

epigenomics

Epigenomics Presents Data Confirming Screening for Methylated DNA in Blood as Key to Early Colorectal Cancer Detection

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Press release, Berlin, Germany and Seattle, WA, USA

Epigenomics AG (Frankfurt, Prime Standard: ECX), a molecular diagnostics company developing tests based on DNA methylation, today confirmed that free-floating DNA gleaned from blood is a key to early detection of colorectal cancer. Epigenomics showed that presence of the methylated form of DNA encoding the so-called Septin 9 gene is found in plasma of up to 57 percent of patients with all stages of colorectal cancer at high levels of specificity (95%). Data from the studies were presented at the 97th AACR Annual Meeting in Washington D.C., USA.

“The presence of methylated Septin 9 DNA in blood is a marker suited as an excellent population screening tool to identify a large number of asymptomatic cancers. Our study is the first of this magnitude and with this level of clinical performance to describe a DNA methylation-based blood test for the early detection of colorectal cancer,” said Catherine Lofton-Day, Ph.D., vice-president, Molecular Biology at Epigenomics. “A blood-based screening assay will be more patient-friendly than the conventional colorectal cancer screening tool, which requires patients to collect and submit fecal samples for fecal occult blood testing – a considerable obstacle to patient compliance.”

The data presented come from two independent studies that determined Septin 9 levels in a total of 1500 patients in three distinct categories. One group was known to be free from colon cancer after examination by colonoscopy. A second group included individuals with non-colorectal cancers and other non-cancerous conditions, and a third group consisted of patients with a confirmed diagnosis of colorectal cancer.

In an initial study of 501 samples, 57% of colorectal cancers were detected. After validating the Septin 9 assay among the three known-status groups in a set of several hundred samples, Lofton-Day and her colleagues predicted the diagnosis of colorectal cancer in an independent set of 790 patients. In this study the detection rate for all colorectal cancers was 50 percent (104 detected in 209 cases). The false positive rate for both studies was between 4 and 6 percent.

“Different stages of colorectal cancers were detected with similar sensitivity, and detection was not affected by location of the tumor in the colon,” Lofton-Day added. “This is a reliable, non-invasive method to detect many patients with colorectal cancer, but who show little or no symptoms.”

While the test to identify methylated Septin 9 DNA in the blood at present is not intended to replace periodic colonoscopy or sigmoidoscopy screening for colon cancer, it can be used more frequently as part of routine yearly physical check-ups to increase the chances of detecting

cancer at early stages.

About Epigenomics' Colon Cancer Screening Test

Epigenomics has successfully validated a panel of DNA methylation markers for incorporation into a colorectal cancer screening test in three large clinical studies involving approximately 2000 patient samples. The first marker from the panel has been exclusively licensed to Roche Diagnostics to be incorporated into a commercially available test. Epigenomics is continuing to identify and validate additional methylation markers for even better sensitivity in detecting colon cancer.

About Epigenomics

Epigenomics is a molecular diagnostic company with a focus on the development of novel products for cancer. By detecting and interpreting DNA methylation patterns, Epigenomics' tests can potentially diagnose disease at an early stage and help guide physicians to select an appropriate therapy. Epigenomics collaborates with Roche Diagnostics on the development of several diagnostic products in cancer. The company has its headquarters in Berlin, Germany, and a wholly owned subsidiary in Seattle, USA. For more information, please visit our website at www.epigenomics.com.

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