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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

ACTION: Notice

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 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 and/or co-development.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702.

FOR FURTHER INFORMATION CONTACT: Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702, Tel. 240-276-5515 or email ncitechtransfer@mail.nih.gov. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Title of invention:

Detection of Colorectal Cancer Using Two Heme-Related Molecules in Human Feces

Description of Technology:

Mortality from colorectal cancer (CRC) can be reduced by detecting the cancer or its precursor, colorectal adenoma (CRA), so that it can be removed at an early stage.

Current tests involve screening stool specimens for blood, especially for hemoglobin.

The fecal immunochemical test (FIT) for hemoglobin is positive in stool for about 60% of early-stage and 85% of advanced CRC cases, with a false-positive rate of less than 10%. Assays with better accuracy are still needed.

The subject technology is a novel assay that detects the presence or absence of one or both of two heme-related peptides, X-18565 and X-19549 in stool samples. The presence of one, and especially both, of these peptides within the stool sample indicates a high likelihood that CRC or CRA is present within the patient. X-18565 was detected in 67% of CRC cases and the specificity of X-18565 was 99%, as it was detected in only 1% of control patients who did not have CRC (e.g., false positives). X-19549 was detected in 48% of CRC cases and the specificity of X-19549 was 97%, as it was detected in only 3% of controls patients who did not have CRC (e.g., false positives). The absence of both X-18565 and X-19549 from the stool sample (or extract) indicates a greater than 95% likelihood that CRC or CRA is not present within the patient from which the stool sample is obtained. The assay can be performed on fresh or frozen samples.

Potential Commercial Applications:

- Diagnostic for colorectal cancer

Value Proposition:

- Assay has high specificity
- Fresh and frozen samples can be utilized by this assay

Development Stage:

Pre-clinical (*in vivo* validation)

Inventor(s):

James J. Goedert (NCI) and Rashmi Sinha (NCI)

Intellectual Property:

HHS Reference No. E-198-2014/0-PCT-02

International PCT Application No. PCT/US2015/038299 (HHS Reference No. E-198-2014/0-PCT-02) filed June 29, 2015 entitled, “Detection of Colorectal Cancer with Two Novel Heme-Related Molecules in Human Feces.”

Publications:

1. J.J. Goedert *et al.* Fecal Metabolomics: Assay Performance and Association with Colorectal Cancer. *Carcinogenesis*. 2014 Sep;35(9):2089-96. [PMID: 25037050]

Collaboration Opportunity:

The NCI seeks licensing or co-development collaborations that would enable eventual commercialization of the diagnostic technology.

Contact Information:

Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: john.hewes@nih.gov.

Dated: August 17, 2016

John D. Hewes

Technology Transfer Specialist, Technology Transfer Center, National Cancer Institute

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