(DHHS Reference No. E–016–2000/0–PCT–02), U.S. Patent Application No. 10/129,424 filed 03 May 2002 (DHHS Reference No. E–016–2000/0–US–03)

Licensing Contact: Matthew Kiser; 301/435–5236; e-mail: *kiserm@mail.nih.gov*

The process of apoptosis, or programmed cell death, can be utilized to eliminate unwanted cells, and it can occur during embryogenesis, turnover of senescent cells or metamorphosis. It can also be part of a defense mechanism against pathogens, *e.g.*, viruses, by allowing the host organism to eliminate infected cells. In an attempt to circumvent this defense mechanism, pathogens can produce gene products that block these apoptotic pathways. For example, *O. pseudotsugata* expresses a family of inhibitors of apoptosis proteins (IAP), and experimental data suggests that these IAPs can play a role in the protection from cellular apoptosis. This application claims nucleic acid and amino acid sequences corresponding to a viral IAP-associated factor, or VIAF. The gene and its product may enhance the anti-apoptotic properties of IAPs although the exact mechanism of this interaction is not clear. This technology could be used to treat disease states where VIAF is under-expressed, *e.g.*, breast adenocarcinomas, where there is an over-expression of VIAF, *e.g.*, neurodegenerative diseases and where apoptosis is undesired, *e.g.*, AIDS and autoimmune diseases. Additional information may be found in Duckett, CS, ''Novel modulators of the apoptotic cell death pathway,'' Mol. Biol. Cell 12: 732 Suppl. S Nov 2001.

Dated: September 16, 2003.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, 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, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies 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.

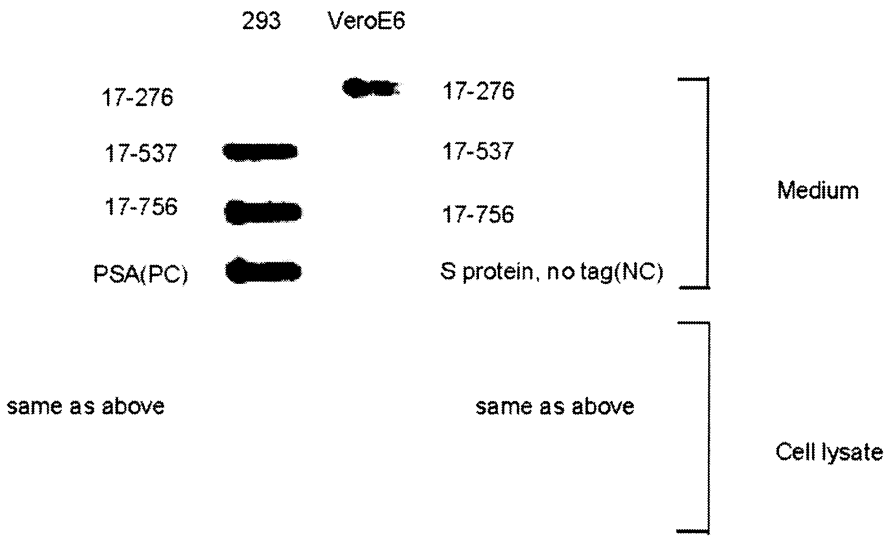
Soluble SARS Coronavirus Spike Protein (S Protein)

Dimiter Dimitrov, Xiadong Xiao (NCI)

DHHS Reference No. E–228–2003/0–US–01 filed 22 Jul 2003

Licensing Contact: Michael Shmilovich; 301/435–5019; *shimlovm@mail.nih.gov*

The SARS coronavirus is etiologically linked to severe acute respiratory syndrome. Soluble forms of the SARS coronavirus spike protein have been isolated and are available for licensing for use in generating vaccines, antibodies, and kits containing antibodies that bind to the spike protein for treating disease. The filed patent application additionally claims the associated spike protein polypeptides, peptide fragments, and conservative variants thereof; nucleic acid segments and constructs that encode the spike protein, polypeptides and peptide fragments of the spike protein, and conservative variants thereof and coupled proteins that include the spike protein or a portion thereof and peptidomimetics.



Internal Control Nucleic Acid Molecule for Real-Time Polymerase Chain Reaction

Michael Vickery, Angelo DePaola, George Blackstone (FDA)

U.S. Provisional Patent Application No. 60/471,121 filed 16 May 2003 (DHHS Reference No. E–213–2003/0–US–01)

Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov*

The invention provides a PCR internal control system for use in both real-time

PCR (also known as kinetic or Q–PCR) and conventional PCR. This flexible system has a number of novel design qualities which make it universally adaptable for use in virtually any real-time or conventional PCR assay, including RT–PCR and multiplex PCR applications, regardless of the organism/gene/nucleic acid being targeted. It provides the user/assay developer a choice of control product sizes, fluorogenic probe reporting systems, and thermal cycling options, allowing ease of incorporation into various assay formats and instrument platforms. This unique internal control also can be readily incorporated into virtually any existing quantitative multiplex real-time PCR assay. The invention also provides methods of using the internal control system and kits of the invention.

Additional information may be found in Vickery *et al.*, ''Detection and Quantification of Total and Potentially Virulent *Vibrio parahaemolyticus* Using a 4-Channel Multiplex Real-Time PCR Targeting the *tl, tdh,* and *trh* Genes and a Novel PCR Internal Control,'' published abstract, 103rd General Meeting of the American Society for Microbiology, May 18–23, 2003, Washington, DC.

Compositions and Methods for Diagnostics and Therapeutics For Hydrocephalus

Perry J. Blackshear *et al.* (NIEHS)

U.S. Provisional Patent Application No. 60/374,184 filed 19 Apr 2002 (DHHS Reference No. E–163–2002/0–US–01); U.S. Provisional Patent Application No. 60/388,266 filed 13 Jun 2002 (DHHS Reference No. E–163–2002/1–US–01); PCT Application No. PCT/US03/12348 filed 18 Apr 2003 (DHHS Reference No. E–163–2002/2–PCT–01)

Licensing Contact: Pradeep Ghosh; 301/435–5282; *ghoshpr@mail.nih.gov*

Congenital hydrocephalus is a public health problem, with approximately 1 in 1667 newborns suffering from this birth defect in the United States. Many cases of congenital hydrocephalus are caused by chromosome X-linked genetic mutations, but the genetic causes of the non-X-linked cases are unknown. This invention relates to RFX4_v3 proteins and nucleic acids encoding the RFX4_v3 proteins. Deficiencies in the RFX4_v3 protein are associated with congenital hydrocephalus in mice; specifically, the hydrocephalus is non-communicating and associated with aqueductal stenosis. The present invention provides assays for the detection of human RFX4_v3 polymorphisms or deficiencies that may lead to the determination of an individual's risk of developing hydrocephalus. Congenital hydrocephalus can have an adverse effect on developing brain and may predispose to neurological defects in children and adults. These defects can be manifested as mental retardation, cerebral palsy, epilepsy and visual disabilities. The cost of treatment for such disorders may exceed $100 million annually. Efficient diagnostics to determine the risks of development of this type of hydrocephalus are lacking in the market. The present invention would be most useful in developing diagnostic tests to determine whether parents are at risk to have a child with this type of hydrocephalus, and also to determine the causes of congenital hydrocephalus in affected children.

Sigma-2 Receptor Agonists Inhibit HIV Infection and Replication in Lymphocytes

Keith W. Crawford (NIDDK), Wayne D. Bowen (NIDDK), James E. Hildreth (EM)

U.S. Provisional Application No. 60/440,367 filed 16 Jan 2003 (DHHS Reference No. E–145–2002/0–US–01)

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This invention describes that the compounds, which activate sigma-2 receptors, decrease a particular lipid called sphingomyelin. Sphingomyelin is a component of lipid rafts, microdomains in the membrane which sequester specific proteins. Lipid rafts have been shown to play a major role in both entry and exit of HIV virus particles in cells. Disruption of lipid rafts blocks HIV infection. Treating lymphocytes with the compounds results in decrease in membrane sphingomyelin, blocks HIV infection and halts the replication of virus in lymphocytes. Thus, this discovery may have direct clinical applications in the treatment of HIV disease. In addition, these compounds should be effective against HIV that is resistant to multiple antiretroviral drugs because viral proteins are not the targets. Then, this finding uncovers a totally new approach for treating HIV infections and may represent potential new therapeutics for treatment of retroviral infections, including AIDS.

This research is also described, in part, in: Crawford *et al., Cancer Research* 62:313–319, 2002; Crawford *et al., Eur. J. Pharmacol.* 443:207–209, 2002; Gebreselassie & Bowen, *Proc. of the American Assoc. for Cancer Research* 43:725, #3597, 2002; Liao *et al., AIDS Res. Hum. Retroviruses,* 17:1009–19, 2001; Nguyen & Hildreth, *J. Virol.,* 74: 3264–3272, 2000; Vilner & Bowen, *J. Pharmacol Exp Ther.,* 292:900–911, 2000.

Hepatitis A Virus Receptor and Methods of Use

Gerardo Kaplan, Stephen M. Feinstone (FDA)

U.S. Patent 5,622,861 issued 22 Apr 1997 (DHHS Reference No. E–150–1994/0–US–01)

Licensing Contact: Brenda Hefti; 301/435–4632; *heftib@mail.nih.gov*

This invention describes the discovery and isolation of HAVcr–1, a simian cellular receptor for the hepatitis A virus (HAV). Cells nonpermissive to HAV infection transfected with HAVcr–1 cDNA, a novel cell surface mucin-like glycoprotein, gain susceptibility to HAV infection. The invention claims nucleic acids encoding cellular receptors to HAV that hybridize with HAVcr–1 probes, including the human homologs of HAVcr–1 (hHAVcr–1). The invention also claims peptides encoded by the above-mentioned HAV receptor nucleic acid, antibodies against HAVcr–1 receptors, and ligands to HAVcr–1 receptors.

The human homolog of HAVcr–1 (hHAVcr–1) has been shown to be a marker of renal injury (given the alias of kidney injury molecule 1 or KIM–1) and kidney cancer as well as a putative asthma determinant gene and modulator of T cell helper responses (given the alias of T-cell immunoglobulin mucin 1 or TIM–1). Use of HAVcr–1 nucleic acids and derived peptides, antibodies, ligands, *etc.* for diagnosis and therapy are also covered in this patent.

Potential areas of application include use of HAVcr–1 receptors and homologs for diagnostics; use of HAVcr–1 receptors for treatment of patients; development of therapeutic compounds capable of interacting with HAVcr–1 receptors that could block or activate these receptors, development of transgenic animals carrying HAVcr–1 receptors or portions of the receptors that could be used for vaccine production and testing and other applications.

HAVcr–1 has been molecularly cloned and its cDNA is available for further development. This invention is available for licensing on an exclusive or nonexclusive basis.

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