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:


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:**


**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 hemispheric 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 monofunctional 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 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 uses, for example:
  — Microparticle propulsion and targeting: ActA/RGD
  — Nanoparticle Antibiotic: Fc/Ab
  — Targeted cell killing: Fc/RGD
  — Arbitrary linkages: Streptavidin-biotin

Competitive Advantages:
• Circumvents issue with current bifunctional microparticles 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

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

Publication:


Licensing Contact: 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 microbes. 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 nonpreferred codons can decrease the replicative fitness of the pathogen, thereby attenuating the pathogen. The nonpreferred 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)

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 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.

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.

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 (LD50)
- 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

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 CDC invented invention entails improved methods for analyzing microneutralization assays, especially for the purposes of determining specific antibody concentrations and optimizing vaccine formulation. More specifically, the invention is a set of SAS based programs using 4-parameter logistic curve fitting algorithms to interpolate between individual data points, allowing for enhanced accuracy and precision when establishing neutralization titers. This method allows every experiment to be analyzed the same way, providing greater accuracy by interpolating curve fits between dilutions, prevents transcription errors or manual calculation errors, develops and applies consistent quantitative control rules, and improves operational speed and efficiency.

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

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

Useful for improved strain selection in future influenza (or other) vaccine development

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

Inventors: Jarad Schiffer and Kathy Hancock

Publications:


- PCT Application No. PCT/US2011/041459 filed 22 Jun 2011, which published as WO 2011/163370 on 29 Dec 2011

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

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
- 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

- 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, Jacquelyn 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 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

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

Publication:


Simple, Rapid, and Sensitive Real-Time PCR Assays for Detecting Drug Resistance of HIV

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:

Intelectual Property:

Real-Time PCR Assays for Human Bovacavirus 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:


Patent protection is not being pursued for this technology.

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:
Laboratory Methods of Anthrax Detection

Description of Technology:

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

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

3. Publications:

4. Intellectual Property:
   - HHS Reference No. E–196–2013/0—
   - Various international filings pending or issued

5. 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

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

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

8. Potential Commercial Applications:
   - Tuberculosis vaccine development and improvement
   - Public health and BCG vaccination programs

9. Description of Technology:

   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/aloever 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
   - 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:**

   **Intellectual Property:**
   - HHS Reference No. E–192–2013/0—
   - 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, Wald Heneine, William Marshall Switzer, Shinji Yamamoto (all of CDC)

**Publications:**

**Intellectual Property:**
  - Various international patents issued or pending
- HHS Reference No. E–232–1993/1—
  - U.S. Patent No. 5,849,494 issued 15 Dec 1998

**Related Technologies:**
- 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

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

**Dated:** January 31, 2014.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**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 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 20852–3904. Telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

**Multivalent Immunogen Peptides (Vaccines) for the Treatment of Prostate and Breast Cancer**

**Description of Technology:** The development of more targeted means of treating cancer is vital. One option for a targeted treatment is the creation of a vaccine that induces an immune response only against cancer cells. In this sense, vaccination involves the introduction of a peptide into a patient that causes the formation of antibodies or T cells that recognize the peptide. If the peptide is from a protein found selectively on/in cancer cells, those antibodies or T cells can trigger the death of those cancer cells without harming non-cancer cells. This can result in fewer side effects for the patient.

TARP (T cell receptor gamma alternate reading frame protein) is a protein that is selectively expressed on the cells of about 95% of prostate cancers and about 50% of breast cancers. This invention concerns the identification of a combination of immunogenic peptides within TARP and their use to create an anti-cancer immune response in patients. By introducing these seven peptides into a patient, an immune response against these cancer cells can be initiated by the peptides, resulting in treatment of the cancer.

**Potential Commercial Applications:**
- Peptides can be used as vaccines to induce an immune response against cancer
- Treatment of any cancer associated with increased or preferential expression of TARP
- Specific diseases include breast cancer and prostate cancer

**Competitive Advantages:**
- Targeted therapy decreases non-specific killing of healthy, essential cells, resulting in fewer non-specific side-effects and healthier patients
- Use of multiple peptides permits production of a more thorough complement of T cells against the antigen

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

**Inventors:** Jay A. Berzofsky, et al. (NCI)

**Publications:**