

corticobasal degeneration, chronic traumatic encephalopathy, progressive supranuclear palsy, and frontotemporal dementias with tau deposition.

- Measurement of levels of pathological tau aggregates in biospecimens.
  - Analysis of tauopathy-associated disease progression
  - Clinical trial/drug development companion diagnostic
- Competitive Advantages:*
- Uses a consistent, concentrated source of truncated tau protein
  - Rapid and economical
  - Highly sensitive and specific
- Development Stage:*
- Research Use.

*Inventors:* Byron Caughey (NIAID), Eri Saijo (NIAID), Allison Kraus (NIAID), Michael Metrick II (NIAID).

*Publications:*

Saijo, Eri et al. "Ultrasensitive and selective detection of 3-repeat tau seeding activity in Pick disease brain and cerebrospinal fluid". *Acta Neuropathologica* vol. 133 (2017):751–765.

Kraus, Allison et al. "Seeding selectivity and ultrasensitive detection of tau aggregate conformers of Alzheimer disease". *Acta Neuropathologica* vol. 137, 4 (2019): 585–598.

Metrick II Michael et al., "Million-fold sensitivity enhancement in proteopathic seed amplification assays for biospecimens by Hofmeister ion comparisons". *Proc Natl Acad Sci USA* vol. 116, 46 (2019):23029–23039.

Saijo, Eri et al. "4-repeat tau seeds and templating subtypes as brain and CSF biomarkers of frontotemporal lobar degeneration". *Acta Neuropathologica* vol 139, 4(2020):63–77.

Metrick II, Michael et al. "A single ultrasensitive assay for detection and discrimination of tau aggregates of Alzheimer and Pick diseases". *Acta Neuropathologica Communications* vol. 8, 1 (2020):22.

*Licensing Contact:* To license this technology, please contact Jeffrey Thruston at 301–594–5179 or [jeffrey.thruston@nih.gov](mailto:jeffrey.thruston@nih.gov), and reference E–015–2017–0.

Dated: February 25, 2020.

**Wade W. Green,**

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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, HHS.

**ACTION:** 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](mailto: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)

*Publications:* Groveman, Bradley R et al. "Rapid and ultra-sensitive quantitation of disease-associated  $\alpha$ -synuclein seeds in brain and cerebrospinal fluid by  $\alpha$ Syn RT-QuIC." *Acta Neuropathologica Communications* vol. 6(1):7, 9 Feb. 2018.

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

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