### ESTIMATED ANNUALIZED BURDEN HOURS—Continued

<table>
<thead>
<tr>
<th>Type of respondent and instrument</th>
<th>Estimated number of respondents</th>
<th>Estimated number of responses per respondent</th>
<th>Average burden hours per response (in hours)</th>
<th>Estimated total annual burden hours requested</th>
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<tbody>
<tr>
<td>Adults—Tobacco Use Form</td>
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<td>1</td>
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Glenda J. Conroy, 
Executive Officer (OM Director), National Institute on Drug Abuse, NIH.

BILLING CODE 4140–01–P

### 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. 209 and 37 CFR Part 404 to achieve expedited 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: 301–496–7067; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

**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:**


**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 current 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:


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

Novel One-Well Limiting-Antigen Avidity Enzyme Immunoassay To Detect Recent HIV–1 Infection Using a Multi-Subtype Recombinant Protein

Description of Technology: This CDC developed Limiting-Antigen avidity Enzyme Immunoassay (LaAg-avidity-EIA) provides an easy way to measure increasing binding strength (avidity) of HIV antibodies as part of maturation HIV antibodies after seroconversion, providing a method to distinguish early-stage from long-term HIV–1 infection. Surveillance of HIV–1 provides information on prevalence rates of the disease, but determination of new infection rates (HIV–1 incidence) is difficult to deduce. Longitudinal follow up is expensive and can be biased.

Unlike assays which use antigens derived from only one subtype and use two wells, this new approach employs a multi-subtype recombinant protein, rDRI–M, to permit equivalent detection of antibody avidity among different subtypes, and measures binding strength of antibody in one well. This assay will allow the simultaneous testing of more specimens and better overall reproducibility due to its design. Further, the approach is likely to be more robust and provide more accurate results. The assay may be used for individual diagnosis of recent or long-term infection, but may also act as an important tool for worldwide HIV–1 surveillance, assessing new trends of infections, and monitoring success of prevention efforts implemented by major public health agencies.

Potential Commercial Applications:
• Population surveillance: estimation of HIV–1 incidence in cross-sectional specimens
• Identifying recent infection risk factors
• Following antibody avidity maturation over time

Competitive Advantages:
• Assay permits equivalent detection of HIV antibody avidity among different subtypes
• Design of LaAg-avidity-EIA allows for testing more samples and better reproducibility when compared to two-well avidity index EIA

Development Stage: In vitro data available.

Inventor: Bharat S. Parekh (CDC).

Publications:


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

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
• Anthrose biomarker assay readout is critically unaffected by ciprofloxacin (anti-anthrax) treatment

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

Inventors: Conrad P. Quinn (CDC), Elke Saile (CDC), Geert-Jan Boons (Univ of Georgia), Russell Carlson (Univ of Georgia)

Publication:


Related Technologies:
• HHS Reference No. E–158–2013/2
• HHS Reference No. E–167–2013/0
• HHS Reference No. E–196–2013/0
• HHS Reference No. E–203–2013/0
• HHS Reference No. E–210–2013/0

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

Therapeutic, Bifunctional Janus Microparticles With Spatially Segregated Surface Proteins and Methods of Production

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

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.

Potential Commercial Applications:
• 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/GRGDSP
  —Nanoparticle Antibiotic: Fc/Ab
  —Targeted cell killing: Fc/GRGDSP
  —Arbitrary linkages: Streptavidin–biotin

Competitive Advantages:
• Circumvents issue with current monofunctional particles having low density attachment and being operatively impotent
• 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

Development Stage: In vitro data available

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

Recombinant Nucleic-Acid Based Flavivirus Nucleic Acids for Development of Vaccines and/or Sero-Diagnostics

Description of Technology: CDC scientists have developed recombinant flavivirus nucleic acids for the generation of broad protective immunity against flaviviruses, as well as the development of sensitive serologic diagnostic tools. Mosquito borne viral encephalitis is often caused by a flavivirus, such as Japanese encephalitis virus, dengue virus or West Nile virus. Infection by these pathogens is often lethal to both humans and animals.

Specifically, these novel recombinant nucleic acids encode critical structural proteins of flaviviruses, such as yellow fever virus. The invention provides for a method of immunizing a subject against infection by a number of pathogenic flaviviruses. Furthermore, generated antigenic subviral particles can also serve as a tool for the development of specific, antibody detection-based flavivirus diagnostic assays.

Potential Commercial Applications:
• Development of a broadly useful commercial vaccine for pathogenic flaviviruses
• Insect-borne disease monitoring and surveillance programs
• Generated antigen can be used for high-specificity serologic diagnostic assays

Competitive Advantages:
• In vivo animal studies demonstrate specific antibody generation and complete protection
• Desired immune response provided by a single intramuscular injection in both murine and equine studies
• Potential for vaccine use and the development of commercial flavivirus infection diagnostic assays and kits

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

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 those 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.

**Potential Commercial Applications:**
- Vaccine design and development
- Functional improvements for current vaccines
- Increasing the phenotypic stability of live attenuated vaccines
- Attenuation optimization endeavors

**Competitive Advantages:**
- 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)
- Likely to possess greater long-term genetic stability than single-point mutations (fewer reversions)

**Development Stage:** In vitro data available

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

**Publication:**

**Intellectual Property:** HHS Reference No. E–328–2013/0—
- 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 pyrosequencing, 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 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.

**Method can readily be used as part of an oligo-labeling kit**

**Development Stage:** In vitro data available

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

**Publication:**

**Intellectual Property:** HHS Reference No. E–292–2013/0—
- Various international filings pending

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

**Viruses Replicon Particles (VRPs) 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–VRP have the potential to become effective and efficient RVF vaccines in livestock animals and humans.

**Potential Commercial Applications:**
- 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:

- Murine survival study showed single-dose immunization completely protected mice against a virulent RVFV challenge at 100,000-fold greater than the 50% lethal dose (LD(50))
- Rapid onset of a systematic antiviral response suggests conference of early protection
- Low genetic diversity for RVF virus indicates a strong potential for broad-use effectiveness with this vaccine

Development Stage:

- In vitro data available
- In vivo data available (animal)

Inventors: Kimberly Dodd, Cesar G. Albarino, Brian H. Bird, Stuart T. Nichol (all of CDC)

Publication:


- U.S. Application No. 61/661,614 filed 19 Jun 2012


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

Molecular Detection and Viral-Load Quantification for HIV–1 Groups M, N and O, and Simian Immunodeficiency Virus-cpz (SIVcpz)

Description of Technology: This invention provides materials, methods, and assays for detecting HIV–1 groups M and O and optionally HIV–1 group N and simian immunodeficiency virus-cpz (SIV-cpz). Specific nucleic acid primers for hybridization, amplification, and detection of HIV–1 are also provided for. The nucleic acid amplification assays can detect small concentrations of HIV–1 and are also useful for in situ data available (on-site)

Publications:


Fluorescent Primer(s) Creation for Nucleic Acid Detection and Amplification

Description of Technology: CDC researchers have developed technology that consists of a simple and inexpensive technique for creating fluorescent labeled primers for nucleic acid amplification. Fluorescent chemical-labeled probes and primers are extensively used in clinical and research laboratories for rapid, real-time detection and identification of microbes and genetic sequences. During nucleic acid amplification, the “UniFluor” primer is incorporated into newly synthesized double stranded DNA. As a consequence, quenching of the dye’s fluorescent signal occurs decreasing the fluorescence of the sample several fold. The decrease in fluorescence can be measured and observed using any commercially available nucleic acid amplification system that measures fluorescence (e.g., real-time PCR/thermocyclers). Because many real-time PCR applications require a multitude of fluorescently labeled primers or probes, the single-labeled primer technique also allows researchers and clinicians to perform their work at lower cost.

Potential Commercial Applications:

- Quantitative detection and/or amplification of specified nucleic acid sequences
- Efficient fluorescence-labeling of oligonucleotides
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, Jacqulyn 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 (Vi) (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 trachea or 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:


Publications:


Real-Time PCR Assays for Human Bocavirus 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:


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:


Exposure and Activity Detection Assays for Anthrax Lethal Factor and Lethal Toxin

Description of Technology: This CDC developed invention identifies an assay for extremely fast and sensitive detection of *Bacillus anthracis* lethal 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, FRET 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.

Potential Commercial Applications:
- Emergency anthrax exposure diagnostics
- Testing of and research into anthrax therapeutics, vaccines
- Biodefense, biosecurity
- Livestock health screening

Competitive Advantages:
- Rapid turnaround
- Highly sensitive-detects picomolar toxin levels
- Reproducible and quantitative anthrax lethal factor (LF) assessment
- Easily adaptable for high-throughput screening of numerous specimens

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:


- Various international filings pending or issued

Related Technologies:
- HHS Reference No. E–158–2013/3
- 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

License 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* polypeptides 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: Suraj Sable, et al. (CDC)

Publication:


- PCT Application No. PCT/US09/030754 filed 12 Jan 2009, which was published as WO 2009/089535 on 16 Jul 2009
- Various international patents issued or pending

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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.

PotentialCommercialApplications:

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

CompetitiveAdvantages:

- 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

DevelopmentStage: In vitro data available

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

Publications:


IntellectualProperty:

- Various international patents issued or pending

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

RelatedTechnologies:

HHS Reference No. E–129–2013/0 —
- U.S. Patent No. 6,787,126 issued 07 Sep 2004
- Various international patents issued

HHS Reference No. E–129–2013/1 —
- U.S. Patent No. 7,691,572 issued 06 Apr 2010

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