

Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Christine D. Berg, Chief, Early Detection Research Group, National Cancer Institute, NIH, EPN Building, Room 3070, 6130 Executive Boulevard, Bethesda, MD 20892, or call non-toll-free number 301-496-8544 or e-mail your request, including your address to: Bergc@mail.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: June 10, 2005.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

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. 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 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 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.

Epitopes of Ebola Virus Glycoproteins Useful for Vaccine Development

Carolyn A. Wilson et al. (FDA)

U.S. Provisional Application No. 60/532,677 filed 23 Dec 2003 (DHHS Reference No. E-271-2003/0-US-01);

PCT Patent Application filed 23 Dec 2004 (DHHS Reference No. E-271-2003/1-PCT-01).

Licensing Contact: Susan Ano; 301/435-5515; anos@mail.nih.gov.

The current technology relates to the identification of two highly conserved linear domains of Ebola or Marburg envelope glycoprotein (GP) and of amino acid residues within these regions critical for virus infection. The identified domains could provide targets for rational design and development of broadly cross-protective antivirals and vaccines. There are currently no licensed vaccines against Ebola and Marburg. The linear domains (or portions) could potentially be used as immunogens in a vaccine. Mutations containing these epitopes have been identified to result in the formation of non-infectious Ebola viral particles, which could be useful for developing vaccines against Ebola virus, a category A biodefense agent. Vaccines utilizing these non-infectious particles may be safer than vaccines that use other common approaches, *e.g.* live-attenuated virus vaccines. This technology describes the polypeptides that form the non-infectious Ebola viral particles, the polynucleotide sequences encoding the polypeptides, vectors comprising the polynucleotides, host cells transformed with such vectors, vaccines and methods suitable for use in the prevention and/or treatment of hemorrhagic fever due to Ebola or Marburg, and a molecular decoy comprising the polynucleotides. These additional materials could also form the basis of an Ebola vaccine or antiviral therapy. Diagnostic applications involving the aforementioned materials are also described. Development of antiviral compounds and vaccines for treatment and prevention of Ebola and Marburg infections would be of tremendous benefit for biodefense and public health. However, the current Ebola vaccine technologies such as DNA-based vaccines and subunit vaccines either have safety risks or lack broad cross-protectivity. Therefore, the present technology could provide a promising technology to make safe and broad cross-reactive antivirals or vaccines against Ebola and Marburg viruses.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Detection and Identification of Mycobacterium Using SecA

Steven H. Fischer and Adrian M. Zelazny (CC)

U.S. Provisional Application No. 60/548,371 filed 27 Feb 2004 (DHHS Ref. No. E-238-2003/0-US-01); PCT Application No. PCT/US05/06609 filed 28 Feb 2005 (DHHS Ref. No. E-238-2003/0-PCT-02).

Licensing Contact: Robert M. Joynes, J.D.; 301/594-6565; joynesr@mail.nih.gov.

This invention relates to a method of detecting a wide variety of Mycobacterium and Nocardia species in a sample. The method involves hybridizing an amplified Mycobacterium/Nocardia genus-specific secA nucleic acid to a Mycobacterium/Nocardia species-specific secA probe oligonucleotide, wherein the amplification utilizes at least two Mycobacterium/Nocardia genus-specific primers, and detecting hybridization of the Mycobacterium/Nocardia-specific secA nucleic acid. The Mycobacterium/Nocardia genus-specific primers bind within a conserved region of the nucleic acid sequence encoding a Mycobacterium/Nocardia bi-genus-specific secA protein, wherein the conserved region is in the 5' half of the Mycobacterium/Nocardia secA gene and includes a substrate specificity domain.

The approach for detection of Mycobacterium/Nocardia species in clinical materials could potentially be used as a universal system for detection of any member of the genus Mycobacterium and the genus Nocardia and identification at the species or complex level. The system currently identifies all mycobacteria tested to date. With a few modifications, we believe it will also detect all Nocardia species of clinical significance. Contrary to commercial methods based on 16S rRNA and ITS, the SecA method will detect both Mycobacterium and Nocardia species. The region targeted has sufficient sequence variation for discrimination at the species or complex level.

Based on the information available to date, the SecA approach could be potentially used to replace acid-fast smears (AFB) and modified acid-fast smears, could provide definitive detection and identification of a large variety of Mycobacterium and Nocardia species present in clinical materials, and could be used as a single confirmation and species identification system for suspected positive Mycobacterium or Nocardia cultures. The invention also contemplates devices, including arrays, and kits for

detecting *Mycobacterium* or *Nocardia* species in a sample.

This technology is related to Dr. Fischer's other technology, E-278-1999/0, "Multiplex Hybridization System for the Identification of Pathogenic *Mycobacterium* and Method of Use" (published in the **Federal Register** on September 7, 2002, 65 FR 54288). The distinguishing feature in the current invention that makes it a vast improvement over E-278-1999/0 is the ability to detect all 29 *Mycobacterium* species tested to date and potentially all *Nocardia* species in a clinical sample.

Cloned Genomes of Infectious Hepatitis C Virus and Uses Thereof

Masayuki Yanagi, Jens Bukh, Suzanne U. Emerson, Robert H. Purcell (NIAID)

U.S. Patent No. 6,153,421 issued on 28 Nov 2000 (DHHS Reference No. E-050-1998/0-US-01); U.S. Patent Application No. 09/662,454 filed 14 Sep 2000 (DHHS Reference No. E-050-1998/0-US-03); Canadian Application 2295552; Australian Application 84889/98; European Application 98935702.5.

Licensing Contact: Chekesha S. Clingman; 301/435-5018; clingmac@mail.nih.gov.

The current invention provides nucleic acid sequences comprising the genomes of infectious hepatitis C viruses (HCV) of genotype 1a and 1b. It covers the use of these sequences, and polypeptides encoded by all or part of the sequences, in the development of vaccines and diagnostic assays for HCV and the development of screening assays for the identification of antiviral agents for HCV.

Additional information can be found in: Yanagi *et al.*, "Transcripts from a single full-length cDNA clone of hepatitis C virus are infectious when directly transfected into the liver of a chimpanzee," *Proc. Natl. Acad. Sci. USA* (1997 August) 94(16):8738-8743; and Yanagi *et al.*, "Transcripts of a chimeric cDNA clone of hepatitis C virus genotype 1b are infectious in vivo," *Virology* (25 April 1998) 244(1):161-172.

Dated: June 6, 2005.

Steven M. Ferguson,

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

[FR Doc. 05-12130 Filed 6-20-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences 2006 Strategic Plan

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), Department of Health and Human Services (DHHS).

ACTION: Request for comments and nominations.

SUMMARY: The NIEHS is updating its 2000 strategic plan entitled NIEHS Strategic Plan 2000—A Five-Year Program: New Opportunities in Environmental Health Research. To anticipate, meet, and set priorities for environmental health research, training, resources, and technologies, NIEHS requests input from scientists, members of the public, and all interested parties. The goal of this strategic planning process is to identify barriers to progress for future research and to define future needs and directions for environmental health. In addition, the NIEHS seeks the nomination of individuals qualified to participate in a workshop to discuss the plan in more detail. The existing NIEHS strategic plan can be viewed at <http://www.niehs.nih.gov/external/plan2000/home.htm>.

DATES: Submit responses to the NIEHS Office of Science Policy and Planning, (see below), on or before August 5, 2005.

ADDRESSES: The Office of Science Policy and Planning, NIEHS/NIH, PO Box 12233, Research Triangle Park, NC 27709, telephone (919) 541-3484, FAX (919) 541-1994, e-mail niehs-plan2006@niehs.nih.gov. Comments may be submitted electronically at the NIEHS Strategic Planning Web site: <http://www.niehs.nih.gov/external/plan2006/home.htm>. They can also be submitted by e-mail, mail or fax to the above address.

SUPPLEMENTARY INFORMATION:

Background

The mission of the NIEHS is to reduce the burden of environmentally-associated disease and dysfunction by defining three elements: (1) How environmental exposures affect our health, (2) how individuals differ in their susceptibility to these exposures, and (3) how these susceptibilities change over time.

The NIEHS achieves its mission through multidisciplinary biomedical research programs and prevention and intervention efforts. The NIEHS also focuses on communication strategies

that encompass training, education, technology transfer, and community outreach. Research is required to disseminate evidence-based environmental health policies that prevent diseases.

Request for Comments

To ensure the continued relevance of its Strategic Plan, the NIEHS seeks input to the following questions relative to the issues described above:

(A) What are the disease processes and public health concerns that are relevant to environmental health sciences?

(B) How can environmental health sciences be used to understand how biological systems work, why some individuals are more susceptible to disease, or why individuals with the same disease may have very different clinical outcomes?

(C) What are the major opportunities and challenges in global environmental health?

(D) What are the environmental exposures that need further consideration?

(E) What are the critical needs for training the next generation of scientists in environmental health?

(F) What technology and infrastructural changes are needed to fundamentally advance environmental health science?

Individuals submitting public comments are asked to include relevant contact information [name, affiliation (if any), address, telephone, fax, e-mail, and sponsoring organization, if applicable].

Request for Nomination of Planning Group Members

The NIEHS solicits nominations for individuals to participate in a workshop to discuss the plan in more detail. Nominations should include the name, degree(s), position title, department, institution name and address, phone and fax numbers, e-mail address, and specific area of expertise. Information of nominated individuals should be sent by August 5, 2005 to the NIEHS office of Science Policy and Planning (contact information provided above).

Dated: June 8, 2005.

David A. Schwartz,

Director, National Institute of Environmental Health Sciences.

[FR Doc. 05-12129 Filed 6-20-05; 8:45 am]

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