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 (DEQC) 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 7:50 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—Supplemental Medical Insurance Program)


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: 301–402–2220. 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 (BBA66 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)


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)


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:

• US Patent No. 8,568,981 issued 29 Oct 2013

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:
• 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)


• US Patent No. 8,568,981 issued 29 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.
**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. Carline, Jacquelyn S. Sampson, Edwin W. Ades (all of CDC)


**Intellectual Property:**
- US Patent No. 8,420,107 issued 16 Apr 2013
- Various international patent applications pending or issued

**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:**
- Osonic therapy
- Passive immunization
- Enhancement of pathogen clearing

**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. (all of CDC)

**Publications:**

**Intellectual Property:**
- US Patent No. 7,919,104 issued 05 Apr 2013
- Various international patent applications pending or issued

**Related Technologies:**
- Various international patent applications pending or issued

**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 Shoppe 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:**

**Intellectual Property:**
- US Patent No. 8,431,134 issued 30 Apr 2013
- PCT Application No. PCT/US2009/052384 filed 31 Jul 2009, which published as WO 2010/14888 on 04 Feb 2010
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 handheld 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 deposition 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
- 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.


**Intellectual Property:**
- HHS Reference No. E–323–2013/0
- US Patent No. 8,544,462 issued 01 Oct 2013
- Various international issued patents

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

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**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 sets 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. Bigerstaff (CDC)

Publications:

• 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)


• 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 rabies and immunocontraceptive vaccines
• 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)


• Various international patent applications pending or deferred

Related Technologies:
• HHS Reference No. E–256–2013–0

• HHS Reference No. E–326–2013–0

—Various international patent applications pending or issued

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

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′ untranslated 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 parechoviruses
Competitive Advantages:
- Detects all Parechovirus genus members with a single assay
- Rapid, accurate, sensitive and specific
- Cost-effective in terms of 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)

- 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. bozemianii, 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.
- 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)


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 any 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)


- US Provisional Patent Application No. 61/642,091 filed 03 May 2012
- PCT Application No. PCT/US13/28034 filed 27 Feb 2013, which was 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:

- US Provisional Application No. 61/642,006 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 two 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, Prithivijaraj Jothikumar, Vincent R. Hill (all of CDC)


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 genome can be engineered for low resource settings. The GEAR technique is an isothermal 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.

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 two 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:
- 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)


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

- 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 (HVDR) 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:**

**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 Molyneux, Eric M. Friets, Mark C. Bagley (all of CDC)

**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

**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.
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 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.

**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)


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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 serological and/or nucleic acid diagnostics
- Cost-effective; useful for developing countries

**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


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

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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 \textit{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 \textit{S. chartarum}. The antibodies disclosed may be used to identify and detect the presence of \textit{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.

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

\textbf{Competitive Advantages:}
- Simple, rapid, and specific detection of \textit{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

\textbf{Real-Time PCR for Detecting Legionella Species and Discriminating \textit{Legionella pneumophila}}

\textbf{Description of Technology:} CDC researchers developed a real-time PCR assay capable of detecting all \textit{Legionella} species and discriminating \textit{L. pneumophila} from other \textit{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 \textit{L. pneumophila}

\textbf{Potential Commercial Applications:}
- Diagnostic for Legionnaires’ disease
- Detection of all Legionella species and specific discrimination of \textit{L. pneumophila}

\textbf{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

\textbf{Development Stage:}
- Early-stage
- In vitro data available

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


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

\textbf{Real-Time PCR Assays for Selective Detection and Differentiation of \textit{B. pertussis}, \textit{B. parapertussis} and \textit{B. homosii}}

\textbf{Description of Technology:} CDC researchers developed a real-time PCR assay targeting insertion sequence (IS481) and pertussis toxin subunit 1 (ptxS1) of \textit{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 \textit{Bordetella} and 64 non-\textit{Bordetella} clinical isolates. This technology can be used to diagnose and distinguish \textit{B. pertussis}, \textit{B. parapertussis} and \textit{B. homosii}, the three most common \textit{Bordetella} human upper respiratory pathogens. A standalone assay or multifaceted kit may be used.

\textbf{Potential Commercial Applications:}
- Diagnostics for \textit{Bordetella} pathogens
- Investigation of acute upper respiratory illness and outbreaks

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

\textbf{Development Stage:}
- Early-stage
- In vitro data available

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


\textbf{US Patent Application No. 13/266,099 filed 26 Apr 2010}

\textbf{Various international patents pending or deferred}

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

\textbf{Antigen-Capture Electrochemiluminescent Assay for Determining Rabies Vaccine Potency}

\textbf{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.

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

\textbf{Competitive Advantages:}
- Efficient vaccine evaluation
- Highly robust, reproducible and flexible
Isolated Lyssavirus Nucleic Acid and Protein Sequences

Description of Technology: A novel strain in the rabies family of viruses, the Shimoni bat virus (SHBV), has been discovered. Phylogenetic and antigenic patterns identify SHBV as a new species of Lyssavirus. Phylogenetic reconstructions of SHBV 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 SHBV 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
- In vivo data available (animal)

Inventors: Todd G. Smith and Charles E. Rupprecht (CDC)


- PCT Application No. PCT/US2013/064911 filed 15 Oct 2013

Related Technologies:
- IHHS Reference No. E–256–2013/0
- PCT Application No. PCT/US2011/041579 filed 23 June 2011, which published as WO 2011/163464 on 29 Dec 2011
- HHS Reference No. E–326–2013/0

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:
- Diagnostic test for HRV–1 and/or HIV–2 infection
- Kits for detection of HRV 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: Xiaoyan Lu and Dean D. Erdman (CDC)


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)

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 water and decaying vegetation. 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:

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:
• 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 serodiagnostic approaches
• No further testing need, presently ready for commercialization

Development Stage:
• Early-stage

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

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)

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)

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 Vorgue-Maldonado, Gilberto A. Santiago (all of CDC)
Publications:

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 Ndau (McGill University), Kay Tomashek (CDC), Betty Poole-Smith (CDC)


- PCT Application No. PCT/US2012/025472 filed 16 Feb 2012, which published as WO 2013/130029 on 06 Sep 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:


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


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

[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 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).

Michelle Trout,
Program Analyst, Office of Federal Advisory Committee Policy.

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