



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: Peter Soukas, J.D., (301) 594-8730; peter.soukas@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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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.

Development of a Transferrable Norwalk Virus Epitope and Detector

Monoclonal Antibody

Description of Technology:

Noroviruses are now recognized as the major cause of non-bacterial gastroenteritis in all age groups, and efforts are underway to develop an effective vaccine. The lack of a robust cell culture system for human noroviruses has complicated vaccine development. Hence, norovirus virus like particles (VLPs) have played an important role in the understanding of virus structure, immune response, antigenic diversity, and vaccine design. The development of monoclonal antibodies (MAbs) against norovirus VLPs has allowed the identification and characterization of key antigenic sites of the virus capsid and facilitated the development of diagnostic assays. During characterization of a panel of MAbs raised against Norwalk virus (NV), a prototype norovirus strain, the inventors identified a monoclonal antibody (MAbNV10) that proved useful in the identification of NV in tissue and in the characterization of an insertion site in the feline calicivirus (FCV) genome. The inventors mapped the precise binding site of the MAb by peptide screening and discovered that the epitope could be expressed when fused to other proteins. The sequence of this peptide (epitope) along with the detector antibody could be used as a new way to tag proteins for functional studies. The small size of the linear epitope, along with the strong avidity of the detector monoclonal antibody makes this system especially useful for many techniques, including immunofluorescence, Western blot, immunoprecipitation (including “pulldown” assays), and immunohistochemistry. The inventors’ epitope system may be comparable to that of the HA tag of influenza virus that is widely used in molecular biology.

This technology is further described in Parra et al., “Mapping and modeling of a strain-specific epitope in the Norwalk virus capsid inner shell,” *Virology*. 2016 May;492:232-41. doi: 10.1016/j.virol.2016.02.019. Epub 2016 Mar 21.

Materials available for licensing comprise: (1) Hybridoma cell line NV10, (2) Plasmid expressing NV10 epitope as positive control, and (3) Plasmid expressing the NV10 scFV.

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:

- Diagnostics
- Vaccines

Competitive Advantages:

- Cross-reactive norovirus antibody
- Ease of manufacture
- Efficient norovirus detection

Development Stage:

- In vivo data available (animal)

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Intellectual Property: HHS Reference No. E-101-2013/0

Licensing Contact: Peter Soukas, J.D., (301) 594-8730; peter.soukas@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 norovirus diagnostics or vaccines. For collaboration opportunities, please contact Peter Soukas, J.D., (301) 594-8730; peter.soukas@nih.gov.

Dated: August 3, 2017.

Suzanne Frisbie,

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Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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