the number of registered participants. Therefore, individuals who wish to make a statement must send an email to *PhysicianCompare@Westat.com* as soon as possible to register for the meeting and to sign up to make a statement. Participants will be permitted to speak in the order in which they sign up starting with participants who attend in person and followed by participants who attend via telephone. Comments from individuals not registered to speak will be heard after scheduled statements, only if time permits. Written submissions will also be accepted through March 3, 2014 at 5:00 p.m. e.s.t.

III. Registration Instructions

The Division of Electronic and Clinician Quality (DECQ) within the Center for Clinical Standards and Quality (CCSQ) of CMS is coordinating the meeting registration for the Town Hall Meeting. Although there is no registration fee, individuals must register to attend. You may register by sending an email to *PhysicianCompare@Westat.com.* Please use the subject line ''Physician Compare Town Hall Registration'' and include your name, address, telephone number, email address, and, if available, fax number. Indicate if you wish to participate in person or via telephone. You will receive a registration confirmation with instructions for your arrival at the CMS complex or for accessing the meeting via telephone. If capacity has been reached, you will be notified that the meeting has reached capacity.

Individuals requiring sign language interpretation or other special accommodations must send an email to *PhysicianCompare@Westat.com* indicating the needed accommodations by the date listed in the **DATES** section of this notice.

IV. Security, Building, and Parking Guidelines

Because this meeting will be located on federal property, for security reasons, any persons wishing to attend this meeting must register by close of business on the date specified in the **DATES** section of this notice. Individuals who have not registered in advance will not be allowed to enter the building to attend the meeting. Seating capacity is limited to the first 250 registrants.

The on-site check-in for visitors starts at 12:00 p.m. e.s.t. on the day of the meeting. Please allow sufficient time to go through the security checkpoints. It is suggested that you arrive at 7500 Security Boulevard no later than 12:30 p.m. so that you will be able to arrive promptly at the meeting by 1:00 p.m. All items brought to the building, whether personal or for the purpose of demonstration or to support a presentation, are subject to inspection.

Security measures will include inspection of vehicles, inside and out, at the entrance to the grounds. Visitors to the complex are required to show a valid U.S. Government issued photo identification, preferably a driver's license, at the time of entry. In addition, all persons entering the building must pass through a metal detector. All items brought to CMS, including personal items such as laptops, cell phones, smart phones, tablets, etc. are subject to physical inspection.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 23, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–01642 Filed 1–28–14; 8:45 am]

BILLING CODE 4120–01–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.

Novel Targets To Prevent Borrelia burgdorferi Infection and Lyme Disease

Description of Technology: B. burgdorferi-infected ticks can cause Lyme disease in mammalian hosts. This technology relates to the use of *B. burgdorferi* outer surface proteins (BBA64 and BBA66) as Lyme disease vaccine candidates. *In vivo* animal studies demonstrate these outer surface proteins inhibit tick-to-host *B. burgdorferi* transmission. Presently, there is no vaccine approved for Lyme disease.

This technology may also be used for creation of antibodies directed against *B. burgdorferi.* Thus, this innovation may prevent *B. burgdorferi* infection by passive immunity and provide new diagnostic tools, which will allow early intervention.

Potential Commercial Applications:

- *B. burgdorferi*/Lyme disease vaccine development
- *B. burgdorferi* diagnostics
- Prevention of *B. burgdorferi* infection by passive immunity
- Zoonotic/tick-borne disease surveillance
- Public health vaccination programs against Lyme disease

Competitive Advantages: Currently no approved Lyme disease vaccines

Development Stage:

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

Inventor: Robert D. Gilmore (CDC)

Publication: Patton TG, et al. Borrelia burgdorferi bba66 gene inactivation results in attenuated mouse infection by tick transmission. Infect Immun. 2013 Jul;81(7):2488–98. [PMID 23630963]

Intellectual Property: HHS Reference No. E–573–2013/0—US Provisional Application No 61/814,741 filed 22 Apr 2013

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

Real-Time RT–PCR Assay for Detection and Quantification of Hepatitis D Virus Infection

Description of Technology: CDC scientists have developed a one-step TaqMan quantitative/real-time reverse transcription-polymerase chain reaction (qRT–PCR) assay for detecting hepatitis D virus (HDV) RNA. Additionally, a quantifiable synthetic RNA control to determine viral load has been created.

HDV is an operatively defective virus that requires hepatitis B virus (HBV) surface antigen (HBsAg) for its assembly. Compared to individuals infected with HBV alone, individuals infected with both HDV and HBV

viruses present with more severe hepatitis, progress to liver disease more quickly, and have a higher mortality rate. Currently, there are no regulated tests available for detection and quantification of HDV RNA. This assay directly addresses this unmet need and has been validated with clinical samples of HDV genotypes 1 and 3. It has the potential to detect all eight HDV genotypes.

Potential Commercial Applications:

- Development of a commercial nucleic acid assay for diagnosis of current hepatitis D virus (HDV) infection
- Public health and vaccination programs
- Testing of individuals infected with hepatitis B and/or liver disease

Competitive Advantages:

- Rapid, accurate, inexpensive and stable
- Unique RNA transcript for this assay can be successfully used as a quantitative standard
- Current anti-HDV antibody assay identifies individuals exposed to HDV, but cannot identify current infection
- Easily adapted for inclusion in a hepatitis testing kit, especially when paired with a hepatitis B diagnostic

Development Stage:

- Pre-clinical
- In vitro data available

Inventors: Maja Kodani, Tonya Mixson-Hayden, Saleem Kamili (all of CDC)

Publication: Kodani M, et al. One-step real-time PCR assay for detection and quantitation of hepatitis D virus RNA. J Virol Methods. 2013 Nov;193(2):531–5. [PMID 23896020]

Intellectual Property: HHS Reference No. E–510–2013/0—US Provisional Application No. 61/792,293 filed 15 Mar 2013

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

Reduced Virulence Crimean-Congo Hemorrhagic Fever Virus for Vaccine Development

Description of Technology: This invention relates to a genetically modified hemorrhagic fever virus that can be used as an effective live vaccine agent. Hemorrhagic fever evades the human immune response using the viral ovarian tumor domain (vOTU) protease, which inhibits critical host-immunity functions. The present genetically modified virus has a vOTU protease with decreased ability to remove ubiquitin (Ub) and ISG15 tags from proteins in cells it infects. Thus, the virulence is reduced, creating an immunogenic and non-pathogenic virus for use as a live vaccine against Crimean-Congo hemorrhagic fever (CCHF) virus. Unlike strains with complete ablation of the vOTU protease, the present modified virus retains enough activity for replication in a human cell line, making vaccine production possible. This technology may be used to create vaccines or therapeutics for other nairoviruses, including the Dugbe, Hazara, and Nairobi sheep disease viruses.

Potential Commercial Applications: Development of vaccines or therapeutics for CCHF virus and other nairoviruses, including Dugbe, Hazara and Nairobi sheep disease viruses

Competitive Advantages:

- Increased safety for CCHF laboratory research (Biosafety Level 2)
- Use of human cell lines allows large-scale manufacturing of vaccines
- vOTU domain-disruption may be used to develop vaccines for all nairovirus viruses affecting humans and/or livestock

Development Stage:

- Pre-clinical
- In vitro data available

Inventors: Eric Bergeron (CDC), Stuart T. Nichol (CDC), et al.

Publications:

1. Bergeron E, et al. Crimean-Congo hemorrhagic fever virus-encoded ovarian tumor protease activity is dispensable for virus RNA polymerase function. J Virol. 2010 Jan;84(1):216–26. [PMID 19864393]
2. Capodagli GC, et al. Structural analysis of a viral ovarian tumor domain protease from the Crimean-Congo hemorrhagic fever virus in complex with covalently bonded ubiquitin. J Virol. 2011 Apr;85(7):3621–30. [PMID 21228232]

Intellectual Property: HHS Reference No. E–486–2013/0—

- US Provisional Application No. 61/683,132 filed 14 Aug 2012
- US Patent Application No. 13/829,105 filed 14 Mar 2013
- PCT Application No. PCT/US13/54760 filed 13 Aug 2013

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

Human Influenza Virus Real-Time RT–PCR Detection and Characterization Panel

Description of Technology: This invention relates to methods of rapidly detecting influenza, including differentiating between type and subtype. Unlike culture and serological tests requiring 5 to 14 days for completion, CDC researchers developed a rapid, accurate assay, which is easily adapted to kit form. This assay also requires less labor input than immunoassays. These methods can be used to quickly identify a broad variety of influenza types and subtypes, including viruses that may be involved in pandemics (such as H5N1, for example).

Potential Commercial Applications:

- Influenza diagnostic using clinical specimens
- High-throughput screenings
- Influenza surveillance programs

Competitive Advantages:

- Already FDA approved
- Especially useful for H5N1 screening
- Sensitive detection
- Specific discrimination of influenza subtypes
- Easily formatted as kit or array
- Faster than culturing and serological identification methods
- Less laborious and more objective than immunoassays

Development Stage: In vitro data available

Inventors: Stephen Lindstrom, Alexander I. Klimov, Nancy J. Cox, Lamorris Loftin (all of CDC)

Publication: Jernigan DB, et al. Detecting 2009 pandemic influenza A (H1N1) virus infection: availability of diagnostic testing led to rapid pandemic response. Clin Infect Dis. 2011 Jan 1;52 Suppl 1:S36–43. [PMID 21342897]

Intellectual Property: HHS Reference No. E–331–2013/0—

- PCT Application No. PCT/US2007/003646 filed 12 Feb 2007, which published as WO 2007/095155 on 23 Aug 2007
- US Patent No. 8,241,853 issued 14 Aug 2012
- US Patent No. 8,568,981 issued 29 Oct 2013
- US Patent Application No. 14/056,810 filed 17 Oct 2013
- Various international patent applications pending or issued

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

Peptide Vaccines Against Group A Streptococci

Description of Technology: This invention relates to synthetic immunoreactive peptides, which are portions of the M proteins of the most prevalent Group A Streptococcus (GAS) serotypes in the United States. These peptides may be useful in development of a flexible, multivalent GAS vaccine. They can be recognized by M type-specific antibodies and are capable of eliciting functional opsonic antibodies. Additionally, the peptides or isolated antibodies raised in response to the peptides may be useful for GAS diagnostics.

Potential Commercial Applications:
- Group A streptococci (GAS) vaccine
- GAS therapeutics and diagnostics
- Lab tools for exploring GAS

Competitive Advantages:
- Easily adaptable to kit form
- Multivalent vaccine that can be tailored for protection against specific GAS serotypes affecting a particular population

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

Inventors: Bernard W. Beall, George M. Carlone, Jacquelyn S. Sampson, Edwin W. Ades (all of CDC)

Publication: Bruner M, et al. Evaluation of synthetic, M type-specific peptides as antigens in a multivalent group A streptococcal vaccine. Vaccine. 2003 Jun 20;21(21–22):2698–703. [PMID 12798606]

Intellectual Property: HHS Reference No. E–330–2013/0—
- US Patent No. 7,407,664 issued 05 Aug 2008
- US Patent No. 7,883,710 issued 08 Feb 2011
- US Patent No. 8,420,107 issued 16 Apr 2013
- US Patent Application No. 13/846,166 filed 18 Mar 2013
- Various international patent applications pending or issued

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

Method of Enhancing Opsonophagocytosis

Description of Technology: This invention aims to bolster the human body's own mechanisms to fight infection by enhancing an innate immune response, opsonophagocytosis. The specific 24 amino acid sequence (P4) acts as a polymorphonuclear cell activator. P4 can be administered *in vivo* along with a disease's specific antibody to enhance systemic bacterial clearance, thus leading to prolonged survival. This technology enhances the body's response to infections such as *S. pneumoniae* and *S. aureus.*

Potential Commercial Applications:
- Opsonic therapy
- Passive immunization
- Enhancement of pathogen clearing
- Synergistic use with other therapies

Competitive Advantages:
- Multiple *in vivo* studies indicate significant improvements in recipient outcomes
- Highly adaptable and can be combined with a number of alternate therapies
- Enhances opsonophagocytosis to achieve therapeutically effective results

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

Inventors: Edwin W. Ades, et al. (CDC)

Publications:

1. Melnick N, et al. Evaluation of a novel therapeutic approach to treating severe pneumococcal infection using a mouse model. Clin Vaccine Immunol. 2009 Jun;16(6):806–10. [PMID 19386795]
2. Weeks JN, et al. Immunotherapy with a combination of intravenous immune globulin and p4 peptide rescues mice from postinfluenza pneumococcal pneumonia. Antimicrob Agents Chemother. 2011 May;55(5):2276–81. [PMID 21383090]
3. Bangert M, et al. P4-mediated antibody therapy in an acute model of invasive pneumococcal disease. J Infect Dis. 2012 May 1;205(9):1399–407. [PMID 22457294]

Intellectual Property: HHS Reference No. E–329–2013/0—
- PCT Application No. PCT/US2009/052384 filed 31 Jul 2009, which published as WO 2010/14888 on 04 Feb 2010
- US Patent No. 8,431,134 issued 30 Apr 2013
- US Patent Application No. 13/851,508 filed 27 Mar 2013
- Various international applications pending or issued

Related Technologies: HHS Reference No. E–338–2013/0—
- PCT Application No. PCT/US2005/027290 filed 29 Jul 2005, which published as WO 2006/127020 on 30 Nov 2006
- US Patent No. 7,919,104 issued 05 Apr 2011
- Australia Patent No. 2005332058 issued 15 Mar 2012
- Various international patent applications pending or issued

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

Collaborative Research Opportunity: The Centers for Disease Control and Prevention (CDC) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Methods and Tools for Enhancing Opsonophagocytosis in Response to a Pathogen. For collaboration opportunities, please contact Suzanne Shope at *sshope@cdc.gov* or 770–488–8613.

Novel Live-Attenuated Rabies Vaccine

Description of Technology: The critical feature of this technology is the Evelyn-Rokitnicki-Abelseth (ERA) rabies whole genome DNA sequence. With the availability of the entire rabies genome, a recombinant vaccine can be developed using reverse genetics. Using this technology, CDC researchers have developed a recombinant, live-attenuated vaccine shown to confer protection against lethal doses of live, street-rabies virus in multiple survival studies. This vaccine offers better protection than traditional inactivated vaccinations, as demonstrated in co-infection studies. Further, a single intramuscular vaccination with the CDC's attenuated-virus was sufficient for survival of 100% of hamsters and mice following lethal challenge.

Potential Commercial Applications:
- Rabies vaccine design and development
- Immunogenic compositions for both prevention and treatment of rabies virus
- Rabies virus research

Competitive Advantages:
- Live attenuated vaccine shows greater efficacy than older inactivated vaccine
- 100% animal survival conferred by a single inoculation before lethal challenge

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

Inventors: Charles E. Rupprecht and Xianfu Wu (CDC)

Publications:

1. Wu X, et al. Are all lyssavirus genes equal for phylogenetic analyses? Virus Res. 2007 Nov;129(2):91–103. [PMID 17681631]
2. Bankovskiy D, et al. Immunogenicity of the ERA G 333 rabies virus strain in foxes and raccoon dogs. Dev Biol (Basel). 2008;131:461–6. [PMID 18634508]
3. Wu X, Rupprecht CE. Glycoprotein gene relocation in rabies virus. Virus Res. 2008 Jan;131(1):95–9. [PMID 17850911]
4. Franka R, et al. Rabies virus pathogenesis in relationship to intervention with inactivated and attenuated rabies vaccines. Vaccine. 2009 Nov 27;27(51):7149–55. [PMID 19925945]
5. Wu X, et al. Live attenuated rabies virus co-infected with street rabies virus protects animals against rabies. Vaccine. 2011 Jun 6;29(25):4195–201. [PMID 21514343]

Intellectual Property: HHS Reference No. E–326–2013/0—
- PCT Application No. PCT/US2006/040134 filed 13 Oct 2006, which published as WO 2007/047459 on 26 Apr 2007
- US Patent No. 7,863,041 issued 04 Jan 2011

• US Patent Application No. 12/956,949 filed 30 Nov 2010
• Various international patent applications pending or issued

Related Technologies: HHS Reference No. E–256–2013/0—
• PCT Application No. PCT/US2011/041579 filed 23 June 2011, which published as WO 2011/163446 on 29 Dec 2011
• US Patent Application No. 13/806,622 filed 21 Dec 2012

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

Intranasal Nebulizer With Disposable Drug Cartridge for Improved Delivery of Vaccines and Therapeutics

Description of Technology: Intranasal delivery is a simple, inexpensive and needle-free route for administration of vaccines and therapeutics. This intranasal delivery technology, developed with Creare, Inc., includes low-cost, disposable drug cartridges (DDCs) that mate with a durable hand-held device. The rechargeable-battery-powered device transmits ultrasonic energy to the DDC to aerosolize the drug and is capable of performing for eight hours at 120 vaccinations per hour. Potential applications for this platform technology include intranasal vaccination (e.g. seasonal or pandemic influenza vaccines) and intranasal delivery of locally active (e.g. antihistamines, steroids) or systemically active (e.g. pain medications, sedatives) pharmaceuticals.

The DDCs themselves offer two unique benefits. First, all components that contact the active agent or the patient may be easily disposed of, which reduces the risk of patient cross-contamination and minimizes cleaning and maintenance requirements of the hand-held device. Second, DDCs provide a low-cost and simple method to package and distribute individual doses.

This technology also allows for significant dose-sparing. Preliminary studies have shown robust immune responses when this technology is used to delivery significantly reduced doses of Live Attenuated Influenza Vaccine in animal models. The intranasal nebulizer produces droplets sized for optimum depositioning in the nasal airway. The small nebulizer droplets essentially ''spray paint'' the internal nasal airway, resulting in an increased tissue surface coverage that may enable a significant dose reduction. In contrast, currently available nasal delivery devices, such as nasal sprays and droppers, do not provide efficient intranasal delivery in humans because the large droplets they generate fail to coat a significant portion of the nasal airway. Large droplets also tend to drip out of the nose or down the throat, which can be unpleasant for the patient in addition to wasting a sizable portion of the active agent.

Potential Commercial Applications:
• Intranasal delivery of vaccines and therapeutics
• Childhood vaccination programs, mass immunization campaigns, or response to epidemics

Competitive Advantages:
• Safe, needle-less delivery
• No patient-to-patient contamination
• Long-life, rechargeable battery
• Consistent delivery and dose-sparing
• Nasal delivery of live-attenuated vaccines may be more effective than traditional injected vaccines
• Cost-effective
• Reduces biohazard waste
• May be administered by personnel with minimal medical training
• Easy means of delivery to children with fear of needles

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

Inventors: Mark J. Papania (CDC), et al.

Publication: Smith JH, et al. Nebulized live-attenuated influenza vaccine provides protection in ferrets at a reduced dose. Vaccine. 2012 Apr 19;30(19):3026–33. [PMID 22075083]

Intellectual Property:
• HHS Reference No. E–323–2013/0—
—PCT Application No. PCT/US2002/007973 filed 13 Mar 2002, which published as WO 2002/074372 on 26 Sep 2002
—US Patent No. 7,225,807 issued 05 Jun 2007
—US Patent No. 8,544,462 issued 01 Oct 2013
—Various international issued patents
• HHS Reference No. E–324–2013/0—
—PCT Application No. PCT/US2005/011086 filed 01 Apr 2005, which published as WO 2006/006963 on 19 Jan 2006
—US Patent No. 7,954,486 issued 07 Jun 2011
—US Patent Application No. 13/099,261 filed 02 May 2011
—Various international issued patents
• HHS Reference No. E–308–2013/0—
—PCT Application No. PCT/US2011/039020 filed on 03 Jun 2011, which published as WO 2011/153406 on 08 Dec 2011
—US Patent Application No. 13/701,992 filed 04 Dec 2012
—Various international pending patents

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.; 301–435–4937; *whitney.blair@nih.gov.*

Real-Time PCR Multiplex Assay for Detection of Bacterial Respiratory Pathogens in Clinical Specimens

Description of Technology: CDC researchers have developed a single-tube, real-time PCR assay for the simultaneous detection of three bacterial respiratory pathogens (*Mycoplasma pneumoniae, Chlamydiophila pneumoniae* and *Legionella* spp.). The assay has an internal control testing for presence of human DNA. This four-plex real-time PCR assay could potentially become a routine screening test for patients with respiratory illness. Ninety four clinical specimens (in a 96-well format) can be tested at once. This assay is non-invasive, rapid and cost-effective. It has the potential for point-of-care applications in population-based pneumonia surveillance.

Potential Commercial Applications:

- Population-based pneumonia surveillance
- Development of broadly-capable respiratory clinical diagnostics

Competitive Advantages:

- Sensitive and specific
- High-throughput friendly
- Rapid and cost-effective compared to screening for individual respiratory pathogens
- Easily developed for use in diagnostic kits

Development Stage:

- Pre-clinical
- In vitro data available

Inventors: Jonas Winchell, Agnes Warner, Kathleen Thurman (all of CDC)

Publication: Thurman KA, et al. Detection of Mycoplasma pneumoniae, Chlamydia pneumoniae, and Legionella spp. in clinical specimens using a single-tube multiplex real-time PCR assay. Diagn Microbiol Infect Dis. 2011 May;70(1):1–9. [PMID 21397428]

Intellectual Property: HHS Reference No. E–300–2013/0—

- PCT Application No. PCT/US2011/032749 filed 15 Apr 2011, which published as WO 2011/133433 on 27 Oct 2011
- US Patent Application No. 13/641,444 filed 28 Nov 2012
- Various international patent applications pending or deferred

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

Novel Recombinant Rabies Vaccine Also Capable of Immunocontraception

Description of Technology: This invention relates to a recombinant, attenuated rabies vaccine that is also capable of inhibiting reproductive fertility. An Evelyn-Rokitnicki-Abelseth (ERA) rabies vaccine backbone, combined with a reproductive-specific protein, such as gonadotropin-releasing hormone (GnRH) or the sperm-binding zona-pellucida-glycoprotein-3 (ZP3) receptor, allows reduction in both rabies transmission and uncontrolled reproduction in stray animals. The ERA rabies vaccine backbone has previously shown strong efficacy in animal studies. This vaccine may be delivered via injection or orally, including in an animal's food.

Potential Commercial Applications:

- Development of rabies and immunocontraceptive vaccines
- Immunogenic compositions for both prevention and treatment of rabies virus
- Animal welfare initiatives and rabies vaccination programs

Competitive Advantages:

- Live, attenuated rabies vaccines show greater efficacy than older, inactivated rabies vaccine in prior animal studies
- Potential for oral delivery, enabling vaccination of feral and difficult-to-reach animal populations
- Novel approach to simultaneously addressing rabies transmission and uncontrolled wild animal reproduction

Development Stage:

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

Inventors: Xianfu Wu and Charles E. Rupprecht (CDC)

Publication: Wu X, et al. Development of combined vaccines for rabies and immunocontraception. Vaccine. 2009 Nov 27;27(51):7202–9. [PMID 19925954]

Intellectual Property: HHS Reference No. E–298–2013/0—

- PCT Application No. PCT/US2009/054502 filed 20 Aug 2009, which published as WO 2010/033337 on 25 Mar 2010
- US Patent Application No. 13/062,680 filed 07 Mar 2011
- Various international patent applications pending or deferred

Related Technologies:

- HHS Reference No. E–256–2013/0—

—PCT Application No. PCT/US2011/041579 filed 23 June 2011, which published as WO 2011/163446 on 20 Dec 2011

—US Patent Application No. 13/806,622 filed 21 Dec 2012

- HHS Reference No. E–326–2013/0—

—PCT Application No. PCT/US2006/040134 filed 13 Oct 2006, which published as WO 2007/047459 on 26 Apr 2007

—US Patent No. 7,863,041 issued 04 Jan 2011

—Various international patent applications pending or issued

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

Diagnostic Assays Utilizing Real-Time Taqman or Seminested RT–PCR for Parechovirus Detection and Discrimination

Description of Technology: The CDC developed a real-time reverse transcription polymerase chain reaction (RT–PCR) Taqman assay and an RT-semi nested PCR (RT-snPCR) assay for the detection of parechoviruses. Similar to enteroviruses, parechoviruses are responsible for gastrointestinal, respiratory and central nervous system infections. All tests target conserved regions in the 5′nontranslated region (5′NTR) of the parechovirus genome and share forward and reverse primers. The Taqman probe and RTsnPCR nested primer target the same conserved site but vary in length. Both assays detect all known human parechoviruses (PPeV) and Ljungan viruses (LV), unlike other published parechovirus 5′NTR assays, which only detect a limited number of PPeV types. Both assays are more sensitive than current methods (culture and multiple, single-serotype nucleic acid amplification assays) and may be used to test isolates or original clinical specimens.

Potential Commercial Applications:

- Diagnostic detection of all known species of Parechovirus from clinical samples, including Human parechovirus and Ljungan virus
- Discrimination of specific species and serotypes
- Public health surveillance programs
- Research tool for all lab strains and clinical isolates of parechovirus

Competitive Advantages:
• Detects all Parechovirus genus members with a single assay
• Rapid, accurate, sensitive and specific
• Cost-effective in terms or resource-input, labor and turnaround time
• Does not require culturing
• Easily adaptable to kit form
Development Stage:
• Early-stage
• In vitro data available
Inventors: William A. Nix and M. Steven Oberste (CDC)
Intellectual Property: HHS Reference No. E–295–2013/0—
• PCT Application No. PCT/US2006/016624 filed 01 May 2006, which published as WO 2007/133189 on 22 Nov 2007
• US Patent No. 8,048,630 issued 01 Nov 2011
• Australian Patent No. 2006343645 issued 05 Apr 2012
• Various international filings pending or issued
Licensing Contact: Whitney Blair, J.D., M.P.H.; 301–435–4937; *whitney.blair@nih.gov*
Collaborative Research Opportunity: The Centers for Disease Control and Prevention (CDC) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Diagnostic Assays Utilizing Real-Time Taqman or Seminested RT–PCR for Parechovirus Detection and Discrimination. For collaboration opportunities, please contact Suzanne Shope at *sshope@cdc.gov* or 770–488–8613.

Simultaneous Detection of Non-Pneumophila *Legionella* Strains Using Real-Time PCR

Description of Technology: Legionnaires' disease is caused by a type of bacteria called *Legionella.* CDC scientists have developed a real-time multiplex PCR assay for diagnosis and identification of *Legionella* strains. The assay consists of five sets of primers (targeting *L. bozemanii, L. dumoffii, L. feeleii, L. longbeachae,* or *L. micdadei*) and corresponding probes. Each probe is labeled with a different fluorophore which allows the detection of a particular strain in a single tube reaction. Using this assay format, the presence of any one of the five pathogenic non-pneumophila strains of *Legionella* can be detected rapidly from clinical or environmental samples. Rapid and sensitive identification enables initiation of appropriate antibiotic therapy and identification of the source of bacteria so that proper public health responses may occur.

Potential Commercial Applications: Rapid and real-time assay to detect the presence of clinically relevant non-pneumophila *Legionella* strains.
Competitive Advantages:
• Currently available tests are time consuming and labor intensive.
• This assay enables rapid identification and differentiation on clinically relevant non-pneumophila *Legionella* strains.
• This assay can be used as a standalone confirmatory assay for the detection of common non-pneumophila *Legionella* species or as one of the valuable assays in conjunction with other standard assays.
Inventors: Jonas M. Winchell and Alvaro J. Benitez (CDC)
Publication: Benitez AJ, Winchell JM. Clinical application of a multiplex real-time PCR assay for simultaneous detection of Legionella species, Legionella pneumophila, and Legionella pneumophila serogroup 1. J Clin Microbiol. 2013 Jan;51(1):348–51. [PMID 23135949]
Intellectual Property:
• HHS Reference No. E–277–2013/0—PCT Application No. PCT/US2013/030217 filed 11 March 2013, which published as WO 2013/187958 on 19 Dec 2013
• HHS Reference No. E–277–2013/1—US Patent Application No. 13/895,898 filed 16 May 2013
Licensing Contact: Whitney Blair, J.D., M.P.H.; 301–435–4937; *whitney.blair@nih.gov.*

Multiplex Real-Time PCR Assay for Detection of Numerous Bacterial Pathogens

Description of Technology: In order to address a global need for rapid, cost-effective, sensitive, and specific assays for many pathogens, CDC scientists have developed a broad-use, multiplexed RT–PCR assay. This comprehensive assay covers numerous pathogens that are common causes of infection in neonates and also important to food-safety. Specifically, this assay (and respective probes, primers, and kits) is capable of detecting one or more of *Acinetobacter baumannii, Pseudomonas aeruginosa, Klebsiella pneumoniae, Toxoplasma gondii, Moraxella catarrhalis, Escherichia coli, Shigella, Staphylococcus aureus, Pneumocystis jirovecii, Chlamydia trachomatis, Ureaplasma urealyticum, Ureaplasma parvum, Ureaplasma spp., Bartonella spp., Streptococcus agalactiae,* and *Neisseria meningitidis* in a biological sample.
Potential Commercial Applications:
• Clinical diagnostic for several pathogens
• Drug-resistance surveillance
• Public health monitoring
• En masse food-safety screening
Competitive Advantages:
• Cost-effective
• Simple to implement
• Rapid, accurate and objectively conclusive
• Easily implemented into kit format
• Ideal for high-throughput scenarios
Development Stage:
• Pre-clinical
• In vitro data available
Inventors: Jonas Winchell, Bernard Wolff, Maureen Diaz (all of CDC)
Publication: Diaz MH, et al. Optimization of Multiple Pathogen Detection Using the TaqMan Array Card: Application for a Population-Based Study of Neonatal Infection. PLoS One. 2013 Jun 21;8(6):e66183. [PMID 23805203]
Intellectual Property: HHS Reference No. E–276–2013/0—
• US Provisional Patent Application No. 61/642,091 filed 03 May 2012
• PCT Application No. PCT/US13/28034 filed 27 Feb 2013, which published as WO 2013/165537 on 07 Nov 2013
Licensing Contact: Whitney Blair, J.D., M.P.H.; 301–435–4937; *whitney.blair@nih.gov.*

Methods of Detecting and Identifying Both Known and Novel Influenza Viruses

Description of Technology: This invention describes materials and methods of detecting novel influenza virus in a sample. As highlighted by the recent H1N1 pandemic strain, influenza viruses are constantly evolving and novel reassortments can quickly spread around the world.

The reagents and methods of this particular technology are capable of detecting any type of influenza virus (such as influenza A virus, influenza B virus, and influenza C virus) in a sample, including novel or previously unknown influenza viruses. Such methods and compositions are useful for diagnosing influenza virus infection in humans and animals.

Potential Commercial Applications:
• Method of rapid, accurate subtype-screening of influenza viruses using ''pan-influenza'' RT–PCR
• Diagnostic tool for clinicians, veterinarians, public health programs, food-safety officials, researchers and forensic scientists
Competitive Advantages:
• A full-spectrum, sensitive and specific assay for identification of influenza viruses, known and novel
• Easily adaptable for commercial production

Development Stage:
- Pre-clinical
- In vitro data available

Inventors: Suxiang Tong and Shannon Rogers (CDC)

Publications:

1. Fouchier RA, et al. Characterization of a novel influenza A virus hemagglutinin subtype (H16) obtained from black-headed gulls. J Virol. 2005 Mar;79(5):2814–22. [PMID 15709000]

2. Fouchier RA, et al. Detection of influenza A viruses from different species by PCR amplification of conserved sequences in the matrix gene. J Clin Microbiol. 2000 Nov;38(11):4096–101. [PMID 11060074]

3. Tong S, et al. Sensitive and broadly reactive reverse transcription-PCR assays to detect novel paramyxoviruses. J Clin Microbiol. 2008 Aug;46(8):2652–8. [PMID 18579717]

Intellectual Property: HHS Reference No. E–274–2013/0—
- US Provisional Application No. 61/642,098 filed 03 May 2012
- PCT Application No. PCT/US2013/029600 filed 07 Mar 2013, which published as WO 2013/165551 on 07 Nov 2013

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

Collaborative Research Opportunity: The Centers for Disease Control and Prevention (CDC) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Methods of Detecting and Identifying Both Known and Novel Influenza Viruses. For collaboration opportunities, please contact Suzanne Shope at *sshope@cdc.gov* or 770–488–8613.

Nucleic Acid Amplification Technique for Rapid Diagnostic Analysis

Description of Technology: CDC researchers developed a simple target-specific isothermal nucleic acid amplification technique, termed Genome Exponential Amplification Reaction (GEAR). The method employs a set of four primers (two inner and two outer). The outer primer pair targets three specific nucleic acid sequences at a constant 60 °C, while the inner pair of primers accelerates and improves the sensitivity of the assay.

The GEAR technique is an improvement over loop-mediated isothermal amplification (LAMP) in three ways. First, the GEAR method uses two Tab primers which target three genomic regions (corresponding LAMP primers target four regions). Second, the GEAR method features complementary 5′ ends between the forward and reverse primers. Third, the GEAR method does not require a second set of outer primers (LAMP requires two outermost primers). Additionally, the GEAR isothermal method can be performed in a relatively inexpensive water bath or heating block, with detection of amplification products by fluorescence, thus making it suitable for low resource settings.

Potential Commercial Applications:
- Rapid diagnostic analysis of biological samples
- Qualitative and quantitative analysis of nucleic acids
- Low-cost diagnostics for malaria, tuberculosis, and other infectious diseases

Competitive Advantages:
- Rapid, portable, cost-effective
- Useful in low resource settings
- A ''single-tube'' assay that eliminates need for thermal cyclers or gel electrophoresis
- Unlike many other isothermal amplification approaches, GEAR can be efficiently performed at temperatures exceeding 60 °C, increasing specificity and accuracy

Development Stage:
- Pre-clinical
- In vitro data available

Inventors: Jothikumar Narayanan, Prithiviraj Jothikumar, Vincent R. Hill (all of CDC)

Publication: Prithiviraj J, et al. Rapid detection of microbial DNA by a novel isothermal genome exponential amplification reaction (GEAR) assay. Biochem Biophys Res Commun. 2012 Apr 20;420(4):738–42. [PMID 22450319]

Intellectual Property: HHS Reference No. E–273–2013/0—PCT Application No. PCT/US2012/049784 filed 06 Aug 2012

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

Diagnostics, Vaccines, and Delivery-Vehicles Related to Novel Phlebovirus

Description of Technology: This CDC invention relates to primers and probes that specifically hybridize with Heartland virus (HRTLDV), a unique member of the genus *Phlebovirus.* It further relates to polyclonal antibodies specific for HRTLDV proteins. Serological detection assays using HRTLDV nucleic acid molecules, proteins, probes, primers, and antibodies are provided. Importantly, the HRTLDV genome can be engineered using reverse genetics to be attenuated, allowing development of a vaccine for other viruses within the *Phlebovirus* genus or *Bunyaviridae* family. Individual proteins or peptides of the HRTLDV can also be used in other FDA-approved virus backbones to act as vaccines. Further, since HRTLDV targets the bone marrow, disclosed HRTLDV delivery vehicles may be used to deliver therapeutic agents to the bone marrow.

Potential Commercial Applications:
- Development of nucleic acid (RT–PCR) and serologic diagnostic assays for phleboviruses
- Phlebovirus vaccines
- Novel delivery vehicles for bone marrow-originating diseases
- Research tool for phlebovirus virulence mechanisms
- Vector or tick-borne illness monitoring programs for both humans and wildlife

Competitive Advantages:
- Antigens and antibodies for diagnostic use have been developed
- RT–PCR allows rapid, quantitative diagnosis
- Potential use as bone marrow therapeutic delivery tools
- Recombinant, pseudo-phlebovirus reporter systems have potential for a wide range of high-throughput drug-screening and research applications

Development Stage:
- Early stage
- In vitro data available

Inventors: Laura K. McMullan, Cynthia S. Goldsmith, Aubree J. Kelly, William L. Nicholson, Stuart T. Nichol (all of CDC)

Publications:

1. McMullan LK, et al. A new phlebovirus associated with severe febrile illness in Missouri. N Engl J Med. 2012 Aug 30;367(9):834–41. [PMID 22931317]

2. CDC FAQs: Novel phlebovirus (Heartland virus) [*http://www.cdc.gov/ncezid/dvbd/heartland/index.html*]

Intellectual Property: HHS Reference No. E–269–2013/0—
- US Provisional Patent Application No. 61/614,926 filed 23 Mar 2012
- PCT Application No. PCT/US2013/033541 filed 22 Mar 2013, which published as WO 2013/142808 on 26 Sep 2013

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

HIV–1 Genotyping Assay for Subtype Diagnosis and Global Surveillance of Drug Resistance

Description of Technology: CDC researchers have developed a set of RT–PCR and sequencing primers based on HIV–1 group M sequences. Evaluation of the primers using samples collected around the world demonstrated broad detection capacity for multiple HIV–1 group subtypes and predominant circulating recombinant forms. Further, commercially available HIV–1 drug resistance (HIVDR) genotyping assays

are expensive and have limited ability to detect non-B subtypes. This optimized assay is broadly sensitive in genotyping HIV–1 group M viral strains and more sensitive than TRUGENE® and ViroSeq® assays in detecting mixed viral populations. Additionally, this assay is useful in resource-limited settings where HIVDR surveillance is recommended to minimize the development and transmission of HIVDR.

Potential Commercial Applications:

- HIV–1 sub-typing diagnostic
- Evaluation of efficacy of anti-HIV therapeutics
- HIV drug resistance (HIVDR) surveillance and monitoring

Competitive Advantages:

- Cost-effective
- Simple to implement
- Rapid, accurate and objectively conclusive
- Easily implemented as a kit
- Assay could be applicable to HIVDR genotyping in both ART-naive and ART-experienced populations

Development Stage:

- Pre-clinical
- In vitro data available

Inventors: Nicholas Wagar, Chunfu Yang, Zhiyong Zhou, Joshua DeVos (all of CDC)

Publications:

1. Zhou Z, et al. Optimization of a low cost and broadly sensitive genotyping assay for HIV–1 drug resistance surveillance and monitoring in resource-limited settings. PLoS One. 2011;6(11):e28184. [PMID 22132237]

2. Yang C, et al. Development and application of a broadly sensitive dried-blood-spot-based genotyping assay for global surveillance of HIV–1 drug resistance. J Clin Microbiol. 2010 Sep;48(9):3158–64. [PMID 20660209]

Intellectual Property: HHS Reference No. E–259–2013/0—

- PCT Application No. PCT/US2012/045523 filed 05 Jul 2012, which published as WO 2013/006684 on 10 Jan 2013
- US Patent Application No. 14/125,564 filed 11 Dec 2013

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

Collaborative Research Opportunity: The Centers for Disease Control and Prevention (CDC) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Real-time PCR Assay for Detection of Pneumococcal DNA and Diagnosis of Pneumococcal Disease. For collaboration opportunities, please contact Suzanne Shope at *sshope@cdc.gov* or 770–488–8613.

Intranasal Dry Powder Inhaler for Improved Delivery of Vaccines and Therapeutics

Description of Technology: This Intranasal Dry Powder Inhaler (DPI), developed with Creare, Inc., allows low-cost delivery of powder vaccines. Nasal delivery has numerous advantages compared to traditional injected vaccines, including: (1) Safe, needle-less administration by minimally-trained staff or patient; (2) better protection due to mucosal and cross-protection; and (3) decreased biohazard waste. Further, dry powder aerosol vaccine delivery is superior to liquid aerosol delivery in a number of ways, including: (1) No dose reconstitution required; (2) highly thermostable and may not need cold chain storage; (3) costs less to store and transport; (4) improved efficacy through elimination of liquid spray nasal-dripping. This CDC-Creare invention is unique in that it is inexpensive and suitable for single-use applications, such as vaccination. It prevents the dose being deposited within the lower respiratory tract, improving safety. This delivery system has a broad range of potential applications including, but not limited to, childhood vaccination programs, self-administered therapeutics, and emergency biodefense.

Potential Commercial Applications:

- Intranasal delivery of vaccines and therapeutics
- Childhood vaccination programs, mass immunization campaigns, or response to epidemics

Competitive Advantages:

- Safe, needle-less delivery
- Allows self-administration
- Improved protection via intranasal immunization
- Decreased biohazard waste
- Dose reconstitution is not required
- Highly thermostable and may not need cold chain storage
- Cost-effective
- Primate study with a thermostable measles vaccine expected in the next year

Development Stage:

- In vitro data available
- Prototype

Inventors: Mark J. Papania, James J. Barry, Darin A. Knaus, Edward Moynihan, Eric M. Friets, Mark C. Bagley (all of CDC)

Intellectual Property: HHS Reference No. E–258–2013/0—

- US Provisional Patent Application No. 61/665,778 filed 28 Jun 2012
- PCT Application No. PCT/US2013/047399 filed 24 Jun 2013, which published as WO 2014/004400 on 03 Jan 2014

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

Recombinant Pan-Lyssavirus for Use in Rabies and Broad-Lyssavirus Vaccination

Description of Technology: CDC researchers have developed recombinant lyssaviruses that can be used for the development of an improved, broad-spectrum vaccine against several rabies genotypes. Lyssaviruses are single-stranded RNA viruses that cause rabies and rabies-like diseases in mammals. Currently, there are commercially available vaccines that are considered to be effective against infections from a single viral phylogroup; however, these vaccines confer little or no protection against viruses outside of the phylogroup. The present recombinants have glycoprotein-encoding genes from at least two different lyssaviruses and can be used as pan-lyssaviral vaccines to provide protection against infection by multiple lyssavirus phylogroups.

Potential Commercial Applications:

- Pan-lyssavirus vaccines
- Rabies surveillance and vaccination programs

Competitive Advantages:

- Broad-spectrum vaccine potential
- Pan-lyssavirus vaccination tools will be particularly beneficial in endemic and developing regions
- Employs a presently commercialized vaccine backbone/platform, making this innovation easily adaptable for industrial R&D and subsequent large-scale production

Development Stage: Pre-clinical

Inventors: Xianfu Wu, Charles E. Rupprecht, Ivan V. Kuzmin (all of CDC)

Publication: Kuzmin IV, et al. Complete genomes of Aravan, Khujand, Irkut and West Caucasian bat viruses, with special attention to the polymerase gene and non-coding regions. Virus Res. 2008 Sep;136(1–2):81–90. [PMID 18514350]

Intellectual Property: HHS Reference No. E–256–2013/0—

- PCT Application No. PCT/US2011/041579 filed 23 June 2011, which published as WO 2011/163446 on 29 Dec 2011
- US Patent Application No. 13/806,622 filed 21 Dec 2012

Related Technologies: HHS Reference No. E–326–2013/0—

- PCT Application No. PCT/US2006/040134 filed 13 Oct 2006, which published as WO 2007/047459 on 26 Apr 2007
- US Patent No. 7,863,041 issued 04 Jan 2011
- 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 Assay for Detection of Pneumococcal DNA and Diagnosis of Pneumococcal Disease

Description of Technology: CDC scientists have developed a real-time PCR assay for diagnosing pneumococcal disease using amplification of the bacterial gene encoding pneumococcal surface adhesin A (PsaA). Pneumococcal isolation and identification is often complicated by (1) antimicrobial suppression of growth in culture and (2) contamination by normal flora alpha-streptococci. Further, pneumococcal detection by culture and serological methods can be time-consuming, relatively expensive, laborious and, ultimately, indeterminate. Sensitive and specific assays that can be completed quickly in the clinical laboratory are essential for early diagnosis and effective therapy. This RT–PCR assay provides a tool for quick and accurate diagnosis by physicians and health care technicians and may be useful in evaluating the efficacy of novel pneumococcal vaccines and therapeutics.

Potential Commercial Applications:

- Pneumococcal disease diagnostics and surveillance programs
- *Streptococcus pneumoniae* vaccine development and improvement
- Evaluation of efficacy of anti-pneumococcal therapeutics

Competitive Advantages:

- Cost-effective
- Simple to implement
- Rapid, accurate and objectively conclusive
- Easily implemented as a kit

Development Stage:

- Pre-clinical
- In vitro data available

Inventors: Jacquelyn S. Sampson, Edwin W. Ades, George Carlone, Maria da Gloria Carvalho, Karen McCaustland (all of CDC)

Publication: Carvalho MG, et al. Evaluation and improvement of real-time PCR assays targeting lytA, ply, and psaA genes for detection of pneumococcal DNA. J Clin Microbiol. 2007 Aug;45(8):2460–6. [PMID 17537936]

Intellectual Property: HHS Reference No. E–250–2013/0—

- PCT Application No. PCT/US2005/010449 filed 28 Mar 2005, which published as WO 2006/104486 on 05 Oct 2006
- US Patent No. 7,476,733 issued 13 Jan 2009
- Various international filings issued or pending

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

Collaborative Research Opportunity: The Centers for Disease Control and Prevention (CDC) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Real-time PCR Assay for Detection of Pneumococcal DNA and Diagnosis of Pneumococcal Disease. For collaboration opportunities, please contact Suzanne Shope at *sshope@cdc.gov* or 770–488–8613.

T24 Antigen for Diagnosing or Treating *Taenia solium* Cysticercosis

Description of Technology: In order to develop a simple detection assay for field use, CDC researchers cloned and sequenced the *Taenia solium* T24 diagnostic protein. The T24 sequences can be used to detect and diagnose *T. solium* infection or can be formulated into a pharmaceutical composition. *T. solium* is a species of tapeworm. Intestinal infection with *T. solium* is referred to as taeniasis. Many taeniasis infections are asymptomatic but may be characterized by insomnia, anorexia, abdominal pain and weight loss. Cysticercosis infection, which can be fatal, may develop if *T. solium* larvae migrate out of the intestine and form cysticerci in various body tissues. This technology may be used to develop a diagnostic, vaccine, or therapeutic for infection related to *T. solium.*

Potential Commercial Applications:

- Vaccine or therapeutic for taeniasis or cysticercosis resulting from *T. solium* infection
- Diagnosis of *T. solium* infection
- Zoonotic disease research and surveillance
- Public health monitoring programs
- Livestock health and food-source monitoring

Competitive Advantages:

- Rapid, accurate, sensitive, and safe compared to current radiologic and biopsy diagnostic methods
- Easy-to-use diagnostic kit that doesn't require abnormal temperatures or specialized equipment
- Can be developed for serologic and/or nucleic acid diagnostics
- Cost-effective; useful for developing countries

Development Stage:

- Early-stage
- In vitro data available

Inventors: Kathy Hancock, Fatima Williams, Melinda L. Yushak, Sowmya Pattabhi, Victor C. Tsang (all of CDC)

Intellectual Property: HHS Reference No. E–237–2013/0—

- US Patent No. 7,547,762 issued 16 Jun 2009
- US Patent No. 7,972,606 issued 05 Jul 2011

Related Technologies: HHS Reference No. E–247–2013/0—US Patent No. 6,379,906 issued 30 Apr 2002

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

HIV–1 Multi-Clade, Multivalent Recombinant Vaccine Construct

Description of Technology: CDC scientists developed immunogenic multi-clade, multivalent (HIV1MCMV) recombinant constructs for use as HIV–1 vaccines. These polypeptides include immunogenic CTL, T- and/or B-cell determinants that are capable of eliciting broad and effective immune responses against diverse subtypes of HIV–1. It is believed that these HIV–1 constructs provide universal vaccines, capable of effective use in any part of the world affected by the HIV–1 epidemic. The construct contains specific cellular targeting epitopes that allow optimized antigen processing and recognition, and the design of the construct allows for the addition or deletion of epitopes. Additionally, the construct may be used to develop multi-pathogen vaccines by combination with other epitope-based constructs.

Potential Commercial Applications: Development of HIV–1 vaccine

Competitive Advantages:

- Allows easy epitope-tailoring
- Broad spectrum protection against HIV–1
- Unlike other HIV-vaccination strategies, this approach specifically primes both arms of the immune system for improved protection
- Can be combined with other epitope-based constructs to generate multi-pathogen vaccines

Development Stage:

- Early-stage
- In vitro data available

Inventors: Renu B. Lal and Sherry B. Owen (CDC)

Intellectual Property: HHS Reference No. E–231–2013/0—

- PCT Application No. PCT/US2004/009767 filed 26 Mar 2004, which published as WO 2004/085466 on 27 Oct 2004
- US Patent No. 7,425,611 issued 26 Mar 2004
- Various international patent applications pending or issued

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

Monoclonal Antibodies for Detection of *Stachybotrys chartarum* Fungi

Description of Technology: This invention provides monoclonal

antibodies that can be used to rapidly and accurately test for the presence of *Stachybotrys chartarum* fungi. Certain fungi found in indoor environments, including homes and businesses, may cause adverse health effects in people and animals by causing infection or provoking allergic reactions. Sick building syndrome, an occupational condition in which workers are sickened by environmental toxins or pathogens, has been associated with the fungus *S. chartarum.* The antibodies disclosed may be used to identify and detect the presence of *S. chartarum* in a biological sample or a sample obtained from the environment. The antibodies may be part of kits to assess human exposure to this fungi and they may be useful for improving occupational health.

Potential Commercial Applications:
- Clinical diagnosis of *S. chartarum* exposure
- Detection of fungal antigens in biological samples or the environment
- Occupational health and home safety

Competitive Advantages:
- Simple, rapid, and specific detection of *S. chartarum* pathogen
- Easily adaptable for kit format
- Less labor-intensive than spore counts or culturing
- More sensitive than chromatographic detection of mycotoxins
- Ensures objective output by directly quantifying spores rather than relying on genetically influenced molecular markers or sample extraction techniques

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

Inventors: Detlef Schmechel and Daniel M. Lewis (CDC)

Intellectual Property: HHS Reference No. E–224–2013/0—US Patent No. 7,368,256 issued 06 May 2008

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

Real-Time PCR for Detecting Legionella Species and Discriminating *Legionella pneumophila*

Description of Technology: Legionella pneumophila is the causative species in most cases of Legionnaires' disease (LD). CDC scientists have developed a real-time PCR assay capable of detecting all *Legionella* species and discriminating *L. pneumophila* from other *Legionella* species. LD is typically difficult to diagnose from a clinical standpoint as it confers no unique clinical features or symptoms. This assay provides a rapid and accurate alternative to laborious PCR assays, prone to aberrant results. It provides a sensitive alternative for diagnosis of Legionnaires' disease and detection of *L. pneumophila.*

Potential Commercial Applications:
- Diagnostic for Legionnaires' disease
- Detection of all Legionella species and specific discrimination of *L. pneumophila*

Competitive Advantages:
- Faster than immunoassays
- Less laborious than current LD diagnostics
- Rapid, sensitive, and specific
- Curtails misdiagnoses associated with serological evaluations
- Easily adaptable to kit form

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

Inventors: Robert F. Benson, Brian F. Holloway, Karen A. McCaustland, Patrick G. Yant (all of CDC)

Publication: Yang G, et al. Dual detection of Legionella pneumophila and Legionella species by real-time PCR targeting the 23S–5S rRNA gene spacer region. Clin Microbiol Infect. 2010 Mar;16(3):255–61. [PMID 19438641]

Intellectual Property: HHS Reference No. E–194–2013/0—
- PCT Application No. PCT/US2009/068461 filed 17 Dec 2009, which published as WO 2010/080493 on 15 Jul 2010
- US Patent Application No. 13/140,922 filed 20 Jun 2011

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

Real-Time PCR Assays for Selective Detection and Differentiation of *B. pertussis, B. parapertussis* and *B. homesii*

Description of Technology: CDC researchers developed a real-time PCR assay targeting insertion sequence (IS481) and pertussis toxin subunit 1 (ptxS1) of *Bordetella pertussis.* This real-time nucleic acid assay offers rapid, sensitive, and quantitative results. The employed primers have been validated through extensive diagnostic testing of 41 *Bordetella* and 64 non-*Bordetella* clinical isolates. This technology can be used to diagnose and distinguish *B. pertussis, B. parapertussis* and *B. homesii,* the three most common *Bordetella* human upper respiratory pathogens. A standalone assay or multi-faceted kit may be used.

Potential Commercial Applications:
- Diagnostics for *Bordetella* pathogens
- Investigation of acute upper respiratory illness and outbreaks

Competitive Advantages:
- Validated for the three major pathogens responsible for *Bordetella*-related upper respiratory infections
- Rapid, sensitive and quantitative
- Easily adapted to kit form
- Useful as an added, internal control for present *Bordetella pertussis* diagnostics

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

Inventors: Kathleen M. Tatti, Kansas Sparks, Maria-Lucia C. Tondella (all of CDC)

Publication: Tatti KM, et al. Development and evaluation of dual-target real-time polymerase chain reaction assays to detect Bordetella spp. Diagn Microbiol Infect Dis. 2008 Jul;61(3):264–72. [PMID 18440175]

Intellectual Property: HHS Reference No. E–193–2013/0—
- PCT Application No. PCT/US2010/032408 filed 26 Apr 2010, which published as WO 2010/124281 on 28 Oct 2010
- US Patent Application No. 13/266,099 filed 26 Apr 2010
- Various international patents pending or deferred

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

Antigen-Capture Electrochemiluminescent Assay for Determining Rabies Vaccine Potency

Description of Technology: CDC researchers developed a more efficient method of assessing rabies vaccine potency using an antigen-capture electrochemiluminescent (ECL) assay. This assay utilizes SULFO–NHS-Ester labeled murine monoclonal antibodies to quantify glycoprotein concentration, which is an indicator of vaccine potency. Currently, the potency of rabies vaccines is determined by the effective-dose (ED50) mouse study evaluation method, which is more than 50 years old. The labor-intensive ED50 evaluation method has high operating costs, extensive biosafety requirements, and requires the sacrifice of a large number of animals. CDC researchers have addressed these issues by developing a competitive in vitro antigen-capture assay that is rapid, highly robust, reproducible, flexible and much less expensive to implement than the traditional ED50-mouse study evaluation.

Potential Commercial Applications:
- Rabies vaccine design and development
- Vaccine quality control and quality assurance testing
- In vitro assay for rabies virus glycoprotein

Competitive Advantages:
- Efficient vaccine evaluation
- Highly robust, reproducible and flexible

• Easily standardized for consistent, universal usage and assurance of batch-to-batch vaccine homogeneity
• In vitro assay may replace the 50 year old ED50 mouse procedure
Development Stage:
• Pre-clinical
• In vitro data available
• In vivo data available (animal)
Inventors: Todd G. Smith and Charles E. Rupprecht (CDC)
Publication: Smith TG, et al. An electrochemiluminescence assay for analysis of rabies virus glycoprotein content in rabies vaccines. Vaccine. 2013 Jul 18;31(33):3333–8. [PMID 23742991]
Intellectual Property: HHS Reference No. E–180–2013/0—
• US Provisional Patent Application No. 61/713,130 filed 12 Oct 2012
• PCT Application No. PCT/US2013/064911 filed 15 Oct 2013
Related Technologies:
• HHS Reference No. E–256–2013/0—
—US Patent Application No. 13/806,622 filed 21 Dec 2012
—PCT Application No. PCT/US2011/041579 filed 23 June 2011, which published as WO 2011/163446 on 29 Dec 2011
• HHS Reference No. E–326–2013/0—
—PCT Application No. PCT/US2006/040134 filed 13 Oct 2006, which published as WO 2007/047459 on 26 Apr 2007
—US Patent No. 7,863,041 issued 04 Jan 2011
—US Patent Application No. 12/956,949 filed 30 Nov 2010
—Various international patent applications pending or issued
Licensing Contact: Whitney Blair, J.D., M.P.H.; 301–435–4937; *whitney.blair@nih.gov.*

Isolated Lyssavirus Nucleic Acid and Protein Sequences

Description of Technology: A novel strain in the rabies family of viruses, the Shimoni bat virus (SHIBV), has been discovered. Phylogenic and antigenic patterns identify SHIBV as a new species of Lyssavirus. Phylogenic reconstructions of SHIBV and monoclonal antibody typing were used to demonstrate a distinct genetic antigenic pattern. This unique genetic information may be used to create antigens or vaccines against SHIBV and provides opportunity for the development of new diagnostics, therapeutics, and prophylactic therapies for viral infection.
Potential Commercial Applications:
• Vaccines, therapies or diagnostics for Shimoni bat virus
• Rabies epidemiology and surveillance
• Lyssavirus/rabies research tool
Competitive Advantages:
• Protects against phylogroup II lyssaviruses, unlike current commercially available rabies vaccines
• Isolated biomaterials provide novel lyssavirus research tools
Development Stage:
• Early-stage
• In vitro data available
Inventors: Ivan V. Kuzmin (CDC), Charles E. Rupprecht (CDC), et al.
Publications:
1. Kuzmin IV, et al. Shimoni bat virus, a new representative of the Lyssavirus genus. Virus Res. 2010 May;149(2):197–210. [PMID 20138934]
2. Kuzmin IV, et al. Commerson's leaf-nosed bat (Hipposideros commersoni) is the likely reservoir of Shimoni bat virus. Vector Borne Zoonotic Dis. 2011 Nov;11(11):1465–70. [PMID 21867415]
Intellectual Property: HHS Reference No. E–179–2013/0—PCT Application No. PCT/US2011/021309 filed 14 Jan 2011, which published as WO 2013/081571 on 17 Oct 2013
Licensing Contact: Whitney Blair, J.D., M.P.H.; 301–435–4937; *whitney.blair@nih.gov.*

Real-Time TaqMan RT–PCR Assays for Selective Detection of Human Rhinovirus

Description of Technology: This invention relates to selective detection of human rhinovirus (HRV) in biological media. Specifically, this invention discloses a real-time TaqMan RT–PCR assay targeting the 5′-noncoding region of the HRV genome. This is a one-step, real-time nucleic acid assay that offers rapid, sensitive, and quantitative results. The assay is validated against all 100 recognized HRV prototype strains.
HRV is the most frequent cause of the common cold. From a clinical standpoint, diagnosis of HRV infection is quite difficult as the related symptoms can be caused by other agents as well. Additionally, laboratory detection of HRV is challenging as HRV exhibits extreme antigenic variability and certain strains cannot be maintained by cell culture.
Potential Commercial Applications:
• Development of human rhinovirus (HRV) diagnostics
• Acute lower respiratory illness diagnostics and investigation
Competitive Advantages:
• Validated against all 100 human rhinovirus prototype strains
• Rapid, sensitive and quantitative
• One-step assay
• Easily adapted to kit form
Development Stage:
• Early-stage
• In vitro data available
Inventors: Xiaoyan Lu and Dean D. Erdman (CDC)
Publication: Lu X, et al. Real-time reverse transcription-PCR assay for comprehensive detection of human rhinoviruses. J Clin Microbiol. 2008 Feb;46(2):533–9. [PMID 18057136]
Intellectual Property: HHS Reference No. E–177–2013/0—US Patent Application No. 12/315,758 filed 05 Dec 2008
Licensing Contact: Whitney Blair, J.D., M.P.H.; 301–435–4937; *whitney.blair@nih.gov.*

Composition and Methods for Rapid Detection of HIV by Loop-Mediated Isothermal Amplification

Description of Technology: This invention relates to methods and compositions for rapid detection of HIV nucleic acids in a biological sample. Specifically, it involves the use of the loop-mediated isothermal amplification (LAMP) for rapid detection of HIV–1 and/or HIV–2. The use of rapid HIV tests is highly attractive for screening of patient samples, especially in developing countries where resources are limited, because they are quick, easy to perform, and do not require any special equipment. Rapid tests for the identification of HIV antibody, however, will remain negative during the 4 to 5 week window post-infection and pre-seroconversion, necessitating the need for a diagnosis based on HIV nucleic acid.
Potential Commercial Applications:
• Diagnostic test for HIV–1 and/or HIV–2 infection
• Kits for detection of HIV nucleic acids
Competitive Advantages:
• High sensitivity and specificity
• No need for thermal cyclers or gel electrophoresis
• Assay can be used in limited-resource settings
• Rapid, portable and cost-effective alternative to PCR and enzyme immune assays
Development Stage:
• Pre-clinical
• In vitro data available
Inventors: Michele S. Owen, Kelly Curtis, Donna L. Rudolph (all of CDC)
Publications:
1. Curtis KA, et al. Isothermal amplification using a chemical heating device for point-of-care detection of HIV–1. PLoS One. 2012;7(2):e31432. [PMID 22384022]
2. Curtis KA, et al. Sequence-specific detection method for reverse transcription, loop-mediated isothermal amplification of HIV–1. J Med Virol.

2009 Jun;81(6):966–72. [PMID 19382260]

3. Curtis KA, et al. Rapid detection of HIV–1 by reverse-transcription, loop-mediated isothermal amplification (RT–LAMP). J Virol Methods. 2008 Aug;151(2):264–70. [PMID 18524393]

Intellectual Property: HHS Reference No. E–173–2013/0—

- PCT Application No. PCT/US09/035130 filed 25 Feb 2009, which published as WO 2009/108693 on 03 Sep 2009
- US Patent Application No. 12/918,536 filed 20 Aug 2010

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

Autocidal Gravid Ovitrap Mosquito Trap for Control and Surveillance of Mosquitoes

Description of Technology: Mosquitoes are responsible for the transmission of a number of important zoonotic diseases, including dengue fever, malaria, and rift valley fever. The CDC–AGO (Autocidal Gravid Ovitrap) mosquito trap is a device that targets older female mosquitoes looking for a suitable place to lay eggs. This device is 45 centimeters tall with a 10-liter capacity to hold an attractant, such as water and decaying vegetation. The mosquitoes are captured by a nontoxic adhesive and eggs are collected on a hydrogel. The use of the hydrogel instead of a liquid prevents the larvae from hatched mosquito eggs from completing development.

Novel aspects of this technology are the use of non-toxic components and slow to dry hydrogel, as opposed to insecticide. While there are a number of chemical methods for controlling mosquitoes, these chemicals are always subject to the evolution of resistance from the mosquito population and, thus, there is a need for additional non-chemical control methods.

Potential Commercial Applications:

- Device for mosquito control
- May be useful in regions of the world affected by vector-borne zoonotic diseases, such as dengue fever, malaria, Rift Valley fever or West Nile virus

Competitive Advantages:

- Many ovitraps are short-lived as insecticide compound degrades over time and/or mosquito population becomes insecticide-resistant
- Utilizes a nontoxic adhesive and hydrogel polymer, as opposed to insecticide

Development Stage:

- Prototype
- In vitro data available

Inventors: Roberto Barrera, Andrew J. Mackay, Manuel Amador (all of CDC)

Publications:

1. Barrera, R. et al. 2010. ''Field Trials of a New Gravid-ovitrap for Integrated Area-wide Control of Aedes Aegypti in Puerto Rico.'' In Abstract Book, 83 (5 Supplement):179. The American Journal of Tropical Medicine and Hygiene. Atlanta, GA, USA. [*http://www.astmh.org/Meeting_Archives.htm*]

2. Mackay AJ, et al. An improved autocidal gravid ovitrap for the control and surveillance of Aedes aegypti. Parasit Vectors. 2013 Aug 6;6(1):225. [PMID 23919568]

Intellectual Property: HHS Reference No. E–166–2013/0—

- PCT Application No. PCT/US2012/025462 filed 16 Feb 2012, which published as WO 2012/112785 on 23 Aug 2012
- U.S. Patent Application No. 13/822,598 filed 12 Mar 2013

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

sodC-Based Real-Time PCR Assay for Detection of *Neisseria meningitidis* Infection

Description of Technology: CDC researchers have developed a real-time PCR assay for the detection of *Neisseria meningitidis* sodC within clinical specimens. The ability to detect all strains of *N. meningitidis,* regardless of individual serogroup, is the central innovation of this technology. Further, the assay is sensitive enough to detect even the very limited sample sizes of *N. meningitidis* that would typically be found in clinical specimens. This technology avoids potentially catastrophic false-negative results associated with current *N. meningitidis* carriage study testing methods. At least 16% of carried *N. meningitidis* lacks the ctrA gene, which is the current target of serogroup-based real-time PCR. *N. meningitidis* is the etiologic agent of epidemic bacterial meningitis and sepsis throughout the world and rapid detection of *N. meningitidis* infection is essential for patient well-being.

Potential Commercial Applications:

- Routine *N. meningitis* surveillance, especially useful in carriage studies
- Rapid, specific identification of *N. meningitis* infection

Competitive Advantages:

- Rapid, sensitive and specific
- Present culture detection methods are limited by low sensitivity and long incubation periods; this assay demonstrates improved detection of meningococci, regardless of encapsulation status or bacteria viability
- Circumvents ctrA-based testing-related false negative results in carriage studies
- No further technical development needed for commercialization

Development Stage:

- Early-stage
- In vitro data available

Inventors: Jennifer D. Thomas, Cynthia P. Hatcher, Raydel D. Mair, Mary J. Theodore (all of CDC)

Publication: Dolan TJ, et al. sodC-based real-time PCR for detection of Neisseria meningitidis. PLoS One. 2011 May 5;6(5):e19361. [PMID 21573213]

Intellectual Property: HHS Reference No. E–165–2013/0—

- PCT Application No. PCT/US2011/055784 filed 11 Oct 2011, which published as WO 2012/048339 on 12 Apr 2012
- US Patent Application No. 13/816,903 filed 03 Apr 2013

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

Real-Time PCR Assay for Specific Detection of *Haemophilus influenzae* Serotypes A and B

Description of Technology: Haemophilus influenzae is responsible for life-threatening respiratory infections including meningitis. This assay allows for the qualitative detection of the bacterial meningitis pathogen *H. influenzae* serotype A (Hia) and serotype B (Hib) in fluid samples, without detecting any of the other serotypes of *H. influenzae.* This invention is capable of detecting even the very small numbers of Hia or Hib within clinical specimens.

Potential Commercial Applications:

- Meningitis nucleic acid-based diagnostics for testing clinical samples
- Useful for public health monitoring programs
- Surveillance of circulating *H. influenzae* serotypes

Competitive Advantages:

- Easily adapted to a real-time PCR assay (monoplex or multiplex) kit
- Rapid, accurate and specific, especially when compared to sero-diagnostic approaches
- No further testing need, presently ready for commercialization

Development Stage:

- Early-stage
- Pre-clinical
- In vitro data available

Inventors: Jennifer D. Thomas, Xin Wang, Cynthia P. Hatcher, Raydel Anderson, Mary J. Theodore, Leonard W. Mayer (all of CDC)

Intellectual Property: HHS Reference No. E–164–2013/0—

- PCT Application No. PCT/US2012/022753 filed 26 Jan 2012, which published as WO 2012/103353 on 02 Aug 2012

• U.S. Patent Application No. 13/996,913 filed 21 Jun 2013

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

Rapid Detection of Multi-Drug-Resistant *Mycobacterium tuberculosis* Using Real-Time PCR and High-Resolution Melt Analysis

Description of Technology: CDC scientists have developed a rapid, sensitive, and specific real-time PCR assay that is capable of detecting the presence of *Mycobacterium tuberculosis* and determining its resistance profile to antibiotics, such as rifampicin and isoniazid. Currently, there are few assays available that are capable of both detecting *M. tuberculosis* and determining the bacteria's drug resistance. This assay incorporates multiple fluorescent chemistries, providing a simple and cost-effective method of determining the bacteria's drug resistance. Additionally, this assay may be used to quickly discriminate *Mycobacterium tuberculosis* complex (MTBC) strains from non-MTBC strains.

Potential Commercial Applications:

• Rapid screening of potential multi-drug-resistant *M. tuberculosis*

• Kits for diagnosis of *M. tuberculosis*

• Public health programs combating emerging drug-resistance in *M. tuberculosis;* clinics working with at-risk populations

Competitive Advantages:

• Robust and inexpensive way to detect dominant *M. tuberculosis* mutations

• Rapid results within 5 hours of obtaining DNA

• More cost-efficient and less complex than culturing and sequencing methods of determining drug-resistant status

Development Status:

• Early-stage

• In vitro data available

Inventors: James E. Posey, Jonas M. Winchell, Kelley Cowart, Melissa Ramirez (all of CDC)

Publication: Ramirez MV, et al. Rapid detection of multidrug-resistant Mycobacterium tuberculosis by use of real-time PCR and high-resolution melt analysis. J Clin Microbiol. 2010 Nov;48(11):4003–9. [PMID 20810777]

Intellectual Property: HHS Reference No. E–160–2013/0—

• PCT Application No. PCT/US2011/035217 filed 04 May 2011, which published as WO 2011/140237 on 10 Nov 2011

• US Patent Application No. 13/695,935 filed 02 Nov 2012

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

Linear Epitopes of Anthrax Toxin Protective Antigen for Development of a Peptide Vaccine

Description of Technology: Bacillus anthracis is a gram-positive, spore-forming bacteria that causes anthrax infection in humans. CDC inventors have identified epitope sequences of *B. anthracis* protective antigen (PA) that may be useful for development of peptide-based anthrax vaccines. This invention also relates to methods for determining whether post-vaccination protection is achieved. Specifically, this invention relates to a screening method for determining protection against *B. anthracis* infection that involves testing a biological sample for the presence of antibodies to one or more predefined regions of *B. anthracis* PA. This technology may be important to any bioterrorism defense strategy.

Potential Commercial Applications:

• Novel anthrax vaccines

• Post-vaccination screening to determine if anthrax protection is achieved

• Biodefense

Competitive Advantages:

• May require fewer vaccination follow-ups, while present anthrax vaccines require numerous rounds of injections and boosters for full-effectiveness

• Identified peptide sequences, representing regions of PA, elicit an immune response in primate and human sera studies

Development Stage:

• Pre-clinical

• In vitro data available

Inventors: Vera A. Semenova, Conrad P. Quinn, Jan Pohl, Pavel Svoboda (all of CDC)

Intellectual Property: HHS Reference No. E–158–2013/2—

• PCT Application No. PCT/US2011/024317 filed 10 Feb 2011, which published as WO 2011/100408 on 18 Aug 2011

• US Patent Application No. 13/577,878 filed 08 Aug 2012

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

Multiplex Assay for Detection of Dengue Virus

Description of Technology: Dengue virus (DENV) is the cause of dengue illness (dengue fever, dengue hemorrhagic fever, and dengue shock syndrome). CDC researchers have developed a RT–PCR multiplex assay that, prior to sero-conversion, selectively detects dengue virus in biological or other fluid media, such as whole blood, plasma, or serum. The primers and probes from this assay are sufficiently specific to amplify and detect all four DENV serotypes. This FDA-approved technology may provide an improved method for rapid and accurate serotyping of dengue virus in clinical and research settings.

Potential Commercial Applications:

• Rapid, simple and accurate dengue virus (DENV) serotype identification

• Diagnostic tool for clinical or research settings

Competitive Advantages:

• Increased sensitivity and efficiency compared to current antigen-based assays and single reaction real-time RT–PCR analyses

• Addresses need for accurate molecular diagnosis of DENV

• FDA approved technology

Development Stage:

• In vitro data available

• In situ data available (on-site)

Inventors: Jorge L. Munoz-Jordan, Edgardo Vergne-Maldonado, Gilberto A. Santiago (all of CDC)

Publications:

1. Munoz-Jordan JL, et al. Genetic relatedness of dengue viruses in Key West, Florida, USA, 2009–2010. Emerg Infect Dis. 2013 Apr;19(4):652–4. [PMID 23632064]

2. Santiago GA, et al. Analytical and clinical performance of the CDC real time RT–PCR assay for detection and typing of dengue virus. PLoS Negl Trop Dis. 2013 Jul 11;7(7):e2311. [PMID 23875046]

Intellectual Property: HHS Reference No. E–148–2013/0—PCT Application No. PCT/US2012/061828 filed 25 Oct 2012, which published as WO 2013/066705 on 10 May 2013

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

Use of Vitronectin as a Biomarker for the Detection of Dengue Hemorrhagic Fever

Description of Technology: Dengue hemorrhagic fever (DHF) is a severe, potentially deadly infection spread by mosquitos. CDC scientists have identified vitronectin as an important biomarker of DHF. They have shown vitronectin is significantly reduced in DHF and severe dengue infections when compared to dengue non-hemorrhagic fever patients. Presently, DHF is established by assessing antibody concentrations and other rule-of-thumb criteria, but often these assays can be difficult to interpret and lead to false conclusions. Establishing vitronectin levels provides a specific, novel biomarker for DHF, leading to increased accuracy in clinical diagnoses and improved patient outcomes.

Potential Commercial Applications:
- Diagnostic biomarker of DHF
- Point-of-care diagnostic testing
- Enzyme-linked immunosorbent assay (ELISA) for clinical and laboratory use

Competitive Advantages:
- While there are commercially-available ELISAs to detect vitronectin, these products have not been used for dengue diagnosis
- Vitronectin assessment assays provide a novel, specific biomarker for the DHF disease state
- Easily developed for serologic diagnostic assays

Development Stage:
- Pre-clinical
- In vitro data available

Inventors: Elizabeth Hunsperger (CDC), Momar Ndao (McGill University), Kay Tomashek (CDC), Betty Poole-Smith (CDC)

Publication: Poole-Smith BK, et al. Discovery and Validation of Prognostic Biomarkers for Severe Dengue by Proteomic Screening. International Conference on Emerging Infectious Diseases 2012: poster and oral presentation abstracts. Emerg Infect Dis. 2012 Mar. [*http://wwwnc.cdc.gov/eid/pdfs/ICEID2012.pdf*]

Intellectual Property: HHS Reference No. E–147–2013/0—
- PCT Application No. PCT/US2012/025472 filed 16 Feb 2012, which published as WO 2013/130029 on 06 Sep 2013
- US Patent Application No. 13/985,507 filed 14 Aug 2013

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

Real-Time RT–PCR Assay for Detection of Noroviruses

Description of Technology: A specific and sensitive TaqMan-based real-time (rt) RT–PCR assay has been developed by CDC scientists for detection of noroviruses in clinical and environmental specimens. This assay can be implemented to rapidly detect and distinguish norovirus strains from genogroups I and II, which are responsible for the majority of human infections. Additionally, the assay is multiplexed with an internal extraction control virus (coliphage MS2) to validate the results of the assay. Since the virus cannot be grown in cell culture and enzyme immunoassays lack the necessary sensitivity, this technology is particularly useful.

Potential Commercial Applications:
- Development of norovirus diagnostics
- Specific rtRT–PCR assay for detecting and distinguishing of the major pathogenic norovirus genogroups (I and II) within clinical and environmental samples

Competitive Advantages:
- This is an internally controlled, multiplexed assay capable of rapid, accurate identification of norovirus genogroups responsible for human illness
- Superior sensitivity compared with immunoassay detection methods

Development Stage:
- Pre-clinical
- In vitro data available

Inventors: Jan Vinje, Nicole Gregoricus, Preeti Chhabra, Leslie Barclay, Hannah Shirley, David Lee (all of CDC)

Publications:

1. Vega E, et al. Novel surveillance network for norovirus gastroenteritis outbreaks, United States. Emerg Infect Dis. 2011 Aug;17(8):1389–95. [PMID 21801614]

2. Schultz AC, et al. Development and evaluation of novel one-step TaqMan realtime RT–PCR assays for the detection and direct genotyping of genogroup I and II noroviruses. J Clin Virol. 2011 Mar;50(3):230–4. [PMID 21195660]

Intellectual Property: HHS Reference No. E–145–2013/0—PCT Application No. PCT/US2012/065269 filed 15 Nov 2012, which published as WO 2013/074785 on 23 May 2013

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

Dated: January 23, 2014.

Richard U. Rodriguez,

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

[FR Doc. 2014–01635 Filed 1–28–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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 concept review and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the concept review, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Fetal Body Composition and Volumes in the NICHD Fetal Growth Studies.

Date: February 12, 2014.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate concept review.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Sathasiva B. Kandasamy, Ph.D., Scientific Review Officer, Division of Scientific Review, National Institute of Child Health and Human Development, 6100 Executive Boulevard, Rockville, MD 20892–9304, (301) 435–6680, *skandasa@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS).

Dated: January 23, 2014.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–01632 Filed 1–28–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meetings

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 meetings.

The meetings 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 Child Health and Human Development; Special Emphasis Panel.

Date: February 3, 2014.