



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: Dr. Natalie Greco, 301-761-7898; Natalie.Greco@nih.gov. Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at 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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Monoclonal Antibody Specific for DNA/RNA Hybrid Molecules

Description of Technology:

NIAID has a hybridoma available for non-exclusive licensing that produces a monoclonal antibody specific for DNA/RNA hybrids. This antibody, which has been extensively characterized by NIH researchers, is already a widely-used research tool. It is currently the only monoclonal antibody available that is specific for DNA/RNA hybrids, making it a unique reagent. It is used in immuno-fluorescence (IF) microscopy, where it can be used to detect sites of transcriptional activity and potentially sites of viral replication. It has also been used in DNA/RNA immunoprecipitation (DRIP) experiments by a variety of researchers.

Aside from its use as a research tool, this antibody has potential to be used in diagnostic kits for viral/bacterial infections, cancers, and a variety of other human diseases. DNA/RNA hybrids arise during normal cellular function, but they are typically present in cells at low levels. When DNA/RNA hybrids are found at high levels in a cell, it indicates that the cell is "abnormal". For example, the cell may be cancerous or infected with a virus. NIH researchers have also incorporated the antibody into a micro-array platform, expanding its potential for use in diagnostic devices.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR Part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

Research tool:

- Detection and visualization of DNA/RNA hybrids, "R-loops", or sites of viral replication in cells
- DNA/RNA immunoprecipitation (DRIP) studies
- Antibody based micro-arrays

For use in diagnostic kits that detect:

- Viral/bacterial infections
- miRNA biomarkers of disease (i.e. certain cancers)

Competitive Advantages:

- Only available monoclonal antibody specific for DNA/RNA hybrids
- Binding properties extensively characterized by NIH researchers
- Widely-accepted as a key research reagent
- Antibody based micro-arrays are inexpensive, efficient, and increase detection of small or structured transcripts, as well as transcripts present at low levels

Development Stage:

- *in vitro* data available

Inventors:

S. Leppla, C. Leysath, D. Phillips, D. Garboczi, L. Lantz (all of NIAID_

Publications:

- Phillips DD, et al. (2013) – PMID: 23784994 – PMCID: [PMC4061737](#) – The sub-nanomolar binding of DNA-RNA hybrids by the single-chain Fv fragment of antibody S9.6
- Hu Z, et al. (2006) – PMID: 16614443 - PMCID: PMC1435976 – An antibody-based microarray assay for small RNA detection

Intellectual Property: HHS Reference No. E-738-2013

Licensing Contact: Dr. Natalie Greco, 301-761-7898; Natalie.Greco@nih.gov

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize antibodies produced by the S9.6 hybridoma. For collaboration opportunities, please contact Dr. Natalie Greco, 301-761-7898; Natalie.Greco@nih.gov.

Dated: December 1, 2017.

Suzanne Frisbie,

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Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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