DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

Construction of Recombinant Baculovirus VLPs Encoding the Major Capsid Protein, VP1, From Calicivirus Strains (Including Norovirus Strains, (strain MD145–12)

Description of Technology: The noroviruses (known as “Norwalk-like viruses”) are associated with an estimated 23,000,000 cases of acute gastroenteritis in the United States each year. Norovirus illness often occurs in outbreaks, affecting large numbers of individuals, illustrated recently by well-publicized reports of gastroenteritis outbreaks on several recreational cruise ships and in settings such as hospitals and schools. Norovirus disease is clearly important in terms of medical costs and missed workdays, and accumulating data support its emerging recognition as important agents of diarrhea-related morbidity.

Because the noroviruses cannot be propagated by any means in the laboratory, an important strategy in their study is the development of molecular biology-based tools. This invention reports the development of recombinant baculovirus carrying the capsid gene from several caliciviruses associated with human disease. Growth of these baculovirus recombinants in insect cells results in the expression of virus-like particles (VLPs) that are antigenically indistinguishable from the native calicivirus particle. These VLPs can be purified in large quantities for use as diagnostic reagents and potential vaccine candidates.

Inventors: Kim Y. Green, Judy F. Lew, Adrienne D. King, Stanislav V. Sosnovtsev, Gael M. Belliot (NIAID).

Publication: An example of the application of these materials is further described in KY Green et al. “A predominant role for Norwalk-like viruses as agents of epidemic gastroenteritis in Maryland nursing homes for the elderly,” J. Infect. Dis. 2002 Jan. 15;185(2):133–146.


Licensing Status: The materials embodied in this invention are available nonexclusively through a biological materials license.

Collaborative Research Opportunity: The Laboratory of Infectious Diseases, NIAID, NIH, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize norovirus VLP antigens. Please contact Kim Y. Green at kgreen@niaid.nih.gov for more information.

Full-Length cDNA Clone Representing the Consensus Sequence of the RNA Genome of a Human Norovirus (strain MD145–12) That Encodes Biologically Active Proteins

Description of Technology: The invention provides for a full-length cloned cDNA copy of the RNA genome of a predominant norovirus strain (Genogroup II.4) designated MD145–12 that was associated with human gastrointestinal illness. The noroviruses, which were formerly known as “Norwalk-like” viruses are estimated to cause 23 million cases of acute gastroenteritis in the USA each year. The virus has been designated into category B of the CDC biodefense-related priority pathogens because it can be used as an agent of bioterrorism. The subject cDNA clone of the virus encodes proteins of the MD145–12 strain that, when expressed in vitro, exhibit properties that would be expected from those produced by the original infectious virus. This cDNA clone is presently the only source to obtain norovirus proteins to facilitate studies...
aimed at developing control strategies such as vaccines and therapeutic drugs.  

**Inventors:** Gael M. Belliot, Kim Y. Green, Stanislav V. Sokovstnev (NIAID)  


**Licensing Status:** The cDNA clone for norovirus strain MD145–12 is available nonexclusively through a biological materials license.  

**Licensing Contact:** Peter A. Soukas, J.D.; 301/435–4646; soukasp@mail.nih.gov  

**Collaborative Research Opportunity:** The Laboratory of Infectious Diseases, NIAID, NIH, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize reagents derived from an infectious cDNA copy of the genome of porcine enteric calicivirus. Please contact Kim Y. Green at kgreen@niaid.nih.gov for more information.  

**Enzymatically-Active RNA-Dependent RNA Polymerase From a Human Norovirus (Calicivirus)**  

**Description of Technology:** The noroviruses (formerly known as “Norwalk-like viruses”) are associated with gastroenteritis outbreaks, affecting large numbers of individuals each year. Emerging data are supporting their increasing recognition as important agents of diarrhea-related morbidity and mortality. The frequency with which noroviruses are associated with gastroenteritis as “food and water-borne pathogens” has led to the inclusion of caliciviruses as Category B Bioterrorism Agents/Diseases. Because the noroviruses cannot be propagated by any means in the laboratory, an important strategy in their study is the development of molecular biology-based tools and replication systems. This invention reports the isolation of the first recombinant, enzymatically-active proteinase and RNA dependent RNA polymerase (RdRp) complex for a human norovirus. This enzyme should facilitate studies aimed at developing therapeutic drugs for norovirus disease.  

**Inventors:** Kyeong-Ok Chang (NIAID), Stanislav V. Sokovstnev, Gael M. Belliot (NIAID), Kim Y. Green (NIAID), et al.  

**Publication:** The materials are further described in L Wei et al., “Proteinase-polymerase precursor as the active form of feline calicivirus RNA-dependent RNA polymerase,” J. Virol. 2001 Feb;75(3):1211–1219.  


**Licensing Status:** The materials embodied in this invention are available nonexclusively through a biological materials license.  

**Licensing Contact:** Peter A. Soukas, J.D.; 301/435–4646; soukasp@mail.nih.gov.  

**Collaborative Research Opportunity:** The Laboratory of Infectious Diseases, NIAID, NIH, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize an active human norovirus proteinase-polymerase enzyme. Please contact Kim Y. Green at kgreen@niaid.nih.gov for more information.  

**Dated:** June 8, 2007.  

**Steven M. Ferguson,**  

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

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**Methods for Prevention and Treatment of Polyomavirus Infection or Reactivation**  

**Description of Technology:** Available for licensing and commercial development are methods of using two MAP kinase kinase (MEK) inhibitors, PD98059 and U0126, in the prevention and treatment of polyomavirus infection. Decrease in viral protein expression upon treatment with the MEK inhibitors has been demonstrated.