

## DETECTION OF COLORECTAL CANCER WITH TWO NOVEL HEME-RELATED MOLECULES IN HUMAN FECES

### SUMMARY

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 only about 60% of early-stage and 85% of advanced CRC cases, with a false-positive rate of less than 10%. Researchers at the NCI have developed an assay with better accuracy and seek licensing and/or co-development research collaborations for the commercialization of the assay.

### REFERENCE NUMBER

E-198-2014

### PRODUCT TYPE

- Diagnostics

### KEYWORDS

- colorectal cancer, CRC, colorectal adenoma, CRA, screening, assay, X-18565, X-19549

### COLLABORATION OPPORTUNITY

This invention is available for licensing and co-development.

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### 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.

Researchers at NCI's [Division of Cancer Epidemiology & Genetics, Metabolic Epidemiology Branch](#) developed an 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 test for earlier detection of colorectal cancer and colorectal adenoma

## COMPETITIVE ADVANTAGES

- Assay has higher specificity than current standard
- Assay can utilize fresh or frozen samples

## INVENTOR(S)

James J. Goedert (NCI, retired), [Rashmi Sinha \(NCI\)](#)

(<http://dceg.cancer.gov/about/staff-directory/biographies/O-Z/sinha-rashmi>)

## DEVELOPMENT STAGE

- Pre-clinical (in vivo)

## PUBLICATIONS

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

## PATENT STATUS

- **Foreign Filed:** [International PCT Application No. PCT/US2015/038299](#)

## THERAPEUTIC AREA

- Cancer/Neoplasm