Dated: August 29, 2006.

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 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.

Oligo Microarray for Detection of All Known Mammalian and Avian Pathogenic Viruses

Description of Technology: The spectrum of pathogenic viruses of importance in human disease, agriculture and biology is not only large and diverse, but continually evolving. The identification or isolation of viral pathogens, in correlation with the presence of specific disease phenotypes, is of paramount importance both to diagnosis of disease and the subsequent management or treatment of viral infection. The limitations of current viral detection methods, such as PCR and immunoassays, led to the development of a novel microarray system for specific detection of viruses. The technology offered here for licensing provides a method for high-throughput screening of known pathogenic viruses along with identification of ''new'' disease-associated viruses.

The novel method is based on a viral microarray containing 10,000 immobilized DNA oligonucleotide features, representing all known mammalian and avian pathogenic viruses (approximately 600). Software was also developed to analyze the viral microarray results. The oligonucleotide features in this system are 60-mer long and distributed across both conserved and non-conserved regions of known viral sequences. This design serves the dual purpose of: (1) Facilitating validation via redundant signals associated with each represented virus and (2) allowing for the discovery of new viruses, which arise due to recombination. In addition, positive and negative controls against human and mouse housekeeping genes are included along with software for analysis of virus microarray results.

Further advantages of the viral microarray include: (a) The use of sample inputs as little as 10ng of either total DNA or RNA extracted from virus infected cells, representing as few as 20 viral particles; (b) detection of viruses of both DNA and RNA classes; (c) a capacity for high-throughput screening of various sample types including serum, saliva and biopsy tissues; and (d) analysis of a large number of samples in parallel on identical arrays.

The detection of viral DNA is unique to this technology, as other available technologies only detect viral genomic RNA or viral mRNA transcripts. Additionally, the viral chip was found to be highly specific and sensitive for detecting different viral genomic sequences in cell lines and multiple viral constructs co-infection in cultured cells.

Applications: (1) Detection and identification of viruses that cause disease; (2) Efficient discovery of new pathogenic viruses; (3) Diagnosis of human and animal disease outbreaks; (4) Identification of viral agents used in bioterrorism.

Development Status: (1) The pre-clinical performance of the viral microarray was evaluated by application of four virally positive infected cell lines (JSC–1-harboring EBV and KSHV, BCBL–1 harboring KSHV, HeLa-harboring HPV18, Cem X 174 harboring SIV). (2) Clinical performance was tested and validated through analysis of total RNA from cold (swab), Japanese Encephalitis, Dengue, Ebola and West Nile virus samples.

Inventors: Cassio S. Baptista (NCI), Xiaolin Wu (NCI), David J. Munroe (NCI).

Patent Status: U.S. Provisional Application No 60/797,334 filed 02 May 2006 (HHS Reference No. E–206–2006/0–US–01).

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

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

Collaborative Research Opportunity: The NCI-Laboratory of Molecular Technology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this oligo microarray for identification and detection of all known mammalian and avian pathogenic viruses. Please contact Betty Tong, PhD at 301–594–4263 or *tongb@mail.nih.gov* for more information.

Novel Monoclonal Antibody Microarray

Description of Technology: Gene expression profiling at the mRNA level has proven to be a powerful and useful tool, however this approach suffers from inherent limitations: (1) The mRNA abundance does not typically correlate well with protein abundance and (2) protein structure, activity, and function can be altered and regulated by post-translational modifications. Thus, there is growing recognition that these approaches should be complemented by profiles of the gene products or proteins themselves. The present invention provides methods for constructing and using a novel Monoclonal Antibody Microarray which allows high-throughput determination of protein expression profiles from serum, tissue, and cultured cells.

The Monoclonal Antibody Microarray consists of more than 1000 different antibodies immobilized on a glass slide, which recognize antigens from several groups of proteins, including cytokines, kinases, apoptotic proteins, growth factor receptors, tumor suppressors, and oncoproteins. Protein samples to be identified and quantified are labeled with fluorescence and hybridized to the antibodies immobilized on the arrays. By differentially labeling two protein samples (dual-color labeling) and co-hybridizing to the same microarray, a direct comparative analysis of protein expression can be performed using as little as 100 μg of total protein. This method allows a large number of samples to be screened in parallel on identical arrays.

Applications: (1) High-throughput analysis of protein expression; (2) Direct measurement of protein expression at

the gene product or post-translational levels.

Development Status: (1) The microarrays' performance was tested by proteomic profiling of two NCI–60 cancer cell lines (Renal UO–31 and Leukemia HL–60), demonstrating a high level of reproducibility. (2) The microarrays' performance was further evaluated by analysis of the protein expression profiles of 12 Borderline ovarian and 9 Adenocarcinoma ovarian tumors using normal ovarian surface epithelial cells as a reference cell line. It was possible to detect 77 proteins that showed statistically significant ($p<0.05$) differences distinguishing Borderline tumors and Adenocarcinoma tumors, demonstrating that the novel microarrays described are useful tools for proteomics.

Inventors: Cassio S. Baptista, Lionel Best, David J. Munroe (NCI).

Patent Status: U.S. Provisional Application No. 60/797,301 filed 02 May 2006 (HHS Reference No. E–207–2006/0–US–01).

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

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

Collaborative Research Opportunity: The NCI-Laboratory of Molecular Technology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this novel monoclonal antibody microarray. Please contact Betty Tong, PhD at 301–594–4263 or *tongb@mail.nih.gov* for more information.

Dated: August 31, 2006.

Steven M. Ferguson,

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

[FR Doc. E6–14831 Filed 9–6–06; 8:45 am]

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Methods for Enhancing Beta Cell Function in Diabetes

Description of Technology: Diabetes results when beta cell performance is compromised through loss of cells or by reduced cell function. Anti-diabetic drugs that stimulate insulin production, such as sulfonylureas and meglitinides, have limited efficacy when beta cell responsiveness is deficient. There exists a critical need, therefore, for new diagnostics and therapeutics that focus on beta cell responsiveness in diabetes.

This technology describes methods for improving pancreatic endocrine function and delaying the onset of diabetes by enhancing beta cell function using ligands and/or regulators of Notch receptors. These methods are directed not only to mature beta cells, but to immature beta cells and to beta cells formed from differentiation of stem cells. This technology also describes isolated pancreatic progenitor cells, and offers an effective method for identifying and isolating these cells using Notch receptor markers.

Applications: (1) Treatment for diabetes that enhances beta cell function or replaces lost beta cells; (2) Isolation and expansion of pancreatic progenitor cells for diabetes therapy; (3) Diagnostic test to monitor beta cell function

Market: (1) Over 20 million people suffer from diabetes in the United States, and approximately 170 million people are affected worldwide. (2) There are an estimated 6.2 million undiagnosed cases of diabetes in the United States.

Development Status: Pre-clinical data are available.

Inventors: Josephine M. Egan, et al. (NIA).

Patent Status: U.S. Provisional Application No. 60/590,281 filed 22 Jul 2004 (HHS Reference No. E–262–2003/0–US–01); PCT Application No. PCT/US2005/026207 filed 22 Jul 2005, which published as WO 2006/023209 on 02 Mar 2006 (HHS Reference No. E–262–2003/0–PCT–02).

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

Licensing Contact: Tara L. Kirby, Ph.D.; 301/435–4426; *tarak@mail.nih.gov.*

A Nurr1-Knockout Mouse Model for Parkinson's Disease and Stem Cell Differentiation

Description of Technology: The researchers have generated Nurr1-knockout mice via genomic locus inactivation using homologous recombination.

Transcription factor Nurr1 is an obligatory factor for neurotransmitter dopamine biosynthesis in ventral midbrain. From a neurological and clinical perspective, it suggests an entirely new mechanism for dopamine depletion in a region where dopamine is known to be involved in Parkinson's disease. Activation of Nurr1 may be therapeutically useful for Parkinson's disease patients; therefore, the mice would be useful in Parkinson's disease research.

Additionally, Nurr1 has been shown to be critical for development of midbrain dopaminergic neurons, and thus may contribute to stem cell-based therapies for neurological disorders. Nurr1 is also important for osteoblast differentiation, suggesting a general role in stem cell differentiation and growth.

Applications: (1) Research and drug testing for Parkinson's disease and other neurological disorders; (2) Stem cell research relating to neurological and other disorders and bone formation.

Inventor: Dr. Vera Nikodem (NIDDK).

Relevant Publication: SO Castillo, JS Baffi, M Palkovits, DS Goldstein, IJ Kopin, J Witta, MA Magnuson, VM Nikodem. Dopamine biosynthesis is selectively abolished in substantia nigra/ventral tegmental area but not in hypothalamic neurons in mice with targeted disruption of the Nurr1 gene. Mol Cell Neurosci. 1998 May, 11(1–2):36–46.

Related Publications:

1. MK Lee, H Choi, M Gil, VM Nikodem. Regulation of osteoblast differentiation by Nurr1 in MC3T3-E1 cell line and mouse calvarial osteoblasts. J Cell Biochem. 2006 June 1 [Epub ahead of print, doi:10.1002/jcb.20990].

2. J Jankovic, S Chen, WD Le. The role of Nurr1 in the development of dopaminergic neurons and Parkinson's disease. Prog Neurobiol. 2005 Sep-Oct, 77(1–2):128–138. Epub 2005 Oct 21, doi:10.1016/j.pneurobio.2005.09.001.