producing biological microparticles with two distinct types of separated proteins. Multifunctional Janus particles generated by the CDC approach possess biologically relevant, native conformational proteins attached to a biologically reactive and safe substrate. They also display high densities of each type of proteins that may enable a range of capabilities that monofunctional particles cannot, such as improved drug targeting and bioimaging capabilities.

The possible uses of these particles are limited only by the biological functions of proteins. For example, two recognition proteins could be used to bring different biological effectors together for enzymatic activation or breakdown. A recognition protein plus an activation molecule could simultaneously bind a cell and stimulate the immune system or facilitate the breakdown of toxic products. Alternatively, a protein drug plus a targeting and internalization motif could target treatment to a specific subset of cells and reduce nonspecific effects of drugs with severe side effects. Such bifunctional Janus particles can be used to create an entirely novel class of smart particle capable of high avidity targeting to and stimulation of multiple cell types. With these new particles, scientists and biomedical engineers can potentially improve the range, specificity and capabilities of therapeutic interventions and research.

PotentialCommercialApplications:

- Development of improved bioimaging agents and approaches for basic research and therapeutic use
- Cellular adhesion and uptake promotion
- Innumerable therapeutic and research usages, for example:
  - Microparticle propulsion and targeting: ActA/RGD
  - Nanoparticle Antibiotic: Fc/Ab
  - Targeted cell killing: Fc/RGD
  - Arbitrary linkages: Streptavidin-biotin

CompetitiveAdvantages:

- Circumvents issue with current multifunctional microparticles having low density attachment and being operatively important
- Enables a range of capabilities that monofunctional particles cannot, such as improved targeting of drugs and bioimaging capabilities
- Provides a dense concentration of antibody binding events to create an artificial immunological recognition milieu that will overcome immunoevasive or-suppressive strategies, and/or mutations by pathogens

DevelopmentStage: In vitro data available

Inventors: David White (CDC), Todd Sulchek (Georgia Tech Research Corp), Jennifer Tang (Georgia Institute of Technology)

Publication:


Inventor: Gwong-Jen J. Chang (CDC)

Publications:


- U.S. Patent No. 8,105,609 issued 31 Jan 2012
- Various international patent applications pending or issued
Vaccine Attenuation via Deoptimization of Synonymous Codons

Description of Technology: Research scientists at CDC have developed compositions and methods that can be used to develop attenuated vaccines having well-defined levels of replicative fitness and enhanced genetic stabilities. Infections by intracellular pathogens, such as viruses, bacteria, and parasites, are cleared in most cases after activation of specific T-cell immune responses that recognize foreign antigens and eliminate infected cells. Vaccines against these infectious organisms traditionally have been developed by administration of whole live attenuated or inactivated microorganisms. Although research has been performed using subunit vaccines, the levels of cellular immunity induced are usually low and not capable of eliciting complete protection against diseases caused by intracellular microbes. CDC inventors discovered that replacement of one or more natural (or native) codons in a pathogen with synonymous unpreferred codons can decrease the replicative fitness of the pathogen, thereby attenuating the pathogen. The unpreferred synonymous codon(s) encode the same amino acid as the native codon(s), but have nonetheless been found to reduce a pathogen’s replicative fitness.

Competitive Advantages:
- Vaccine design and development
- Functional improvements for current vaccines
- Increasing the phenotypic stability of live attenuated vaccines
- Attenuation optimization endeavors

Potential Commercial Applications:
- Retains the protective and immunogenic advantages of native-codon live attenuated vaccine strains
- Alleviates some critical safety issues associated with using live attenuated vaccines
- Likely to possess greater long-term genetic stability than single-point mutations (fewer reversions)
- Basic laboratory research

Development Stage: In vitro data available

Inventors: Olen M. Kew, Cara C. Burns, Raymond Campagnoli, Jacqueline Quay, Jing Shaw (all of CDC)

Publication:

- Various international patent applications pending or issued

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

Photoinduced Electron Transfer Fluorescent Primer for Nucleic Acid Amplification

Description of Technology: CDC scientists have developed a rapid and cost-efficient method for generating fluorescently labeled primers for PCR and real-time PCR. At present, fluorescent primers are useful for detecting and identifying microbes and specific nucleic acid sequences, amplifying nucleic acids for pyro-sequencing, determining the levels of gene expression, and many other uses. However, problems exist with current techniques used to create fluorescent primers. For one, labeling is not one hundred percent efficient, leading to inaccurate results. Further, it is expensive and time consuming for researchers to make and label their own unique primers. This technology allows for the creation of custom primers in which fluorescent dye attaches to all oligomers.

This technology employs photoinduced electron transfer (PET) nucleic acid molecules that can be used to detect and amplify target nucleic acid molecules. PET tags are attached to the 5’-end of a target-specific oligo for fluorescent labeling of the primer. PET tag activity can be quenched by at least two consecutive guanosines (G–G) within the tag sequence and activity is un-quenched when the PET tag hybridizes with its complementary nucleic acid molecule.

Competitive Advantages:
- Allows for multiplex reactions
- Cost-efficient for time, sample preservation and cost of analysis
- Method can readily be used as part of an oligo-labeling kit
- No need for HPLC purification
- Does not require a quencher dye

Development Stage: In vitro data available

Inventors: Jothikumar Narayanan, Vincent R. Hill, Brian F. Holloway (all of CDC)

Publication:

- Various international filings pending

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

Virus Replicon Particles as Rift Valley Fever Vaccines

Description of Technology: Rift Valley fever (RVF) virus primarily infects animals but also has the capacity to infect humans. The disease causes abortion and death among RVF-infected livestock, resulting in substantial economic loss to people living in many parts of Africa and Arabian Peninsula. Currently, there is no commercial vaccine for RVF. CDC scientists have developed a RVF virus replicon particle (VRP) vaccine candidate. Research findings revealed that immunization of mice with a single dose of the RVF–VRP was found to be safe and elicited immune response that offered 100% protection following exposure to lethal dose of virulent virus. RVF–VRPs have the potential to become effective and efficient RVF vaccines in livestock animals and humans.

Competitive Advantages:
- Rift Valley fever vaccine for livestock and/or humans
- VRPs may serve as useful laboratory tool to study the basic mechanisms of virus replication, assembly, kinetics, and virus maturation
Competitive Advantages:
- Requires minute quantities of virus for use, making this assay ideal for confirmation of early-stage infection
- Sensitive and highly specific
- Easily formulated for kits
- Established efficacy in patient samples

Potential Commercial Applications:
- Commercial virus vaccine evaluation and strain selection
- Virus strain surveillance programs
- Harmonize data analysis and standardize reporting procedures for improved worldwide, health-program cohesion

Competitive Advantages:
- Broad-use, generic viral detection for groups M, N and O HIV–1, and also SIVcpz

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

Inventors: Jarad Schiffer and Kathy Hancock (CDC)

Publications:
• Pyro-sequencing
• Basic laboratory research
  Competitive Advantages:
• Simple to implement
• Rapid, real-time detection
• Used with standard laboratory equipment capable of monitoring fluorescence-intensity shifts
• Cost-effective
• Easily adapted for use in kits or arrays

Development Stage: In vitro data available

Inventors: Vincent R. Hill and Jothikumar Narayanan (CDC)

• PCT Application No. PCT/US2006/000175 filed 03 Jan 2006, which published as WO 2006/074222 on 13 Jul 2006
• U.S. Patent No. 7,709,626 issued 04 May 2010
• Several international patent applications pending or issued

Related Technologies:
• HHS Reference No. E–273–2013/0—
• HHS Reference No. E–248–2013/1—

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

Multi-Antigenic Peptide(s) Vaccine and Immunogen for Conferring Streptococcus Pneumoniae Immunity

Description of Technology: Disease caused by Streptococcus pneumoniae (pneumococcus) is an important cause of morbidity and mortality in the United States and developing countries. Pneumococcal disease is prevalent among the very young, the elderly and immunocompromised individuals. This invention is an improved, immunogenic peptide construct consisting of a combination of antigenic epitopes of the PsaA (37-kDa) protein from S. pneumoniae. In addition, the peptides of the invention have the capability of serving as specific immunogens in a subject, effectively eliciting the production of antibodies and conferring protective immunity against S. pneumoniae infection following immunogen administration.

Potential Commercial Applications:
• Development or improvement of S. pneumoniae vaccines
• Public health vaccination programs
• Clinical serodiagnostic development
  Competitive Advantages:
• May provide better immune protection than current, single-epitope vaccines
• Broader spectrum of S. pneumoniae serotypes addressed
• Immunization with these peptides was shown to reduce carriage in murine studies

Development Stage:
• In vitro data available
• In vivo data available (animal)
  Inventors: Edwin W. Ades, George M. Carlone, Jacqueline S. Sampson, Scott E. Johnson, Danny L. Jue (all of CDC)

• U.S. Patent No. 6,903,184 issued 07 Jun 2005
• U.S. Patent No. 8,642,048 issued 04 Feb 2014
• Various international patent applications pending or issued

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

Device To Measure Muscle Contractile-Relaxant and Epithelial Bioelectric Responses of Perfused, Intact Tracheal Airways Tissue In Vitro

Description of Technology: CDC and collaborative researchers have developed a device allowing for simultaneous measurement of smooth muscle contractile-relaxant activity and transepithelial potential difference (Vt) or short circuit currents (Isc) and resistance (Rt) within an intact airway in vitro. Investigation of the underlying mechanisms of lung diseases, such as asthma or cystic fibrosis, involves understanding the roles of airway smooth muscle and epithelium. Smooth muscle is involved in the control of the airway diameter; epithelium regulates the ionic composition of the liquid lining the airways through electrogenic ion transport and releases factors that regulate the ability of smooth muscle to contract.

This invention allows for the measurement and study of pulmonary diseases under conditions retaining normal spatial relationships between all the cell types and an unmanipulated/undistorted tracheal airway wall. Further, the device permits evaluation of epithelial functional integrity using pharmacological techniques. Agents can be separately added to the lumen, where they must first cross the epithelium to reach the smooth muscle, or to the outside of the airway, where there is no hindrance of said agents to the muscle. The invention also permits the effective in vitro screening of the effects of agents and drugs on airway epithelium and smooth muscle within the same preparation.

Potential Commercial Applications:
• Investigations into physiological mechanisms of airway diseases, such as cystic fibrosis and asthma
• Screening of drugs and therapeutic compounds directed to complex, multi-tissue type matrices
• Biomedical research exploring pharmacology-physiology integration

Competitive Advantages:
• Allows simultaneous measurement of transepithelial potential difference, transepithelial resistance, smooth muscle activity and changes in tracheal diameter
• In vitro analysis of tracheal segments retaining native, in situ structure
• Pharmacological agents may be added separately to the lumen for screening purposes
• First and only such “single-preparation” device allowing for such broad array of data output

Development Stage:
• Early-stage
• In vitro data available
• In situ data available (on-site)
• Prototype

Inventors: Jeffrey S. Fedan (CDC), Yi Jing (CDC), Michael Van Scott (East Carolina University)

Publication:


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

A Bias-Free Sampling and Collection Trap for Resting Mosquitoes

Description of Technology: This CDC developed collection device is a small (approximately 1 cubic foot) open-sided container that attracts mosquitoes seeking a daytime resting location. The container is dark-colored and constructed of molded wood-fiber or recycled, high-density plastic. Mosquitoes that enter the dark space of the container are aspirated through a battery-powered fan into a collection receptacle. The receptacle is especially attractive to Culex and Anopheles mosquitoes’ vectors of West Nile Virus and malaria parasites, respectively.

For research aims, this device avoids the sampling biases associated with
CO2-baited traps (attracting mosquitoes in host-seeking mode, about a tenth of the population, and only females) or ovitraps/gravid traps (attract egg-laying females, again about a tenth of the population), making this device superior to other mosquito-sampling traps currently in use. Because all adult mosquitoes must find secluded locations to rest every day, this device samples all sectors of the mosquito population. It also represents a highly effective trap for blood-engorged mosquitoes that rarely enter other types of traps.

Potential Commercial Applications:

- Mosquito sampling for research and epidemiological surveillance purposes
- Mosquito control programs
- Ecological and/or population-genetics interests

Competitive Advantages:

- Receptacle circumvents sampling biases inherent to other mosquito traps.
- Device is particularly adept at luring Culex and Anopheles mosquitoes
- Development Stage: In situ data available (on-site)

Inventors: Nicholas A. Panella, Rebekah J. Kent, Nicholas Komar (all of CDC)

Publication:


Related Technologies:

- HHS Reference No. E–166–2013/0
- HHS Reference No. E–175–2013/0
- HHS Reference No. E–641–2013/0

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

Real-Time PCR Assays for Human Bovacovirus Detection and Diagnosis

Description of Technology: CDC researchers have developed a real-time PCR assay for the detection and viral-load quantitative estimations of human bocavirus (HBoV) from clinical specimens. At present, there have been few reports on the epidemiology, geographic distribution or clinical features of HBoV infection. Additionally, symptoms affiliated with bocavirus infections overlap with numerous other respiratory illnesses. This CDC assay provides sensitive, specific, and quantitative detection of HBoV in patients with respiratory illness by a method of real-time PCR targeting the HBoV NS1 and NP–1 genes. Use of this assay in conjunction with additional diagnostic methods and treatments should facilitate improved diagnosis and, subsequently, directed treatment and patient outcome.

Potential Commercial Applications:

- Human bocavirus (HBoV) research tools
- Respiratory illness diagnostics and research
- Public health surveillance
- Confirmation/diagnosis of HBoV infection

Competitive Advantages:

- Specific and sensitive
- Capable of rapid HBoV detection and distinction from alternate respiratory-illness linked pathogens
- Superior to other HBoV detection methods in cost-efficiency, accuracy and quantitation of viral load
- Development Stage: In vitro data available

Inventors: Dean D. Erdman and Teresa C. Peret (CDC)

Publication:


Potential Commercial Applications:

- Clinical management of HIV-infected patients
- Pre-treatment evaluation baseline HIV infection to tailor appropriate drug combinations
- Monitor the spread of resistant viruses
- Blood donation screening
- Research tool to study emergence and biology of drug resistance mutations

Competitive Advantages:

- Cost-effective
- Sensitive and rapid
- Capable of resistance mutation detection in both subtype B and non-B subtypes of HIV–1, and in HIV–2
- Easily formatted for use in kits
- High-throughput capable

Development Stage: In vitro data available

Inventors: Jeffrey A. Johnson, Walid M. Heneine, Jonathan T. Lipscomb (all of CDC)

Publications:


Real-Time PCR Assays for Human Bovacovirus Detection and Diagnosis

Description of Technology: This novel assay features real-time PCR reagents and methods for detecting drug-resistance related mutations in HIV, for newly diagnosed patients and those individuals currently receiving antiretroviral therapies. As the use of antiretroviral compounds to treat HIV infection proliferates, viruses adapt and evolve mutations limiting the efficacy of these drugs and disrupting the success of treatment. To address this problem, CDC researchers have developed this RT–PCR assay, intended for diagnosis of different point mutations in patient samples at an achievable sensitivity of 1–2 log greater than conventional point-mutation sequencing methods. More specifically, this assay measures the differential amplifications of common and mutation-specific reactions that target specific codons of interest. Given its low cost, simplicity, high-throughput capability, and tremendous diagnostic sensitivity, this assay will be useful for detection and surveillance of drug resistance-associated mutations and will aid in the clinical management of HIV infection.

Potential Commercial Applications:

- Clinical management of HIV-infected patients
- Pre-treatment evaluation baseline HIV infection to tailor appropriate drug combinations
- Monitor the spread of resistant viruses
- Blood donation screening
- Research tool to study emergence and biology of drug resistance mutations

Competitive Advantages:

- Cost-effective
- Sensitive and rapid
- Capable of resistance mutation detection in both subtype B and non-B subtypes of HIV–1, and in HIV–2
- Easily formatted for use in kits
- High-throughput capable

Development Stage: In vitro data available

Inventors: Jeffrey A. Johnson, Walid M. Heneine, Jonathan T. Lipscomb (all of CDC)

Publications:

Easily adaptable for high-throughput
Rapid turnaround

Testing of and research into anthrax
Emergency anthrax exposure

facility) human serum samples.

meat in a Bangladesh processing
naturally-exposed (by contaminated
have been confirmed in animals and
extraordinary specificity and sensitivity.
check for LF rapidly and with
LF’s natural target. By using techniques
a peptide substrate designed to mimic
(LF). In one scenario, the assay
protective antigen (PA) and lethal factor
(toxin (LTx), the toxin responsible for the
lethal effects of anthrax infection. This
assay has already been successfully
tested in animals and will allow for
early detection of anthrax exposure and
screening of lethal factors to monitor
anthrax toxicity, for example for vaccine
trial candidates.

LTx is composed of two proteins,
protective antigen (PA) and lethal factor
(LF). In one scenario, the assay
effectively detects LF by first using
magnetic protein G beads to capture and
concentrate LF in samples, then testing
for LF on the bead by reacting it with
a peptide substrate designed to mimic
LF’s natural target. By using techniques
such as mass spectrometry, PRET or
liquid chromatography, this test can
check for LF rapidly and with
extraordinary specificity and sensitivity.
Methodology and basic assay validation
have been confirmed in animals and
naturally-exposed (by contaminated
meat in a Bangladesh processing
facility) human serum samples.

Development Stage:
• In vitro data available
• In vivo data available (animal)
• In vivo data available (human)
• In situ data available (on-site)

Inventors: Anne E. Boyer, Conrad P.
Quinn, John R. Barr (all of CDC)

Publications:
1. Boyer AE, et al. Detection and
quantification of anthrax lethal factor in
serum by mass spectrometry. Anal
[PMID 17929949]
and poly-D-glutamic acid antigenemia
during inhalational anthrax in rhesus
Aug;77(8):3432–41. [PMID 19506008]
TOF–MS and HPLC–ESI–MS/MS for
endopeptidase activity-based
quantification of Anthrax lethal factor in
serum. Anal Chem. 2011 Mar
1;83(5):1760–5. [PMID 21302970]
4. Boyer AE, et al. Lethal factor toxemia and
anti-protective antigen antibody activity
in naturally acquired cutaneous anthrax.
[PMID 21908727]

Intellectual Property: HHS Reference
No. E–196–2013/0—
• PCT Application No. PCT/US2007/
004156 filed 15 Feb 2007, which
published as WO 2007/136436 on 29
Nov 2007
• U.S. Patent Application No. 11/
675,233 filed 15 Feb 2007
• Various international filings pending
or issued

Related Technologies:
• HHS Reference No. E–158–2013/2
• HHS Reference No. E–167–2013/0
• 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

Select M. Tuberculosis Peptides as
Mucosal Vaccines Against Pulmonary
Tuberculosis

Description of Technology: This CDC
developed technology relates to novel
vaccines or boosters directed against
pulmonary tuberculosis. There is
currently only a single vaccine against
tuberculosis, the (Bacillus Calmette-
Guérin) BCG vaccine. Reports suggest
widely variable effectiveness for the
BCG vaccine and that BCG
administration has very limited success
against prevention of the primary
pulmonary form of the disease. With a
marginally useful vaccine and rising
rates of multidrug-resistant and
extensively drug-resistant (MDR and
XDR) tuberculosis strains, it is clear
there is a public health need that must
be met.

Researchers working at CDC have
developed improved vaccine
formulations and processes of delivery
for enhancing the immune response
against M. tuberculosis. These
improvements may be implemented as
stand-alone vaccines or in conjunction
with BCG as part of a prime-boost
strategy. Intranasal immunization
engenders a strong immune response in
the lungs, which is beneficial because the
M. tuberculosis pathogen primarily
gains entry through the respiratory/
alveolar mucosa. By specifically
stimulating mucosal immunity with
select recombinant M. tuberculosis
peptides at the typical site of
pathogen entry, it is envisioned that
these formulations and delivery
methods will be able to prevent M.
tuberculosis infection and subsequent
pulmonary tuberculosis disease.

Potential Commercial Applications:
• Tuberculosis vaccine development and
improvement
• Public health and BCG vaccination
programs

Competitive Advantages:
• Versatile, has potential as stand-alone
vaccine or booster for use with
current BCG vaccine
• Peptides specifically selected for
generating mucosal immunity, to
address the protective-failings of the
BCG vaccine
• Potential for needle-free delivery that
elicits robust, well-directed immune
response

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

Inventors: Sura Sable, et al. (CDC)

Publication:
Sable SB, et al. Cellular immune responses
to nine Mycobacterium tuberculosis
vaccine candidates following intranasal vaccination. PLoS One.
2011;6(7):e22718. [PMID 21799939]

Intellectual Property: HHS Reference
No. E–192–2013/0—
• PCT Application No. PCT/US09/
030754 filed 12 Jan 2009, which
published as WO 2009/089535 on 16
Jul 2009
• U.S. Patent Application No. 12/
812,541 filed 08 Oct 2010
• Various international patents issued
or pending

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

Detection of Retroviruses and HIV–1
Groups -M and -O Discrimination
Within Clinical Serum Samples

Description of Technology: CDC
researchers have developed methods for
detecting retroviruses within a patient blood sample and discriminating HIV–1 samples within serum specimens. HIV–1 can be genetically classified into two major groups, group M (major) and Group O (outlier) with group O comprising all divergent viruses that do not cluster with group M. The identification of group O infections raised public health concerns about the safety of the blood supply because HIV–1 screening by group M-based serologic tests does not consistently detect group O infection. The assay is based on the selective inhibition of Amp-RT reactivity of Group M viruses by nevirapine, a non-nucleoside RT inhibitor. Group O viruses can be generically identified by the resistance of their Amp-RT activity to nevirapine. The assay can be used to screening of the blood supply and to rapidly differentiate group M from group O virus.

**Potential Commercial Applications:**

- Clinical monitoring of individual patient antiretroviral therapy
- HIV/AIDS public health programs
- Surveillance of retroviral drug resistance
- Screening of blood donations

**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
- Useful for high-throughput serum samples screening

**Development Stage:** In vitro data available

**Inventors:** Thomas M. Folks, Walid Heneine, William Marshall Switzer, Shinji Yamamoto (all of CDC)

**Publications:**


**Intellectual Property:**

- Various international patents issued or pending

**Related Technologies:**

- HHs Reference No. E–232–1993/1 —
  - U.S. Patent No. 5,849,494 issued 15 Dec 1998

**Potential Commercial Applications:**

- The assay is based on the selective inhibition of Amp-RT reactivity of Group M viruses by nevirapine, a non-nucleoside RT inhibitor. Group O viruses can be generically identified by the resistance of their Amp-RT activity to nevirapine. The assay can be used to screening of the blood supply and to rapidly differentiate group M from group O virus.

- Potential Commercial Applications:
  - Clinical monitoring of individual patient antiretroviral therapy
  - HIV/AIDS public health programs
  - Surveillance of retroviral drug resistance
  - Screening of blood donations

- 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
  - Useful for high-throughput serum samples screening

- Development Stage: In vitro data available

- Inventors: Thomas M. Folks, Walid Heneine, William Marshall Switzer, Shinji Yamamoto (all of CDC)

- Publications:

- Intellectual Property:
  - Various international patents issued or pending

- Related Technologies:
  - HHs Reference No. E–232–1993/1 —
    - U.S. Patent No. 5,849,494 issued 15 Dec 1998

- Potential Commercial Applications:
  - The assay is based on the selective inhibition of Amp-RT reactivity of Group M viruses by nevirapine, a non-nucleoside RT inhibitor. Group O viruses can be generically identified by the resistance of their Amp-RT activity to nevirapine. The assay can be used to screening of the blood supply and to rapidly differentiate group M from group O virus.

- 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
  - Useful for high-throughput serum samples screening

- Development Stage: In vitro data available

- Inventors: Thomas M. Folks, Walid Heneine, William Marshall Switzer, Shinji Yamamoto (all of CDC)

- Publications: