Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at http://www.regulations.gov.


Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. E8–9882 Filed 5–5–08; 8:45 am]

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. 202 to achieve expedient commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage to parties interested in collaborative research to further develop, evaluate, or commercialize HPV-induced aberrant expression of microRNAs for cervical cancer diagnostics and therapeutics. Please contact John D. Hewes, PhD at 301–435–3121 or hewesj@mail.nih.gov for more information.

Microarray Binding Sensors Using Carbon Nanotube Transistors

Description of Technology: Available for licensing and commercial development are: (a) An apparatus containing microarray binding sensors having biological probe materials and carbon nanotube transistors (CNTs) and (b) various methods of using the highly sensitive CNTs for the electronic detection of nucleic acid hybridization for performing microarray gene expression experiments and detection of DNA–DNA, DNA–RNA, Peptide Nucleic Acid (PNA)–DNA, PNA–RNA, DNA–protein or PNA-protein binding. By analogy to the microarray concept, each transistor is associated with a distinct probe oligonucleotide. Each transistor is operated as a field effect transistor (FET) and the transconductance between the source and drain electrodes is measured before and after a hybridization event. The expected advantages are, besides higher sensitivity and ease of use, the elimination of chemical labeling and enzymatic manipulation and the further miniaturization. The unique distinction of this design over other CNT-based biomolecular sensing schemes is the complete isolation of the CNTs from chemical reactions concomitant with probe immobilization and target capture, and the CNTs functioning only as charge sensors. In contrast, current methods rely on enzymatic amplification of nucleic acids, fluorescent labeled targets, hybridization, amplification of signal and detection by optical scanners, which are time consuming and have limited sensitivity.

Applications: The apparatus and method can be used for numerous applications, among them: High-throughput monitoring of genome-wide

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1 There are no capital costs or operating and maintenance costs associated with this collection of information.

Human Papillomavirus microRNA Diagnostics and Therapeutics

Description of Technology: Available for licensing and commercial development are patent rights that cover the uses of a p53 specific microRNA (miRNA). It has been reported that the tumor suppressive miRNA miR–34a [a downstream target of p53] is downregulated in HPV-infected primary keratinocytes. miR–34a arrests the cell cycle at G2 phase and promotes apoptosis. Therapeutic restoration of normal expression levels of miR–34a and/or simultaneous stabilization of p53 (inhibited by HPV E6) induces miR–34a accumulation in G0/G1 phase and can arrest tumor growth. Neoplasia and cancer cell progression has also been associated with p18Ink4c overexpression which can be regulated with the introduction of a therapeutic amount of miR–34a. Tumor reduction/suppression by down regulating p18Ink4c is also a therapeutic benefit provided by this invention.

Applications: Cervical cancer; Human papillomavirus; Therapeutics.

Inventors: Zhi-Ming Zheng and Xiaohong Wang (NCI).

Publications:

Patent Status:

Licensing Status: Available for licensing.

Licensing Contact: Michael A. Shmilovich, Esq.: 301–435–5019; shmilovm@mail.nih.gov.

Collaborative Research Opportunity: The National Cancer Institute HIV and AIDS Malignancy Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize HPV-induced aberrant expression of microRNAs for cervical cancer diagnostics and therapeutics.

CONFIDENTIAL DISCLOSURE AGREEMENT

Inventors: Zhi-Ming Zheng and Xiaohong Wang (NCI).
DNA, mRNA copy number changes; sequencing of DNA; miRNA levels in cancer; or identifying targets of transcription factors.

Furthermore, given the intensity of effort in linking gene expression with diseases, it is only a matter of time before diagnosis and prognosis of certain ailments can be performed on the basis of gene expression. At the present, most such analyses require costly apparatus and labor-intensive laboratory procedures.

Development Status: In the process of developing prototypes.

Inventors: Javed Khan (NCI) et al.

Publications:

Patent Status:


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

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

Collaborative Research Opportunity:
The Oncogenomics Section, Center for Cancer Research, National Cancer Institute, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize electrical detection of nucleic acid and protein levels. Please contact Javed Khan, M.D. at 301–435–2937 or khanjav@mail.nih.gov for more information.

Segmenting Colon Wall Via Level Set Techniques

**Description of Technology:** Virtual Colonoscopy (VC) has become a more prevalent and accepted method of colorectal cancer diagnosis. An essential element for detecting cancerous polyps using VC, in conjunction with computer-aided detection, is the accurate segmentation of the colon wall. While the inner boundary of the colon wall, the lumen-mucosal boundary, has often been the focus of previous segmentation work, detection of the outer wall, the serosal tissue boundary, allows for the segmentation of the colon wall, which is useful in determining potential polyps, muscular hypertrophy, and diverticulitis of the colon.

Unfortunately, automatic determination of the outer colon wall position often is difficult due to the low contrast between CT attenuation values of the colon wall and the surrounding fat tissue. This invention is a level set based method to determine, from a CT colonography (CTC) scan, the location of the colon serosal tissue boundary. After determining this location, the algorithm segments the entire colon wall at subvoxel accurate precision.

In this algorithm, the loops in the colon caused by over-distention are detected and removed when the centerline calculation is performed. Also, a newly developed method for the detection and segmentation of the outer wall of the colon is used to connect collapsed portions where the lumen segmentation failed to produce a connected centerline. These two methods allow for a complete and accurate centerline to be calculated in uniformly distended colons as well as colons containing segments which are over and/or under-distended.

**Applications:**

**Inventors:** Robert L. Van Uitert, Ronald M. Summers, Ingmar Bitter (CC).

**Publications:**


**Licensing Status:** Available for licensing.

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


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

[FR Doc. E8—9871 Filed 5–5–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

**National Cancer Institute; 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 Cancer Institute Special Emphasis Panel; The Colon Cancer Family Registry.

**Date:** May 29, 2008.

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

**Agenda:** To review and evaluate grant applications.

**Place:** Marriott Courtyard Gaithersburg Washingtonian Ctr, 204 Boardwalk Place, Gaithersburg, MD 20878.

**Contact Person:** Gerald G. Lovinger, PhD, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Room 8101, Bethesda, MD