downloads/Food/GuidanceRegulation/FSMA/UCM380212.pdf.

3. Food and Drug Administration. ''U.S. Food and Drug Administration, Reportable Food Summary Report, Definitions.'' Available at *http://www.fda.gov/downloads/Food/FoodSafety/FoodSafetyPrograms/RFR/UCM211534.pdf.* Last Modified April 2012.

Dated: January 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02255 Filed 2–3–14; 8:45 am]

BILLING CODE 4160–01–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 expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

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

Description of Technology: This invention pertains to the development of oligonucleotides for the rapid nucleic acid-based identification of the Candida fungi species *C. haemulonii, C. kefyr, C. lambica, C. lusitaniae, C. norvegensis, C. norvegica, C. rugosa, C. utilis, C. viswanathii, C. zeylanoides, C. dubliniensis,* and *C. pelliculosa* within biological samples. This identification is accomplished by targeting the internally transcribed spacer-2 (ITS2) region that is specific for each species. The assay is sensitive, specific and rapid. Implementation of the technology will facilitate earlier specific diagnoses, and lead to better antifungal therapy implementation for infected patients.

Potential Commercial Applications:

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

Competitive Advantages:

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

Development Stage: In vitro data available

Inventors: Christine J. Morrison, Errol Reiss, Cheryl M. Elie, Timothy J. Lott (all of CDC)

Publication: Shin JH, et al. Rapid identification of up to three Candida species in a single reaction tube by a 5' exonuclease assay using fluorescent DNA probes. J Clin Microbiol. 1999 Jan;37(1):165–70. [PMID 9854084]

Intellectual Property: HHS Reference No. E–340–2013/0—

- PCT Application No. PCT/US1998/015840 filed 30 Jul 1998, which published as WO 1999/006596 on 11 Feb 1999
- US Patent No. 6,242,178 issued 05 Jun 2001
- Various international issued patents

Related Technologies:

- HHS Reference No. E–293–2013/0
- HHS Reference No. E–332–2013/0
- HHS Reference No. E–232–2013/0
- HHS Reference No. E–335–2013/0
- HHS Reference No. E–339–2013/0

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

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

Description of Technology: This invention pertains to the development of oligonucleotides for the rapid nucleic acid-based identification of Candida or Aspergillus fungi species in biological samples. This identification is accomplished by the targeting the internally transcribed spacer-2 (ITS2) region that are unique to various Candida species. The assay is sensitive, specific and rapid. Implementation of the technology will facilitate earlier specific diagnoses, and lead to better antifungal therapy implementation for infected patients.

Potential Commercial Applications:

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

Competitive Advantages:

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

Development Stage: In vitro data available

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

Publication: Shin JH, et al. Rapid identification of up to three Candida species in a single reaction tube by a 5' exonuclease assay using fluorescent DNA probes. J Clin Microbiol. 1999 Jan;37(1):165–70. [PMID 9854084]

Intellectual Property: HHS Reference No. E–339–2013/0—

- PCT Application No. PCT/US1997/016423 filed 15 Sep 1997, which published as WO 1998/011257 on 19 Mar 1998
- US Patent No. 6,235,890 issued 22 May 2001
- Various international issued patents

Related Technologies:

- HHS Reference No. E–293–2013/0
- HHS Reference No. E–332–2013/0
- HHS Reference No. E–232–2013/0
- HHS Reference No. E–335–2013/0

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

Nucleic Acid Assays for the Detection and Discrimination of Aspergillus Fungi Species within Biological Samples

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

Potential Commercial Applications:

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

Competitive Advantages:

• Easily adapted for use in kits
• Assay may be used in real-time PCR, in enzyme immunoassays and/or in microarrays
• High-throughput capable
Development Stage: In vitro data available
Inventors: Christine J. Morrison and Hans Peter Hinrikson (CDC)
Publications:
1. Hinrikson HP, et al. Assessment of ribosomal large-subunit D1–D2, internal transcribed spacer 1, and internal transcribed spacer 2 regions as targets for molecular identification of medically important Aspergillus species. J Clin Microbiol. 2005 May;43(5):2092–103. [PMID 15872227]
2. CDC Fact Sheet: Aspergillosis [*http://www.cdc.gov/fungal/aspergillosis/*]
Intellectual Property: HHS Reference No. E–335–2013/0—
• PCT Application No. PCT/US2003/016076 filed 16 May 2003, which published as WO 2003/097815 on 27 Nov 2003
• US Patent No. 7,384,741 issued 10 Jun 2008
• US Patent No. 7,871,779 issued 18 Jan 2011
• Various international patents issued or pending
Related Technologies:
• HHS Reference No. E–293–2013/0
• HHS Reference No. E–332–2013/0
• HHS Reference No. E–232–2013/0
Licensing Contact: Whitney Blair, J.D. M.P.H.; 301–435–4937; *whitney.blair@nih.gov*

Nucleic Acid-based Differentiation and Identification of Medically Important Fungi

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

Potential Commercial Applications:
• Directing antifungal drug therapy for improved patient outcomes
• Detection, discrimination of fungal pathogens
• Addressing secondary infections of immunosuppressed individuals or asthmatics
Competitive Advantages:
• Rapid, sensitive, simple and specific
• Potential for automation and high-throughput screening
• Easily adaptable to kit form
Development Stage: In vitro data available
Inventors: Mark D. Lindsley, Zhenyu Qin, Christine J. Morrison, Jong S. Choi (all of CDC)
Publication: Lindsley MD, et al. Rapid identification of dimorphic and yeast-like fungal pathogens using specific DNA probes. J Clin Microbiol. 2001 Oct;39(10):3505–11. [PMID 11574564]
Intellectual Property: HHS Reference No. E–332–2013/0—
• PCT Application No. PCT/US2002/030605 filed 25 Sep 2002, which published as WO 2003/027329 on 03 Apr 2003
• US Patent No. 7,427,472 issued 23 Sep 2008
• Various international patents issued or pending
Related Technologies:
• HHS Reference No. E–293–2013/0
• HHS Reference No. E–232–2013/0
• HHS Reference No. E–335–2013/0
Licensing Contact: Whitney Blair, J.D. M.P.H.; 301–435–4937; *whitney.blair@nih.gov*

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

Description of Technology: This invention relates to detecting *Histoplasma capsulatum* by PCR using oligonucleotide probes specific for the fungus. Histoplasmosis is a mycotic infection of varying severity, usually localized in the lungs. Caused by *H. capsulatum,* infections are usually symptomatic but can develop into chronic disease, especially in immunocompromised individuals.

Test samples may originate from the environment (soil, for example), where *H. capsulatum* spores are found or from clinical samples obtained from patients. Furthermore, the invention also provides for methods that detect the presence of *H. capsulatum* in a sample using a nested, or two-stage, PCR assay.

Potential Commercial Applications:
• Directing antifungal drug therapy for improved patient outcomes
• Occupational health and safety screening for workers who may encounter bird or bat waste
• Screening biological or soil samples for the presence of fungal pathogens
• Environment testing for immunocompromised patients
Competitive Advantages:
• Rapid and precise
• Cost-effective
• Easily adapted for *H. capsulatum* detection kits
• Can positively identify small sample sizes of as few as 10 spores
• High-throughput capable
Development Stage: In vitro data available
Inventors: Millie Schafer and Thomas Reid (CDC)
Publications:
1. Reid TM, Schafer MP. Direct detection of Histoplasma capsulatum in soil suspensions by two-stage PCR. Mol Cell Probes. 1999 Aug;13(4):269–73. [PMID 10441199]
2. CDC Fact Sheet: Histoplasmosis [*http://www.cdc.gov/fungal/histoplasmosis/*]
Intellectual Property: HHS Reference No. E–313–2013/0—US Patent No. 6,469,156 issued 22 Oct 2002
Related Technologies:
• HHS Reference No. E–293–2013/0
• HHS Reference No. E–332–2013/0
• HHS Reference No. E–232–2013/0
• HHS Reference No. E–335–2013/0
Licensing Contact: Whitney Blair, J.D. M.P.H.; 301–435–4937; *whitney.blair@nih.gov*

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

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

This new technique uses microsphere/microbead-based flow-analysis as a platform. Because of a basis in a pre-existing technology, the technique can be easily incorporated into current state and health department diagnostic testing protocols. The method is particularly unique because the assay-generated data can be standardized and then classified via discriminant analysis to determine the presence or absence of antibodies of interest within the clinical sample tested.

Furthermore, along with allowances for single-result generation, data manipulation and classification algorithms allow for assay output comparisons to the original large data set references used in development. In this way, results from different laboratories can now be directly compared to one another, provided that the same controls are used.

Potential Commercial Applications:

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

Competitive Advantages:

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

Development Stage: In vitro data available

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

Publications:

1. Basile AJ, et al. Removal of species constraints in antibody detection. Clin Vaccine Immunol. 2010 Jan;17(1):56–61. [PMID 19923570]

2. Basile AJ, et al. Multiplex microsphere immunoassays for the detection of IgM and IgG to arboviral diseases. PLoS One. 2013 Sep 25;8(9):e75670. [PMID 24086608]

Intellectual Property: HHS Reference No. E–302–2013/0—

- US Patent No. 7,933,721 issued 26 Apr 2011
- US Patent No. 8,433,523 issued 30 Apr 2013
- Various international patent applications pending or issued

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

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

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

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

Potential Commercial Applications:

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

Competitive Advantages:

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

Development Stage:

- Early-stage
- In vitro data available

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

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

Intellectual Property: HHS Reference No. E–293–2013/0—

- PCT Application No. PCT/US2006/037640 filed 26 Sep 2006, which published as WO 2007/038578 on 05 Apr 2007
- US Patent No. 8,119,788 issued 21 Feb 2012
- Several international filings issued or pending

Related Technologies:

- HHS Reference No. E–232–2013/0
- HHS Reference No. E–332–2013/0
- HHS Reference No. E–335–2013/0
- HHS Reference No. E–339–2013/0

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

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

Description of Technology: CDC researchers have isolated and characterized the novel primate T-lymphotropic viruses denoted human T-lymphotropic viruses 3 and 4 (HTLV–3 and HTLV4), that are believed to have resulted from cross-species transmission at some point in the past. It has been previously established that HTLV–1 causes adult T cell leukemia and other inflammatory diseases; HTLV–2 is considered less pathogenic than HTLV–1 and has been associated with a neurologic disease similar to HTLV–1-associated myelopathy. At present, the human pathologies of HTLV–3 and HTLV–4 are yet uncharacterized, but have been identified as infecting rural Central African hunters who have much greater risk of contact with non-human primates, sometimes infected with simian T-lymphotropic viruses (STLVs). As HTLV infected individuals from rural, isolated populations have increasing contact with their urban brethren, there is increased potential for the rapid spread of new viral zoonotic-originating pathogens, much like the theorized ''bushmeat'' origins of HIV. There is a present and unmet need for increased surveillance, study, and preventative therapeutics directed towards mitigating the public health impact of these viruses. This CDC developed technology provides methods and tools to that end.

Potential Commercial Applications:

- Development of HTLV diagnostics
- Simian/human T-cell lymphotropic virus research
- Zoonosis surveillance
- Vaccine design and development

Competitive Advantages:

- Provides tremendous opportunity for phylogenetic, clinical and epidemiological investigations of HTLV and STLV
- Facilitates monitoring of viral diversity and study of zoonotic disease transmission
- Provides tools needed to address and mitigate a newly emergent blood-borne disease before widespread, regional/global viral dissemination occurs

Development Stage:

- Early-stage
- In vitro data available

Inventors: Donald S. Burke (Johns Hopkins Univ), Thomas M. Folks (CDC), Walid Heneine (CDC), Eitel Mpoudi

Ngole (CDC), William M. Switzer (CDC), Nathan D. Wolfe (Johns Hopkins Univ)

Publications:

1. Wolfe ND, et al. Emergence of unique primate T-lymphotropic viruses among central African bushmeat hunters. Proc Natl Acad Sci U S A. 2005 May 31;102(22):7994–9. [PMID 15911757]

2. Switzer WM, et al. Ancient, independent evolution and distinct molecular features of the novel human T-lymphotropic virus type 4. Retrovirology. 2009 Feb 2;6:9. [PMID 19187529]

Intellectual Property:

• HHS Reference No. E–281–2013/0—

—PCT Application No. PCT/US2006/005869 filed 21 Feb 2006, which published as WO 2006/091511 on 31 Aug 2006

—Various international patents granted and pending

• HHS Reference No. E–281–2013/1—

—US Patent No. 7,794,998 issued 14 Sep 2010

—US Patent No. 8,541,221 issued 24 Sep 2013

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

• PCT Application No. PCT/US2008/064270 20 May 2008, which published as WO 2008/144700 on 27 Nov 2008

• U.S. Patent Application No. 12/600,995 filed 19 Nov 2009

• U.S. Patent Application No. 14/013,947 filed 29 Aug 2013

• Various international patents granted and pending

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

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

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

Potential Commercial Applications:

• Observation and data analysis

• Determining concentrations

• Improving calculations and estimations

• Enhancing consistency and reproducibility of outcomes for bio and chem assays

Competitive Advantages:

• Less output-data subjectivity than alternate methods

• Rapid, accurate and simple to implement

• Quality control and assurance for a number of assays such as PCR, ELISA, toxin neutralization assays (TNA), flow cytometry, cell death assays, titrations, etc.

• Reduces data variability due to errant input

• Easily adapted to high-throughput analyses

• Demonstrated efficacy quantifying anthrax lethal toxin neutralization activity

Development Stage: In vitro data available

Inventor: Thomas H. Taylor (CDC)

Publication: Li H, et al. Standardized, mathematical model-based and validated in vitro analysis of anthrax lethal toxin neutralization. J Immunol Methods. 2008 Apr 20;333(1–2):89–106. [PMID 18304568]

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

• PCT Application No. PCT/US2004/008566 filed 19 Mar 2004, which published as WO 2004/084708 on 07 Oct 2004

• US Patent No. 7,469,186 issued 23 Dec 2008

• Australia Patent No. 2004224317 issued 25 Feb 2010

• Various international patent applications pending or issued

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

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

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

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

Potential Commercial Applications:

• Validation studies, proficiency testing

• Public health and veterinary/zoonotic disease monitoring programs

• Diagnostic testing, especially within the poultry industry

• Disease screening of companion birds

Competitive Advantages:

• Rapid and simple

• Simultaneous detection and discrimination of *C. psittaci* genotypes

• Improved efficiency in time and cost

• Easily adapted for use in kits

Development Stage: In vitro data available

Inventors: Stephanie L. Mitchell and Jonas M. Winchell (CDC)

Publication: Mitchell SL, et al. Genotyping of Chlamydophila psittaci by real-time PCR and high-resolution melt analysis. J Clin Microbiol. 2009 Jan;47(1):175–81. [PMID 19005152]

Intellectual Property: HHS Reference No. E–266–2013/0–US Patent Application No. 13/322,787 filed 28 Nov 2011

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

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

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

deer pox, tanapox/Orf virus, Bovine popular stomatitis virus). Some poxvirus species impart unique and obvious symptoms making them easy to diagnose, while many others are clinically ambiguous. For instance, parapoxvirus infections are often misdiagnosed as cutaneous anthrax, which unnecessarily contributes to overuse of antibacterial agents. There is therefore a demonstrated need to develop better diagnostic tools to detect and properly identify the agent of poxvirus infections. Regardless of the symptoms, this universal assay can quickly and reliably detect chordopoxvirus presence in clinical samples, allowing for proper identification, diagnosis, treatment, and improved patient outcomes.

Potential Commercial Applications:

• Nucleic acid-based diagnostic for 'unknown rash' illnesses and identifying novel poxviruses

• Disease surveillance programs, including public health and veterinary (livestock, domestic, wild/exotic)

Competitive Advantages:

• Rapid and simple

• Allows for high-throughput, simultaneous sample screening

• Detects, identifies all low-G/C content non-avipox chordopoxviruses and most known high-G/C content chordopoxviruses

Development Stage: In vitro data available

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

Publication: Li Y, et al. GC content-based pan-pox universal PCR assays for poxvirus detection. J Clin Microbiol. 2010 Jan;48(1):268–76. [PMID 19906902]

Intellectual Property: HHS Reference No. E–265–2013/0—

• PCT Application No. PCT/US2010/055061 filed 02 Nov 2010, which published as WO 2011/056771 on 12 May 2011

• US Patent Application No. 13/505,719 filed 02 May 2012

• Various international patent applications pending

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

Novel Rift Valley Fever Virus Vaccines

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

Potential Commercial Applications:

• Rift Valley fever (RVF) virus vaccine development or improvement

• Prevention of RVF virus infection in livestock and humans

• Biodefense, biosecurity

Competitive Advantages:

• In vivo evidence shows single-dose protection

• Allows for discrimination between vaccinated and naturally-infected subjects

• Useful for controlled screening of therapeutic compounds

Development Stage:

• In vitro data available

• In vivo data available (animal)

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

Publications:

1. Bird BH, et al. Rift valley fever virus lacking the NSs and NSm genes is highly attenuated, confers protective immunity from virulent virus challenge, and allows for differential identification of infected and vaccinated animals. J Virol. 2008 Mar;82(6):2681–91. [PMID 18199647]

2. CDC Fact Sheet: Rift Valley Fever [*http://www.cdc.gov/vhf/rvf/*]

Intellectual Property: HHS Reference No. E–254–2013/2—

• PCT Application No. PCT/US2008/087023 filed 16 Dec 2008, which published as WO 2009/082647 on 02 Jul 2009

• US Patent Application No. 12/809,561 filed 18 Jun 2008 (select claims allowed as of 24 Oct 2013)

• Additional applications granted and pending

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

Personal Air Sampler for Collecting Airborne Aerosol Particulates for Molecular Analysis

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

Potential Commercial Applications:

• Analysis of ambient air particulates

• Environmental surveillance

• Occupational safety monitoring

• Biodefense

• Long-term exposure assessment

Competitive Advantages:

• Rapid, on-site sampling and analysis

• Alternative to surface-sampling and culturing for aerosolized biological agents

• Superior extraction efficiency compared to filters, impingers, and impactors

• Real-world testing demonstrated device's ability to collect airborne mold and mycotoxins, pollen and pollen fragments, airborne dust particulates, as well as airborne influenza virus in a hospital environment.

Development Stage:

• In situ data available (on-site)

• Prototype

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

Publications:

1. Lindsley WG, et al. A two-stage cyclone using microcentrifuge tubes for personal bioaerosol sampling. J Environ Monit. 2006 Nov;8(11):1136–42. [PMID 17075620]

2. Blachere FM, et al. Bioaerosol sampling for the detection of aerosolized influenza virus. Influenza Other Respir Viruses. 2007 May;1(3):113–20. [PMID 19453416]

3. Lindsley WG, et al. Measurements of airborne influenza virus in aerosol particles from human coughs. PLoS One. 2010 Nov 30;5(11):e15100. [PMID 21152051]

4. Cao G, et al. Development of an improved methodology to detect infectious airborne influenza virus using the NIOSH bioaerosol sampler. J Environ Monit. 2011 Dec;13(12):3321–8. [PMID 21975583]

5. CDC-NIOSH Cyclone Bioaerosol Sampler Web page: *http://www.cdc.gov/niosh/topics/aerosols/biosampler.html*

Intellectual Property: HHS Reference No. E–244–2013/0—

• US Patent No. 7,370,543 issued 13 May 2008

• US Patent No. 8,205,511 issued 26 June 2012

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

Warning System for Mobile Machinery Hazardous Zones

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

Potential Commercial Applications:

- Auxiliary safety equipment for heavy machinery
- Occupational health and safety
- Mining worker safety

Competitive Advantages:

- Easy transmitter installation
- Signal can be adjusted for an audio or visual ''warning zone alert'' and a proximal ''imminent danger zone alert''

Development Stage:

- In situ data available (on-site)
- Prototype

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

Publication: Schiffbauer WH. A workplace safety device for operators of remote-controlled continuous mining machines. Am J Ind Med. 1999 Sep;Suppl 1:69–71. [PMID 10519790]

Intellectual Property: HHS Reference No. E–239–2013/0—US Patent No. 5,939,986 issued 17 Aug 1999

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

Species-specific Nucleic Acid Detection Assay for Fungi

Description of Technology: This invention pertains to nucleic acid-based assays for the detection of *Aspergillus* and other filamentous fungi. Assays cover the species-specific detection and diagnosis of infection by *Aspergillus, Fusarium, Mucor, Penecillium, Rhizomucor, Absidia, Cunninghamella, Pseudallescheria* or *Sporthrix* in a subject. This can reduce identification time from several days by conventional culture methods to a matter of hours. Furthermore, genus-specific probes are also provided for *Aspergillus, Fusarium* and *Mucor,* in addition to an ''all-fungus'' nucleic acid probe. This technology is readily adaptable as kits used for species-specific identification of opportunistic pathogen infections or possible work/home contamination.

Potential Commercial Applications:

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

Competitive Advantages:

- Rapid, sensitive, simple and specific
- Cost-efficiency compared to culture or sero-diagnostic methods
- Easily adaptable to kit form
- High-throughput screening

Development Stage: In vitro data available

Inventors: Christine J. Morrison, Errol Reiss, Jong Soo Choi, Liliana Aidorevich (all of CDC)

Intellectual Property: HHS Reference No. E–232–2013/0—

- US Patent No. 6,372,430 issued 16 Apr 2002
- US Patent No. 7,052,836 issued 30 May 2006

Related Technologies:

- HHS Reference No. E–293–2013/0
- HHS Reference No. E–332–2013/0
- HHS Reference No. E–335–2013/0

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

Improved Protein Quantification Process and Vaccine Quality Control Production

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

Potential Commercial Applications:

- Vaccine production, especially influenza-related
- Quality assurance, quality control
- Influenza surveillance programs

Competitive Advantages:

- Simultaneous, precise protein detection and quantification for complex mixtures
- Rapid; method cuts investigation/research time needed to formulate and optimize novel vaccines for emergent influenza strains
- Improved vaccine cost and production efficiency

Development Stage:

- Early-stage
- In vitro data available

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

Publications:

1. Williams TL, et al. Quantification of influenza virus hemagglutinins in complex mixtures using isotope dilution tandem mass spectrometry. Vaccine. 2008 May 12;26(20):2510–20. [PMID 18440105]
2. Pierce CL, et al. Quantification of immunoreactive viral influenza proteins by immunoaffinity capture and isotope-dilution liquid chromatography-tandem mass spectrometry. Anal Chem. 2011 Jun 15;83(12):4729–37. [PMID 21591780]
3. Williams TL, et al. Simultaneous quantification of hemagglutinin and neuraminidase of influenza virus using isotope dilution mass spectrometry. Vaccine. 2012 Mar 23;30(14):2475–82. [PMID 22197963]
4. Woolfitt AR, et al. Amino acid analysis of peptides using isobaric-tagged isotope dilution LC–MS/MS. Anal Chem. 2009 May 15;81(10):3979–85. [PMID 19364092]

Intellectual Property: HHS Reference No. E–212–2013/0—

- PCT Application No. PCT/US2008/013396 filed 05 Dec 2008, which published as WO 2009/110873 on 11 Sep 2009
- US Patent No. 8,530,182 issued 10 Sep 2013

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

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

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

Potential Commercial Applications:

• Diagnostic tests assessing active Lethal Factor in a sample
• Anthrax neutralizing therapeutics and vaccines for *B. anthracis*
• Biodefense, biosecurity

Competitive Advantages:
• Potentially faster, lower-input assay compared to current Edema Factor detection methods
• Easily adaptable for high-throughput screening of numerous specimens

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

Inventors: Jason Goldstein, Conrad Quinn, Dennis Bagarozzi, Anne Boyer (all of CDC)

Publication: Boyer AE, et al. Detection and quantification of anthrax lethal factor in serum by mass spectrometry. Anal Chem. 2007 Nov 15;79(22):8463–70. [PMID 17929949]

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

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–474–2013/0

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

Respiratory Syncytial Virus Immunogens for Vaccine and Therapeutics Development

Description of Technology: CDC researchers have developed specific Respiratory Syncytial Virus (RSV) immunogens for use in the development of RSV-directed vaccines and therapeutics. RSV is the most common cause of serious respiratory disease in infants and young children and an important cause of disease in the elderly. To date, efforts to make a mutually safe and effective vaccine have been largely unsuccessful. This invention addresses both problems.

CDC and collaborative researchers have demonstrated that a vaccine based on amino acid sequences corresponding to group-specific regions of the RSV G-protein can effectively induce antibodies, facilitate virus clearance, decrease the virus-induced inflammatory response to RSV challenge, and also decrease the enhanced disease following RSV challenge. This composition may be used alone as a vaccine to safely protect infants, children, and adults from RSV, as a booster with other RSV proteins or with inactivated virus as a vaccine to ensure that it can be given safely and effectively improve protection from RSV.

Potential Commercial Applications:
• Prophylactic and therapeutic for the prevention and treatment of RSV infections
• Single or multi-component vaccine against RSV
• Improvements to currently developed/developing vaccines
• Developed antibodies may be employed for use in passive immunity or RSV research

Competitive Advantages:
• Increased safety, effectiveness compared to current vaccines
• Findings suggest likely prevention or mitigation of RSV-related pulmonary disease for previously established infections

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

Inventors: Larry J. Anderson (CDC), Lia M. Haynes (CDC), Ralph A. Tripp (University of Georgia)

Publications:

1. Haynes LM, et al. Therapeutic monoclonal antibody treatment targeting respiratory syncytial virus (RSV) G protein mediates viral clearance and reduces the pathogenesis of RSV infection in BALB/c mice. J Infect Dis. 2009 Aug 1;200(3):439–47. [PMID 19545210]

2. Miao C, et al. Treatment with respiratory syncytial virus G glycoprotein monoclonal antibody or F(ab')2 components mediates reduced pulmonary inflammation in mice. J Gen Virol. 2009 May;90(Pt 5):1119–23. [PMID 19264600]

Intellectual Property:
• HHS Reference No. E–197–2013/0—
—US Patent Application No. 13/763,822 filed 11 Feb 2013
• HHS Reference No. E–197–2013/2—
—PCT Application No. PCT/US2010/044434 filed 04 Aug 2010, which published as WO 2011/017442 on 10 Feb 2011
—Several international patent applications pending

Related Technologies:
• HHS Reference No. E–699–2013/0
• HHS Reference No. E–694–2013/0
• HHS Reference No. E–151–2013/0
• HHS Reference No. E–233–2013/0

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

Controlled Expression and Assembly of Human Group-C Rotavirus-like Particles for Creation of Rotavirus Diagnostic Assays and Improved Vaccine Formulations

Description of Technology: CDC researchers have developed methods of producing unlimited quantities of Group-C (GpC) rotavirus antigens. GpC rotaviruses are a major, worldwide cause of acute gastroenteritis in children and adults that is distinct from Group-A rotavirus. However, GpC rotaviruses cannot be grown in culture, resulting in a lack of tools for detection and treatment of GpC rotavirus disease. Consequently, the true clinical burden of GpC rotavirus disease has not been clearly established.

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

Potential Commercial Applications:
• Development or improvement of rotavirus vaccines
• Rotavirus vaccine composition research
• Childhood illness vaccination programs and rotavirus monitoring endeavors
• Development of novel rotavirus diagnostic tools

Competitive Advantages:
• Permits large-scale production of Group-C rotavirus antigens, previously impractical
• Produced virus-like particles/antigens can be used for rotavirus vaccines, other immunogenic uses and/or sero-diagnostic assay development
• Diagnostic tools for Group-C rotavirus are currently unavailable; this technology fulfills an unmet need for accurate assessment of the Group-C rotaviral global health burden

Development Stage: In vitro data available

Inventor: Baoming Jiang (CDC)

Publication: Clark KB, et al. Expression and characterization of human group C rotavirus virus-like particles in insect cells. Virology. 2009 May 10;387(2):267–72. [PMID 19285329]

Intellectual Property: HHS Reference No. E–191–2013/2—
• PCT Application No. PCT/US09/045688 filed 29 May 2009, which

published as WO 2009/148964 on 10 Dec 2009
• US Patent Application No. 12/995,024 filed 26 Jan 2011
• Various international filings pending and/or deferred

Related Technologies:
• HHS Reference No. E–122–2013/0
• HHS Reference No. E–150–2013/0
• HHS Reference No. E–153–2013/0
• HHS Reference No. E–521–2013/0

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

Diisocyanate Specific Monoclonal Antibodies for Occupational and Environmental Monitoring of Polyurethane Production Exposure-related Asthma and Allergy and Clinical Diagnosis

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

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

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

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

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

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

Publications:
1. Lemons AR, et al. Development of sandwich ELISAs for the detection of aromatic diisocyanate adducts. J Immunol Methods. 2013 Nov 29;397(1–2):66–70. [PMID 24012971]
2. Ruwona TB, et al. Monoclonal antibodies against toluene diisocyanate haptenated proteins from vapor-exposed mice. Hybridoma (Larchmt). 2010 Jun;29(3):221–9. [PMID 20568997]
3. Ruwona TB, et al. Production, characterization and utility of a panel of monoclonal antibodies for the detection of toluene diisocyanate haptenated proteins. J Immunol Methods. 2011 Oct 28;373(1–2):127–35. [PMID 21878336]

Intellectual Property: HHS Reference No. E–189–2013/0—US Patent Application No. 12/577,241 filed 12 Oct 2009

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

Real-time RT–PCR Assay for the Detection of Rift Valley Fever Virus in Humans and Livestock

Description of Technology: A quantitative RT–PCR-based assay has been developed to rapidly detect all known strains of Rift Valley fever virus (RVFV). RVFV infections occur in both humans and livestock animals resulting in significant mortality and economic loss. Upon outbreak, RVFV has been known to cause devastating loss among livestock (primarily sheep and cattle) with outbreaks characterized by sweeping ''abortion storms'' and elevation newborn animal mortality approaching 100% in affected areas. The CDC-developed assay is capable of detecting and quantifying RVFV infection in both human and veterinary samples.

Potential Commercial Applications:
• Diagnostic assay for the detection of Rift Valley fever virus in human and veterinary samples
• Research tool to quantitatively measure viral load in laboratory specimens

Competitive Advantages:
• Assay detects positive infections for 33 known variants of Rift Valley fever virus
• Easily adaptable to kits for high-throughput screening of a large number of samples at once, useful for ensuring herd-health for example

Development Stage: In vitro data available

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

Publications:
1. Bird BH, et al. Complete genome analysis of 33 ecologically and biologically diverse Rift Valley fever virus strains reveals widespread virus movement and low genetic diversity due to recent common ancestry. J Virol. 2007 Mar;81(6):2805–16. [PMID 17192303]
2. Bird BH, et al. Multiple virus lineages sharing recent common ancestry were associated with a Large Rift Valley fever outbreak among livestock in Kenya during 2006–2007. J Virol. 2008 Nov;82(22):11152–66. [PMID 18786992]

Intellectual Property: HHS Reference No. E–187–2013/0—Research Tool. Patent protection is not being pursued for this technology.

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

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

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

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

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

Development Stage: Prototype

Inventor: Robert Wirtz (CDC)

Intellectual Property: HHS Reference No. E–175–2013/0—US Patent Application No. 61/772,790 filed 05 Mar 2013

Related Technologies:
• HHS Reference No. E–223–2013/0
• HHS Reference No. E–166–2013/0

• HHS Reference No. E–218–2013/1
• HHS Reference No. E–354–2013/1
Licensing Contact: Whitney Blair, J.D., M.P.H.; 301–435–4937; *whitney.blair@nih.gov*

Sensitive Method for Detection and Quantification of Anthrax, Bordetella pertussis, Clostridium difficile, Clostridium botulinum and Other Pathogen-Derived Toxins in Human and Animal Plasma

Description of Technology: CDC research scientists have developed a method to identify and quantify the activity of pathogenic bacterial adenylate cyclase toxins by liquid chromatography tandem mass spectrometry (LC–MS/MS). Bacterial protein toxins are among the most potent natural poisons known, causing paralysis, immune system collapse, hemorrhaging and death in some cases. A useful tool for quantitative detection of specific toxin activity in clinical samples will provide insights into the kinetics of intoxication, stage of infection and present stage of pathogenesis.

This rapid, high-throughput analysis method will provide measurements that quantify the efficacy of toxin-based therapeutics and support patient management decisions during treatment. This technology is specific, ultrasensitive and can be implemented to detect toxins from a wide range of pathogenic bacteria. This method could be fabricated into a kit format to deliver to state or research laboratories for use during an anthrax emergency or for research purposes, i.e. animal studies evaluating anthrax therapeutics. This technology may be easily applied to detection/diagnosis of additional pathogenic bacterial species infections as well.

Potential Commercial Applications:
• Detect toxins from a wide range of pathogenic bacteria
• Biodefense, biosecurity diagnostics
Competitive Advantages:
• Presently no individual patient screening assay for anthrax-exposure is widely available; exposure is determined by public health investigation and environmental-sampling tests
• Current tests lack sensitivity and evidence of effectiveness
• Relatively rapid and exquisitely sensitive method for the detection and quantification of bacterial toxin activity from very small blood samples, accurately assessing exposure and infection
Development Stage:
• In vitro data available
• In vivo data available (animal)
• In vivo data available (human)
Inventors: Anne E. Boyer, Renata C. Lins, Zsuzsanna Kuklenyik, Maribel Gallegos-Candela, Conrad P. Quinn, John R. Barr (all of CDC)
Publications:
1. Duriez E, et al. Femtomolar detection of the anthrax edema factor in human and animal plasma. Anal Chem. 2009 Jul 15;81(14):5935–41. [PMID 19522516]
2. Boyer AE, et al. Quantitative mass spectrometry for bacterial protein toxins—a sensitive, specific, high-throughput tool for detection and diagnosis. Molecules. 2011 Mar 14;16(3):2391–413. [PMID 21403598]
Intellectual Property: HHS Reference No. E–167–2013/0—
• US Patent Application No. 13/878,378 filed 08 Apr 2013
• PCT Application No. PCT/US2011/059739 filed 08 Nov 2011, which published as WO 2012/074683 on 07 Jun 2012
• Various international filings pending
Related Technologies:
• HHS Reference No. E–157–2013/0
• HHS Reference No. E–158–2013/2
• HHS Reference No. E–196–2013/0
• HHS Reference No. E–203–2013/0
• HHS Reference No. E–210–2013/0
• HHS Reference No. E–474–2013/0
Licensing Contact: Whitney Blair, J.D., M.P.H.; 301–435–4937; *whitney.blair@nih.gov*

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

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

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

Potential Commercial Applications:
• Quality assurance, fraud prevention for anti-malarials
• Public health and humanitarian concerns
• Artesunate, artemisinin sales and distributions
Competitive Advantages:
• Potentially life-saving technology in developing nations and malaria affected regions
• Simple assay with an unaided-eye readout
• Inexpensive and field-adapted for use in low-resource environments
Development Stage:
• In vitro data available
• In situ data available (on-site)
Inventor: Michael D. Green (CDC)
Publications:
1. Green MD, et al. A colorimetric field method to assess the authenticity of drugs sold as the antimalarial artesunate. J Pharm Biomed Anal. 2000 Dec;24(1):65–70. [PMID 11108540]
2. Green MD, et al. Authentication of artemether, artesunate and dihydroartemisinin antimalarial tablets using a simple colorimetric method. Trop Med Int Health. 2001 Dec;6(12):980–2. [PMID 11737833]
Intellectual Property: HHS Reference No. E–161–2013/0—
• PCT No. PCT/US2008/082466 filed 05 Nov 2008, which published as WO 2009/061808 on 14 May 2009
• US Patent 8,435,794 issued 07 May 2013
Licensing Contact: Whitney Blair, J.D., M.P.H.; 301–435–4937; *whitney.blair@nih.gov*

Use of Detector Response Curves to Optimize Settings for Mass Spectrometry

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

This technology can be used to optimize the CV with the following advantages over conventional methods: (1) No need to use biological samples,

(2) fewer materials are consumed in the process, (3) improved CV and thus more reproducible results, (4) fewer man hours required to find ideal machine settings, and (5) potential full-automation of the process of optimizing CV. This idea is beneficial to all scientists and clinicians that use MALDI/SELDI for biomarker discovery and clinical diagnostics. Further, manufacturers of MALDI/SELDI mass spectrometer devices would find incorporation of this technology quite beneficial.

Potential Commercial Applications:

- MALDI/SELDI mass spectrometer calibration improvement
- Biomarker discovery studies
- Quality control techniques
- Automated coefficient of variation (CV) optimization of mass spectrometer devices

Competitive Advantages:

- Lower resource input requirement
- Increased cost efficiency
- Simplifies SELDI/MALDI setup, reducing technician man-hours and need for extensive training
- Improves experimental optimization providing greater reproducibility
- Potential for automation of CV optimization

Development Stage: In vitro data available

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

Publications:

1. Emanuele VA 2nd, Gurbaxani BM. Quadratic variance models for adaptively preprocessing SELDI–TOF mass spectrometry data. BMC Bioinformatics. 2010 Oct 13;11:512. [PMID 20942945]

2. Emanuele VA 2nd, et al. Sensitive and specific peak detection for SELDI–TOF mass spectrometry using a wavelet/neural-network based approach. PLoS One. 2012;7(11):e48103. [PMID 23152765]

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

- PCT Application No. PCT/US2011/055376 filed 07 Oct 2011, which published as WO 2012/048227 on 12 Apr 2012
- US Patent Application No. 13/575,317 filed 26 Jul 2012

Related Technology: HHS Reference No. E–167–2013/0

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

Immunogenic Hepatitis E Virus Polypeptides for Vaccine and Diagnostics Development

Description of Technology: This technology comprises specific hepatitis E virus (HEV) antigenic polypeptides. HEV causes epidemic and sporadic cases of hepatitis outbreaks with a mortality rate as high as 20% for pregnant women. In order to address this problem, CDC scientists carried out thorough HEV antigen screenings and subsequently developed recombinant proteins that efficiently model major HEV neutralization epitope(s). These recombinant proteins may be considered as candidates for the development of an HEV subunit vaccine, as well as for the development of highly sensitive and specific diagnostic tests.

Potential Commercial Applications:

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

Competitive Advantages:

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

Development Stage: In vitro data available

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

Publication: Meng J, et al. Identification and characterization of the neutralization epitope(s) of the hepatitis E virus. Virology. 2001 Sep 30;288(2):203–11. [PMID 11601892]

Intellectual Property: HHS Reference No. E–152–2013/0—

- PCT Application No. PCT/US2001/010696 filed 03 Apr 2001, which published as WO 2001/077156 on 18 Oct 2001
- Various international patents issued

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

New Human Rotavirus Vaccine Strains

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

Potential Commercial Applications:

- Novel rotavirus vaccines
- Childhood vaccination initiatives
- Rotavirus surveillance programs

Competitive Advantages:

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

Development Stage: In vitro data available

Inventors: Baoming Jiang, Roger I. Glass, Yuhuan Wang (all of CDC)

Publications:

1. Esona MD, et al. Molecular characterization of human rotavirus vaccine strain CDC–9 during sequential passages in Vero cells. Hum Vaccin.;6(3). (Epub ahead of print) [PMID 20009519]

2. Wang Y, et al. Inactivated rotavirus vaccine induces protective immunity in gnotobiotic piglets. Vaccine. 2010 Jul 26;28(33):5432–6. [PMID 20558244]

Intellectual Property: HHS Reference No. E–150–2013/0—

- PCT Application No. PCT/US2010/034537 filed 12 May 2010, which published as WO 2010/132561 on 18 Nov 2010
- US Patent Application No. 13/320,095 filed 11 Nov 2011
- Various international filings pending or deferred

Related Technologies:

- HHS Reference No. E–122–2013/0
- HHS Reference No. E–153–2013/0
- HHS Reference No. E–191–2013/2
- HHS Reference No. E–521–2013/0

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

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

Description of Technology: This CDC developed invention is a novel device for a miniature, nonradioactive bipolar charger to electrically charge aerosol particles for use in personal and portable aerosol instrumentation. Such devices are an integral component of aerosol instruments employing electrical mobility-based techniques. Current, commercial state-of-the-art mobility instruments employ aerosol chargers using radioactivity to achieve bipolar particle charging and, therefore, are not suitable for field-portable instruments. Due to strict regulatory restrictions on use of radioactive materials, these radioactive chargers also tend to be too bulky for use in compact aerosolization instruments.

This invention circumvents these two critical drawbacks by eliminating radioactivity and miniaturizing overall unit size (1x0.75 x 0.5 inch). Other unique aspects of the invention entail elimination of the need for additional air flows (other than the aerosol sample flow), minimal power consumption, a low per-unit cost, and simplicity of operation. In all, excellent transmission efficiency, steady-state charging characteristics and the miniature size make this bipolar particle charger well-suited for integration with portable or personal aerosol instrumentation.

Potential Commercial Applications:

• Personal and portable aerosol instrumentation

• Component of field-use device for determining workplace/environmental exposure to ultrafine aerosols and airborne nanoparticles

• Tool for environmental/occupational health, toxicology, workplace control evaluations and hazard identification involving aerosol exposure

Competitive Advantages:

• Non-radioactive; no associated regulatory or transportation issues

• Low-cost and requires very little power to operate

• Additional air flows other than sample airflow are unnecessary

• Unit is small (1x0.75x0.5in; 2.54x1.91x1.27cm) and highly portable

• Eliminates a major barrier for reliable aerosol sampling using ''bipolar charger + differential mobility analyzer + condensation particle detector'' scheme in a compact device

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

Inventors: Prarnod Kulkarni and Chaolong Qi (CDC)

Intellectual Property: HHS Reference No. E–146–2013/0—US Patent No. 8,611,066 issued 17 Dec 2013

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

Rapid Detection of Antiretroviral(s) Drug-Resistant HIV–1 Within Clinical Samples

Description of Technology: One of the problems with the development of current therapies for HIV infection is that the virus rapidly develops resistance to drugs such as reverse transcriptase (RT) inhibitors. CDC researchers have developed an enzyme-based methodology for detecting phenotypic resistance to antiretroviral drugs whose mode of action decreases the efficiency of the HIV–1 RT enzyme.

This invention will enhance clinical monitoring by providing data that tells physicians if and when the HIV–1 infecting a patient has become resistant to commonly used antiretroviral drugs, such as zidovudine/azidothymidine (AZT), nevirapine and lamivudine (3TC). This invention provides physicians and patient care facilities with a simple, rapid lab test that will tell them when a particular antiviral drug is not or no longer beneficial for a patient. Additionally this technology is superior to current culture-based methods for determining phenotypic resistance to HIV antiviral drugs, which are time-consuming and labor-intensive and therefore impractical for clinical monitoring.

Potential Commercial Applications:

• Clinical monitoring of individual patient antiretroviral therapy

• HIV/AIDS public health programs

• Surveillance of retroviral drug resistance

Competitive Advantages:

• Rapid diagnostic which greatly reduces time and labor for improved clinical monitoring of HIV treatment

• Ready for commercialization

• Easily adapted to kit format

• Assists continued usefulness of common antiretroviral therapeutics

Development Stage: In vitro data available

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

Publication: Qari SH, et al. A rapid phenotypic assay for detecting multiple nucleoside analogue reverse transcriptase inhibitor-resistant HIV–1 in plasma. Antivir Ther. 2002 Jun;7(2):131–9. [PMID 12212925]

Intellectual Property:

• HHS Reference No. E–129–2013/0—

—PCT Application No. PCT/US1999/013957 filed 16 Jun 1999, which published as WO 1999/66068 on 23 Dec 1999

—US Patent No. 6,787,126 issued 07 Sep 2004

—Various international patents issued

• HHS Reference No. E–129–2013/1—

—US Patent No. 7,691,572 issued 06 Apr 2010

Related Technologies: HHS Reference No. E–232–1993—

• PCT Application No. PCT/US1996/001257 filed 26 Jan 1996, which published as WO 1996/023076 on 01 Aug 1996

• US Patent No. 5,849,494 issued 15 Dec 1998

• US Patent No. 6,136,534 issued 24 Oct 2000

• Various international patents issued or pending

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

Antigen, Encoding Gene, Related Monoclonal Antibody and Hybridoma Clones for *Streptococcus pneumoniae* Serological Diagnostics

Description of Technology: This CDC developed invention pertains to *Streptococcus pneumoniae* protein ''pneumococcal fimbrial protein A (PfpA),'' as well as the encoding *pfpA* gene. *S. pneumoniae* linked pneumococcal disease is prevalent among the very young, the elderly and also immunocompromised individuals. This invention covers the breadth of directly PfpA-related technology that might be employed for development of diagnostic tests for *S. pneumoniae* and/or vaccines directed against the pathogen. In addition to the intellectual property protected amino acid sequence and encoding plasmid, monoclonal antibodies and corresponding hybridomas are also available.

Potential Commercial Applications:

• Screening diagnostic young, elderly and immunocompromised patients for possible *S. pneumoniae* infection

• Pneumococcal disease vaccine development or refinement

Competitive Advantages:

• Easily adapted to a high-throughput assay for mass screening purposes

• Can be formatted as an on-site, lateral-flow diagnostic; both PfpA antigen and anti-PfpA mAb are available

Development Stage: In vitro data available

Inventors: Harold Russell, Jacquelyn Sampson, Steven P. O'Connor (all of CDC)

Publications:

1. Russell H, et al. Monoclonal antibody recognizing a species-specific protein from Streptococcus pneumoniae. J Clin Microbiol. 1990 Oct;28(10):2191–5. [PMID 2229341]

2. Sampson JS, et al. Cloning and nucleotide sequence analysis of psaA, the Streptococcus pneumoniae gene encoding a 37-kilodalton protein homologous to previously reported Streptococcus sp. adhesins. Infect Immun. 1994 Jan;62(1):319–24. [PMID 7505262]

Intellectual Property: HHS Reference No. E–157–1991/0—US Patent No. 6,312,944 issued 06 Nov 2001

Related Technologies:

• HHS Reference No. E–030–2010/0

• HHS Reference No. E–250–2013/0

• HHS Reference No. E–325–2013/0

• HHS Reference No. E–660–2013/0

• HHS Reference No. E–661–2013/0

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

Dated: January 27, 2014.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2014–02252 Filed 2–3–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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

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

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

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

Date: February 26, 2014.

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

Agenda: To review and evaluate grant applications.

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

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

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

Dated: January 28, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

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

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2013–0066]

Privacy Act of 1974; Department of Homeland Security/ALL—001 Freedom of Information Act and Privacy Act Records System of Records

AGENCY: Department of Homeland Security, Privacy Office.

ACTION: Notice of Privacy Act System of Records.

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

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

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

- *Federal e-Rulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Karen L. Neuman, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

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

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

FOR FURTHER INFORMATION CONTACT: For general questions and privacy issues please contact: Karen L. Neuman (202–343–1717), Chief Privacy Officer and Chief Freedom of Information Act Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS) proposes to modify a current DHS system of records titled ''DHS/ALL—001 Freedom of Information Act and Privacy Act Records System of Records,'' 74 FR 55572 (October 28, 2009).

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