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Dated: May 10, 1999.

John L. Williams,

Director, Procurement and Grants Office,
Centers for Disease Control and Prevention
(CDC)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Government-Owned Inventions; Availability for Licensing

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

ACTION: Notice.

The inventions named in this notice are owned by agencies of the United States Government and are available for licensing in the United States (U.S.) in accordance with 35 U.S.C. 207 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 U.S. companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to Thomas E. O'Toole, M.P.H., Deputy Director, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), Mailstop E-67, 1600 Clifton Rd., Atlanta, GA 30333, telephone (404) 639-6270; facsimile (404) 639-6266. Please note that a signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Oligonucleotide Probes for Detecting Enterobacteriaceae and Quinolone-Resistant Enterobacteriaceae

Specific oligonucleotide probes have been developed to be incorporated into methods for the species-specific identification of these *Enterobacteriaceae* in a sample as well as detection and diagnosis of *Enterobacteriaceae* infection in a subject. This invention further provides methods for species-specific

identification of these quinolone-resistant *Enterobacteriaceae* as well as the detection and diagnosis thereof.

Inventor: Linda M Weigel, et al.
U.S. Patent Application SN: 60/080,375
(CDC Ref. #: I-003-98/0)

Compositions and Methods for Detecting Adult Taenia Solium

Compositions and methods for the detection of adult *Taenia solium* and the diagnosis and treatment of *T. solium* infection are described. The compositions contain one or more adult *T. solium* polypeptides which can be useful as diagnostic agents for the detection of adult tapeworm infection.

Inventor: Victor Tsang, et al.
U.S. Patent Application SN: 60/111,334
(CDC Ref. #: I-028-97/0)

Recombinant Multi-Valent Malarial Vaccine

This invention relates generally to the development and use of a recombinant, multi-valent and multi-stage malaria vaccine and more specifically relates to an antigenic protein useful for preventing or treating *P. falciparum* malarial infections. The invention further provides a vaccine against malaria that is effective in inhibiting reproductive growth of the parasite within a human or animal after initial infection. Also, this invention provides a method for conferring immunity against different stages in the life cycle of the malarial parasite, *P. falciparum*. Furthermore, the invention includes antibodies against a recombinant protein containing antigenic epitopes to various stages of a malarial Plasmodium species that may be useful as research or diagnostic reagents for the detection and measurement of *P. falciparum* in a biological sample.

Inventor: Altaf A. Lal, et al.
U.S. Patent Application SN: 60/097,703
(CDC Ref. #: I-004-98/0)

Reagent and Method for Detecting Cryptosporidium Parvum Oocysts

A reagent and method for the specific and highly sensitive detection of *C. parvum* in which the reagent is an antibody for a soluble *C. parvum* sporozoite antigen. The method comprises of an immunoassay in which the antibody is used to detect or quantify *C. parvum* sporozoite in a sample. The assay allows recognition and detection of *C. parvum* in turbid samples. And since there exists a lack of crossreactivity with other *Cryptosporidium* species, the assay is also highly specific for *C. parvum* contamination or infection.

Inventor: Victor Tsang, et al.

U.S. Patent Application SN: 60/111,225
(CDC Ref. #: I-039-98/0)

Isolation of a New Human Retrovirus

A new isolate of a human retrovirus has been identified in several cases of foamy virus infection in persons at risk for this occupational exposure to simian retroviruses. This new isolate demonstrates a number of phenotypic differences from previously isolated foamy viruses by its immune reactivity, cell tropism, cytopathicity and growth kinetics. Due to its human-derived/adapted nonpathogenic nature, this new isolate may be suitable as a potential gene therapy vector.

Inventor: Paul A. Sandstrom
U.S. Patent Application SN: 60/105,811
(CDC Ref. #: I-034-97/0)

Methods and Compositions for the Detection of Human Herpesvirus

Methods and compositions for the detection and diagnosis of infectious diseases are provided. In particular, efficient and sensitive compositions and methods for the detection of human herpesvirus 8 are provided. The diagnostic compositions and methods of the invention involve the use of peptides representative of dominant antigenic regions of human herpesvirus in detection assays. Such assays are highly specific, sensitive and accurate.

Inventor: Chou-Pong Pau
U.S. Patent Application SN 60/086,695
(CDC Ref. #: I-018-98/0)

Methods and Reagents for Molecular Detection of HIV-1 Groups M, N, and O

This invention provides reagents and assays for detecting HIV-1 groups M and O and optionally HIV-1 group N and SIVcpz. Nucleic acid primers for the hybridization to, amplification and subsequent detection are also provided for. The nucleic acid amplification assays can detect small concentrations of HIV and are also useful for qualitative and quantitative examinations.

Inventor: Renu B. Lal, et al.
U.S. Patent Application SN: 60/118,357
(CDC Ref. #: I-020-98/0)

Nucleic Acid Vaccines for the Prevention of Flavivirus Infection

This novel vaccine for flaviviruses comprises of recombinant nucleic acids that contain genes for structural proteins of flaviviruses, such as Japanese encephalitis virus (JEV). These vaccines serve as a transcriptional unit for the biosynthesis of the virus protein antigens when administered in vivo. Furthermore, the invention provides for a method of immunizing a subject against infection by a flavivirus.

Inventor: Gwong-Jen J. Chang
U.S. Patent Application SN: 60/087,908
(CDC Ref. #: I-008-97/0)

Method and Devices for Detection of Retroviral Infection

This invention comprises of methods, devices and compositions for detection of endogenous retroviruses found in xenotransplant materials. The methods and compositions are suited for detection of endogenous type-C retroviruses and in particular, for porcine endogenous retrovirus (PERV). Detection of such is necessary following xenotransplantation of porcine cellular products.

Inventor: Walid Heneine, et al.
U.S. Patent Application SN 60/090,972
(CDC Ref. #: I-021-98/0)

Methods and Devices for Detection of Xenogeneic Infectious Agents

Compositions, methods and diagnostic devices for monitoring porcine graft integrity and detecting the presence of porcine endogenous retrovirus (PERV) in a biological sample. The compositions, methods and devices are useful for determining or monitoring graft survival and rejection in recipients of xenografts and are useful for detecting PERV infections in a xenotransplant recipient or donor. In addition, the compositions, methods and devices are useful for screening therapeutic products to be administered to humans to ensure that the products are free of PERV contamination prior to administration.

Inventor: Bill Switzer, et al.
U.S. Patent Application SN: 60/093,202
(CDC Ref. #: I-024-98/0)
Associated U.S. Patent Application SN:
60/098,262 (CDC Ref. #≤ I-024-98/1)

Methods for the Prevention and Treatment of Diseases Caused by an Inflammatory Response

This invention provides methods for preventing or treating a disease in a subject caused by an inflammatory response to a disease or syndrome that is mediated by endogenous substance P. The methods include administration of anti-substance P antibodies or anti-substance P antibody fragments.

Inventor: Ralph A. Tripp, et al.
U.S. Patent Application SN: 60/116,835
(CDC Ref. #: I-009-98/0)

Preparation and Use of Recombinant Influenza A Virus M2 Constructs in Vaccines

M2, a structurally conserved influenza A viral surface protein, is capable of inducing broader, more cross-

reactive immunity to type A influenza viruses. This invention solves the problems of the prior art approaches to recombinant M2 production by providing new recombinant forms of M2 whose structure has been modified to allow simple prokaryotic expression as a soluble, readily purified variant protein which retains antigenic and immunogenic properties. The invention relates to vaccines comprised of these new recombinant forms of M2, and to methods of prevention and treatment of influenza A virus infections.

Inventor: A. Michael Frace, et. al.
U.S. Patent Application SN: 08/906,930
(CDC Ref. #: I-020-97/0)

Method and Kit for Detecting Resistance to Antiviral Drugs

One of the problems with the development of current therapies for HIV infection is that the HIV virus rapidly develops resistance to drugs such as reverse transcriptase inhibitors. This invention provides for an assay and kit for the detection of phenotypic resistance to a reverse transcriptase inhibitor drug in a biological sample.

Inventor: Walid Heneine, et al.
U.S. Patent Application SN: 60/090,051
(CDC Ref. #: I-005-98/0)

Novel Granulocytic Ehrlichia Genes and Uses Thereof

Granulocytic ehrlichiosis is an acute, potentially fatal tick-borne infection. This invention provides for granulocytic ehrlichia specific genes encoding thirteen proteins that can be used as diagnostic reagents and vaccines. Isolated nucleic acid molecules, purified polypeptides, nucleic acid probes, and antibodies to the thirteen proteins are provided for. The recombinant nucleic acid molecule, vectors, cells and many other forms of the molecule are provided for along with the methods and kit for detection.

Inventor: Cheryl I. Murphy, et al.
U.S. Patent Application SN: 09/178,316
(CDC Ref. #: I-011-99/0)

Invasion Associated Genes from *Neisseria Meningitidis* Serogroup B

The invention provides nucleic acids and encoded polypeptides associated with invasion of *Neisseria meningitidis*. The polypeptides are used as diagnostic reagents, as immunogenic reagents, and as components of vaccines. The nucleic acids are used as diagnostic reagents, as components of vectors and vaccines, and to encode the polypeptides of the invention. The invention also provides strains of *Neisseria meningitidis* which have an invasion deficient phenotype.

Inventors: Frederick D. Quinn, et. al.

U.S. Patent Application SN: 60/030,432
(Ref. #: I-002-95/0)

Dated: May 10, 1999.

Joseph Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

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Occupational Safety

Isocyanate Derivatizing Agent and Methods of Production and Use

This invention provides for a novel isocyanate derivatizing agent, 9-anthracenylmethyl-1-piperazinecarboxylate (PAC), that may be useful for the determination of isocyanates in an environmental sample. This agent is capable of derivatizing all isocyanate species. A method for producing PAC as well as a rapid, sensitive, inexpensive and efficient method for measuring the total level of isocyanate in an environmental sample are also provided.

Inventor: Robert P. Streicher