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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: 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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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.

Enhanced Tissue Clearing Solution, Clearing-Enhanced 3D (Ce3D), Compatible with Advanced Fluorescence Microscopy Imaging

Description of Technology:

NIH immunologists have created a solution, Clearing-enhanced 3D (Ce3D), that can

be used to make entire organs extremely transparent. This allows the tissue to be imaged using advanced fluorescence microscopy techniques. Unlike current tissue clearing solutions, the Ce3D tissue clearing solution is robustly compatible with a variety of staining methods, and preserves tissue morphology and reporter fluorescence. Ce3D enabled microscopy provides unprecedented insight into the spatial organization of cells within intact organs. Further, when Ce3D enabled microscopy is coupled with multiplexed staining and a newly developed analysis pipeline, investigators are able to extensively characterize densely packed cells *in situ*, providing advantages to phenotyping cells with flow cytometric techniques.

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 reagent – can be applied to a variety of biological disciplines

• Diagnostic medical imaging reagent – characterization of disease state/condition

Competitive Advantages:

- Simple, quick and inexpensive procedure that has been extensively validated
- Generates excellent tissue transparency, resulting in high quality images
- Compatible with highly multiplexed staining/labeling techniques, including antibody-based methods, fluorescently tagged reporter proteins, and RNA-FISH
- Fluorescence is maintained in diverse fluorescent proteins and fluorophores
- Enables quantitative analysis of tissue composition and cellular distribution in whole organs, and has advantages over flow cytometric techniques

Development Stage:

- Prototype

Inventors:

Ronald N. Germain, Michael Y. Gerner, Weizhe Li (All from NIAID)

Publications:

Li W, et al. (2017) – Multiplex, quantitative cellular analysis in large tissue volumes with clearing-enhanced 3D microscopy (Ce3D) [PMID: 28808033 - PMCID: PMC5584454]

Intellectual Property: PCT Patent Application – PCT/US2017/049133, HHS Reference No. E-168-2016

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 tissue-clearing technologies. For collaboration opportunities, please contact Dr. Natalie Greco, 301-761-7898; Natalie.Greco@nih.gov.

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Suzanne Frisbie,
Deputy Director
Technology Transfer and Intellectual Property Office
National Institute of Allergy and Infectious Diseases
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