cell isolation technology. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Ectopic Thymidylate Synthase Accelerates the Development of Hyperplastic Foci and Adenomas in Pancreatic Islets

Description of Technology: Thymidylate synthase (TS) is an E2F1-regulated enzyme essential for DNA synthesis and repair. Elevated levels of TS protein and mRNA levels are associated with many human cancers. Previous research by the NIH inventors has demonstrated that ectopic expression of catalytically active TS is sufficient to induce a transformed phenotype in mammalian cells as manifested by foci formation, anchorage independent growth, and tumor formation in nude mice. Overexpression of hTS in murine islets provides a model to study genetic alterations associated with the progression from normal cells to hyperplasia and adenoma and suggests that this mouse model may be useful for cancer prevention and the development of therapeutic strategies.

Applications:

• Transgenic mouse model to develop cancer therapeutics.

• Drug screening for tumor reduction and prevention.

Market: Cancer therapeutic development.

Development Status: Thymidylate synthase transgenic mice available.

Inventor: Maria Zajac-Kaye (NCI).

Patent Status: HHS Reference No. E–088–2006/0—Research Tool. Patent prosecution is not being pursued for this technology.

Publications:

1. L Rahman, D Voeller, M Rahman, S Lipkowitz, C Allegra, JC Barrett, FJ Kaye, M Zajac-Kaye. Thymidylate synthase as an oncogene: a novel role for an essential DNA synthesis enzyme. Cancer Cell. 2004 Apr; 5(4):341–351.

2. D Voeller, L Rahman, M Zajac-Kaye. Elevated levels of thymidylate synthase linked to neoplastic transformation of mammalian cells. Cell Cycle. 2004 Aug; 3(8):1005–1007.

3. M Chen, L Rahman, D Voeller, E Kastanos, SX Yang, L Geigenbaum, C Allegra, FJ Kaye, P Steeg, M Zajac-Kaye. Transgenic expression of human thymidylate synthase accelerates the development of hyperplasia and tumors in the endocrine pancreas. Oncogene. 2007 Jul 19; 26(33):4817–4824.

Licensing Status: Available for licensing.

Licensing Contact: Betty B. Tong, Ph.D.; 301–594–6565; *tongb@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Medical Oncology Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the Thymidylate Synthase Transgenic Animal Model. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: *November 24, 2008.*

Richard U. Rodriguez,

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

[FR Doc. E8–28611 Filed 12–1–08; 8:45 am]

BILLING CODE 4140–01–P

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.

Detection and Quantification of HIV Antigen

Description of Technology: The invention relates to a novel, cost-effective method of detecting HIV antigens, in particular HIV Gag (p24) antigen, in human biological samples. The method relies on using a novel combination of a bead coated with a primary high affinity monoclonal antibody specific for p24 antigen and a secondary antibody conjugated with a fluorescent label that is also specific for p24 antigen. This detection method requires only approximately 50 µl of sample, and is able to detect the presence of HIV p24 antigen over a range of concentrations from 20,000 picograms down to 0.3 picograms with very low intrasample variability. The upper and lower limits of the detection method can be adjusted by altering the components of the assay.

Applications: Detection of HIV antigens in biological samples.

Advantages:

• Cost-effective

• Minimal amounts of sample required

• High sensitivity and dynamic range

Development Status: In vitro data can be provided upon request.

Market: HIV Diagnostics.

Inventors: Jean-Charles Grivel *et al.* (NICHD).

Publications: Manuscript in press.

Patent Status: U.S. Provisional Application No. 61/082,937 filed 23 Jul 2008 (HHS Reference No. E–240–2008/0–US–01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Kevin W. Chang, PhD; 301–435–5018; *changke@mail.nih.gov*.

Compositions and Methods for Inhibition of Fat-Specific Protein 27

Description of Technology: FSP27 expression is regulated by PPARγ, a gene known to play a critical role in the development of fatty liver. Over-expression of FSP27 results in an increase in triglyceride accumulation and an increase in cystolic vacuoles containing lipid droplets which are associated with development of fatty liver disease or hepatic steatosis. This abnormal retention of lipids in liver cells occurs in diabetes and alcoholism and is correlated with decreased liver function which can often lead to cirrhosis and sometimes death. Presently, there are no adequate therapies for fatty liver disease.

This technology is directed towards compositions and methods of inhibiting FSP27, which include antisense compounds, small molecule inhibitors and antibodies that target FSP27.

Application: Potential new shRNA based therapy for steatotic liver disease (fatty liver).

Market: Approximately 20 to 30% of the U.S. population has some degree of fatty liver disease, making it the most prevalent liver disease. Meanwhile, cirrhosis is one of the top ten causes of death in the U.S.

Development Status: Preclinical studies are in progress.

Inventors: Frank J. Gonzalez (NCI) *et al.*

Publication: K Matsusue, T Kusakabe, T Noguchi, S Takiguchi, T Suzuki, S Yamano, FJ Gonzalez: Hepatic steatosis in the leptin-deficient mouse is promoted by the PPARgamma target gene, fat-specific protein 27. Cell Metab. 2008 Apr; 7(4):302–311.

Patent Status: U.S. Provisional Application No. 61/043,330 filed 08 Apr 2008 (HHS Reference No. E–145–2008/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Fatima Sayyid, M.H.P.M.; 301–435–4521; *Fatima.Sayyid@hhs.nih.gov*.

Collaborative Research Opportunity: The Laboratory of Metabolism, National Cancer Institute, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize inhibitors of FSP27 for treatment of fatty liver disease. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Detection of Hereditary Prostate Cancer

Description of Technology: Inherited prostate cancer susceptibility genes with high penetrance are responsible for 5% to 10% of all cancer cases and up to 30% to 40% of early onset of the disease. Previous genetic linkage studies indicated that germline variations in a gene or genes on Xq27 were involved in prostate carcinogenesis. The linkage peak for prostate cancer overlies a region containing five *SPANX* genes whose expression has been detected in a variety of cancers. The investigators have identified an intra-chromosomal inversion involving more than a 400 kb sequence in prostate cancer patients but not in unaffected individuals. This technology can be used as an accurate, early prostate cancer susceptibility diagnostics method.

Applications: High throughput screening assay to predict patient susceptibility to prostate cancer.

Advantages: Easy, ready to use early stage prostate cancer diagnostic.

Development Status: The technology is currently in the pre-clinical stage of development.

Market:

• Among men, prostate cancer is the most common cancer and the second leading cause of death.

• There will be approximately 186,320 newly diagnosed cases of prostate cancer and an estimated 28,660 deaths are expected to occur in the United States in 2008.

• An estimated 5 to 10 percent of all prostate cancers are considered hereditary and as many as 30% to 40% of early onset of the disease.

Inventors: Natalay Kouprina (NCI) *et al.*

Patent Status: U.S. Provisional Application No. 61/010,209 filed 01 Jan 2008 (HHS Reference No. E–241–2007/0–US–01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov*.

Mouse Monoclonal Antibody to the Nitrone Spin Trap 5,5-dimethyl-1-pyrroline N-oxide (DMPO)

Description of Technology: Oxidative stress resulting in the formation of biological radicals has been implicated in a number of human diseases, such as cancer as well as aging. There is, however, a paucity of reliable methods for *in vivo* or *ex vivo* detection of radical formation. Until now the only general technique that allowed for the detection of these highly reactive species was electron spin resonance (ESR) using spin traps. One of the most popular of these spin traps is 5,5-dimethyl-1-pyrroline *N*-oxide (DMPO). In the ESR method, radicals are trapped by DMPO, and the DMPO spin adduct signal is measured quantitatively by an ESR spectrometer.

The Research Tool available is a mouse monoclonal antibody that specifically reacts with DMPO-protein and DMPO–DNA adducts. The inventors have used DMPO-octanoic acid conjugated to ovalbumin as the antigen to develop this monoclonal antibody. This product was assayed by ELISA and found to be reactive against DMPO-protein adducts at a dilution of 1 μg/ml of affinity purified mouse IgG when used in combination with alkaline phosphatase conjugated, affinity purified anti-mouse IgG (Goat).

Applications:

• ELISA and Immunoblotting of protein-DMPO adducts.

• Immuno-spin trapping analyses of DNA radicals.

• Immunoprecipitation of protein-DMPO adducts.

Market: DMPO is one of the most frequently used spin traps to detect free radicals and cited in over one thousand publications (Pubmed).

Inventors: Ronald P. Mason and Marilyn Ehrenshaft (NIEHS).

Patent Status: HHS Reference No. E–175–2006/0—Research Material. Patent protection is not being pursued for this technology.

Licensing Status: Hybridoma producing the monoclonal antibody and the monoclonal antibody are available for Biological Material Licensing.

Licensing Contact: Suryanarayana (Sury) Vepa, PhD, J.D.; 301–435–5020; *vepas@mail.nih.gov*.

HIV gp41-Membrane Proximal External Region Arrayed on Hepatitis B Surface Antigen Particles for HIV Diagnostic and Vaccine Applications

Description of Technology: This technology describes vectors encoding the membrane proximal external region (MPER) and select variants from HIV–1 gp41 linked to the hepatitis B surface antigen (HBsAg) and the resulting expressed particles for use in HIV diagnostic and vaccine applications. HIV–1 gp41 membrane proximal region contains two epitopes recognized by broadly neutralizing human monoclonal antibodies 2F5 and 4E10. However, immunization with gp41 MPER or the 2F5 or 4E10 epitopes have failed to raise neutralizing antibodies. In the subject technology, the particles were shown to bind antibodies from broadly neutralizing human sera and to the two known broadly neutralizing antibodies 2F5 and 4E10 with high relative affinities, demonstrating that the relevant epitopes are accessible for antibody binding and the potential utility of the particles in diagnostic applications. Additionally, these particles could be used to screen phage-display libraries for novel broadly cross-reactive neutralizing antibodies, of which only five are currently known. These particles could also be used for selection of MPER specific B cells. Lastly, these particles have been shown to be immunogenic and raise antibodies that recognize HIV–1 Env gp160 expressed on the cell surface. These immunogens can elicit neutralizing antibodies specific for HIV gp41 MPER, the MPER of gp41 is highly conserved across various HIV clades and therefore is likely to generate broadly neutralizing antibodies when administered in a proper presentation in a lipid context as is the case in HBsAg particles. Multiple copies of the MPER of HIV–1 gp41 arrayed on the particles could significantly increase the immunogenic potential compared to monomeric molecules. An increase of this nature has been observed with HBsAg and HPV virus-like particles in hepatitis B and cervical cancer vaccines, respectively, suggesting that particulate array may improve the presentation of selected epitopes to the immune system.

Applications: HIV vaccines; HIV diagnostics.

Advantages: These immunogens can elicit neutralizing antibodies specific for HIV gp41 MPER, which is highly conserved across various HIV clades and therefore is likely to generate broadly neutralizing antibodies when administered in a proper presentation in a lipid context as is the case in HBsAg particles. Multiple copies of the MPER of HIV–1 gp41 arrayed on the particles could significantly increase the immunogenic potential compared to monomeric molecules.

Inventors: Richard T. Wyatt (NIAID), Sanjay K. Phogat (NIAID), Ira Berkower (FDA).

Patent Status:

• U.S. Provisional Application No. 60/653,930 filed 18 Feb 2005 (HHS Reference No. E–123–2005/0–US–01).

• PCT Application No. PCT/US2006/005613 filed 17 Feb 2006, which published as WO 2006/112929 on 30 Nov 2006 (HHS Reference No. E–123–2005/1–PCT–01).

• U.S. Patent Application No. 11/816,069 filed 10 Aug 2007 (HHS Reference No. E–123–2005/1–US–02).

Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: Cristina Thalhammer-Reyero, PhD, M.B.A.; 301/435–4507; *thalhamc@mail.nih.gov*.

Dated: November 24, 2008.

Richard U. Rodriguez,

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

[FR Doc. E8–28614 Filed 12–1–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Transmission and Pathogenesis of HIV in Women

Date: December 10–12, 2008.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel and Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Thames E. Pickett, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIH/NIAID/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–496–2550, *pickettte@niaid.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Deciphering Pathogenisis for Developing Effective Therapies for Viral Infections.

Date: December 15, 2008.

Time: 9:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817. (Telephone Conference Call)

Contact Person: Edward W. Schroder, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, 301–435–8537, *eschroder@niaid.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 21, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–28493 Filed 12–1–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908), on September 30, 1997 (62 FR 51118), and on April 13, 2004 (69 FR 19644).

A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at *http://www.workplace.samhsa.gov* and *http://www.drugfreeworkplace.gov*.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, Room 2–1042, One Choke Cherry Road, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. Subpart C of the Mandatory Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards that laboratories must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies. To become certified, an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A laboratory must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Mandatory Guidelines dated April 13, 2004 (69 FR 19644), the following laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens: