[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-up Exclusive License: Premarket Approved Diagnostic for Identifying JC Virus

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of a start-up exclusive license to Pro Arc Diagnostics, Inc., which is located in Missouri, to practice the inventions embodied in the following patents: U.S. Patent Application 14/408,919, filed December 17, 2014 (HHS reference E-088-2012/0-US-03).

The patent rights in these inventions have been assigned to the United States of America. The prospective start-up exclusive license territory may be worldwide and the field of use may be limited to FDA premarket approved (PMA) diagnostics for the detection of JC Virus.

DATES: Only written comments and /or applications for a license which are received by NINDS Technology Transfer on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated start-up exclusive license should be directed to: Susan Ano, Ph.D., NINDS Technology Transfer, 31 Center Drive, Suite 8A52, MS2540, Bethesda, MD 20892; Telephone: (301) 435-5515; E-mail: anos@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This invention provides a multiplex PCR-based method for detecting JC virus, and distinguishing between the non-pathogenic and pathogenic JC virus that causes progressive multifocal leukoencephalopathy (PML) in individuals that are immunocompromised. The invention helps to identify individuals at risk of developing PML by detecting two regions of the viral genome. The assay detects JC viral DNA with high sensitivity using the T protein coding DNA that is highly specific and does not allow mutations. It also detects a genome variable region in the non-coding region that detects changes from the nonpathogenic genotype in the urine to the pathogenic type seen in tissues especially in the brain, bone marrow, plasma/serum or immune cells of PML patients.

The prospective start-up exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated start-up exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: June 21, 2016.

Susan Ano

Technology Development Coordinator

NINDS Technology Transfer

National Institutes of Health

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