



[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.

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. 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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.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:

A Rapid Ultrasensitive Assay for Detecting Prions Based on the Seeded Polymerization of Recombinant Normal Prion Protein (rPrP-sen)

Description of Technology:

Prion diseases are neurodegenerative diseases of great public concern as humans may either develop disease spontaneously or, more rarely, due to mutations in their prion protein gene or exposures to external sources of infection. Prion disease is caused by the accumulation in the nervous system of abnormal aggregates of prion protein. This technology enables rapid, economical, and ultrasensitive detection of disease-associated forms of prion protein. Specifically, prion aggregates (contained in a biological sample) seed the polymerization of recombinant, monomeric prion protein (rPrP-sen) and the polymerized product is detected as a highly amplified indicator of infectious prions in the sample. This assay differs from the protein-misfolding cyclic amplification assay (PMCA) because it enables the effective use of bacterially expressed rPrP-sen and does not require multiple amplification rounds. In its current embodiment, this assay can be used to detect prions in tissues or fluids from humans (Creutzfeldt-Jakob disease (CJD)), sheep (scrapie), cattle (bovine spongiform encephalopathy), and deer (chronic wasting disease (CWD)). For example, analyses of cerebrospinal fluid and/or nasal brushings from living sporadic CJD patients has allowed for nearly 100% accurate diagnosis.

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:

- A test/screen for infectious prions in live animals and food products
- Cervid CWD monitoring
- A human diagnostic for early detection of prion diseases
- Medical equipment screening
- A monitor for effectiveness of treatments or disease progression
- A high through-put screen for inhibitors of prion replication

Competitive Advantages:

- Uses a consistent, concentrated source of normal prion protein (rPrP-sen)
- Prions are detectable to low levels after a single amplification round
- Demonstrated to be effective at detecting prions from different species
- May be applicable to blood products, nasal brushings, skin, eye components and other accessible biospecimens
- Economical and rapid

Development Stage:

- Research Use

Inventors: Ryuichiro Atarashi (NIAID), Roger Moore (NIAID), Byron Caughey (NIAID)

Publications: Atarashi, Ryuichiro et al. “Simplified ultrasensitive prion detection by recombinant PrP conversion with shaking.” *Nature Methods* **5**, pages 211–212 (2008).

Licensing Contact: To license this technology, please contact Jeffrey Thruston at 301-594-5179 or *jeffrey.thruston@nih.gov*, and reference E-109-2007-0.

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