Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to OIRA *submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Dated: November 24, 2008.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E8–28541 Filed 12–1–08; 8:45 am]

BILLING CODE 4165–15–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.

Method for Detection of Cancer Based on Spatial Genome Organization in the Cell Nucleus

Description of Technology: The successful treatment of cancer is correlated with the early detection of the cancerous cells. Conventional cancer diagnosis is largely based on qualitative morphological criteria, but more accurate quantitative tests could greatly increase early detection of malignant cells. It has been observed that the spatial arrangement of DNA in the nucleus is altered in cancer cells in comparison to normal cells. Therefore, it is possible to distinguish malignant cells by mapping the position of labeled marker genes in the nucleus.

This NIH invention provides methods of detecting abnormal cells in a sample using the spatial position of one or more genes within the nucleus of a cell, as well as a kit for detecting abnormal cells using such methods. The invention also provides methods of identifying gene markers for abnormal cells using the spatial position of one or more genes within the nucleus of a cell.

Applications: Diagnostic for cancer from tumor biopsies after non-invasive techniques such as a mammogram or PSA assay have suggested cancer.

Advantages:

- Sensitive detection of cancer.
- Very small sample (100–200 cells) reduces the need for invasive procedures.
- Does not require mitotic chromosomes.
- Applicable to solid tumors and blood cancers.
- Single cell assay allows analysis of subpopulations from biopsy.
- Probes to all genomic regions are available.
- Alternative or complementary to conventional diagnostics.
- Measures metastatic potential of cancer cells.
- Determination of tumor type.

Market:

- This novel in vitro diagnostic test for cancer has use in oncology laboratories of hospitals and commercial clinical laboratories.
- In the United States, almost 1.5 million new cancer cases are expected to be diagnosed in 2008.

Development Status: Presently in the process of validating the assay using a larger set of tumor samples.

Inventors: Tom Misteli and Karen Meaburn (NCI).

Publication: KJ Meaburn and T Misteli. Locus-specific and activity-independent gene repositioning during early tumorigenesis. J Cell Biol. 2008 Jan 14;180(1):39–50.

Patent Status: U.S. Provisional Application No. 61/094,318 filed 04 Sep 2008 (HHS Reference No. E–283–2008/0-US–01).

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

Licensing Contact: Whitney Hastings; 301–451–7337; *hastingw@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute, Cell Biology of Genomes Group, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize diagnostic methods for detection of cancer using spatial genome organization. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

A Novel, Non-Invasive and Therapeutically Useful High Throughput Technique To Isolate Highly Enriched Tumor Reactive Lymphocytes From Peripheral Blood-Potential Use in Adoptive Immunotherapy

Description of Technology: The adoptive transfer of autologous antigen reactive lymphocytes has been shown to mediate significant tumor regression in some patients with metastatic cancer. However, the isolation of these T lymphocytes requires invasive surgery, which can lead to post-operative complications and delays in initiating adoptive immunotherapy with T cells.

This technology is directed to the use of a novel high throughput technique to isolate highly enriched tumor reactive lymphocytes in a non-invasive manner from the peripheral blood of cancer patients for the purpose of cancer immunotherapy. The technique utilizes a highly sensitive PCR based screening assay.

Applications: The isolated T lymphocytes can be used in adoptive immunotherapy for the treatment of metastatic cancer.

Advantages:

- A rapid and non-invasive high throughput method of isolating tumor reactive T cells, which is otherwise difficult with conventional peripheral blood isolating techniques.
- The method is easy to use and based on a highly sensitive PCR based screening assay.
- The method can detect the presence of extremely rare T cells in a bulk population of peripheral blood cells.

Development Status: The method of isolating tumor reactive T lymphocytes has been established. The method was successfully used to isolate tumor reactive T cells from peripheral blood of cancer patients.

Inventor: Udai S. Kammula (NCI).

Patent Status: U.S. Patent Application No. 61/027,623 filed 11 Feb 2008 (HHS Reference No. E–003–2008/0–US–01).

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

Licensing Contact: Sabarni K. Chatterjee, PhD; 301–435–5587; *chatterjeesa@mail.nih.gov*

Collaborative Research Opportunity: The National Cancer Institute, Surgery Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this high throughput T

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.

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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.