[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, HHS.

ACTIONS: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing 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.

FOR FURTHER INFORMATION CONTACT: Jeffrey Thruston at 301-594-5179 or jeffrey.thruston@nih.gov. Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.
SUPPLEMENTARY INFORMATION: Technology description follows:

**Alpha-Synuclein RT-QuIC: An Ultrasensitive Assay for the Detection of Alpha-Synuclein Seeding Activity Associated with Synucleinopathies**

**Description of Technology:**

Synucleinopathies are a category of neurodegenerative diseases defined by the abnormal aggregation and accumulation of misfolded alpha-synuclein protein molecules within the brain. These aggregates are of particular concern to humans as they are a primary cause of Parkinson’s disease, dementia with Lewy bodies, and other neurological disorders. This technology enables rapid, economical and ultrasensitive detection of disease-associated forms of alpha-synuclein as biomarkers or indicators of synucleinopathy in a biological sample. Specifically, alpha-synuclein aggregates (contained in a biological sample) seed the polymerization of vast stoichiometric excesses of recombinant, normally folded alpha-synuclein into amyloid fibrils that are then detectable by an amyloid-sensitive fluorescent dye. This reaction can thereby amplify the seeds in a biospecimen by many orders of magnitude. For example, in its current embodiment, this assay has been used to detect alpha-synuclein seeds in cerebral spinal fluid from living patients with Parkinson’s disease and Lewy-body dementia, giving high diagnostic sensitivity and specificity with unprecedented speed.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. § 209 and 37 CFR Part 404.

**Potential Commercial Applications:**

- Pre-mortem diagnosis of synucleinopathies, including Parkinson’s disease and Lewy-body dementia.
• A monitor of the disease progression of dementia and synucleinopathies
• Clinical trial / drug development companion diagnostic

**Competitive Advantages:**
• Uses a consistent, concentrated source of truncated alpha-synuclein protein substrate
• Capable of disease detection prior to onset of symptoms
• Rapid and economical

**Development Stage:**
• Research Use.

**Inventors:** Byron Caughey (NIAID), Bradley Groveman (NIAID), Christina Orru (NIAID), Lynne Raymond (NIAID)


**Licensing Contact:** To license this technology, please contact Jeffrey Thruston at 301-594-5179 or jeffrey.thruston@nih.gov, and reference E-233-2017-0.


_________________________________________

Wade W. Green,
Acting Deputy Director,
Technology Transfer and Intellectual Property Office,
National Institute of Allergy and Infectious Diseases.

[FR Doc. 2020-04534 Filed: 3/4/2020 8:45 am; Publication Date: 3/5/2020]