epigenomics

Press release

Epigenomics AG: Journal of the American Medical Association (JAMA) publishes "letter to the editor" that clarifies clinical performance data for Epi proColon®

Berlin (Germany) and Germantown, MD (U.S.A.), October 26, 2016 – The Journal of the American Medical Association (JAMA) published a "letter to the editor" discussing the importance of participation and clarifying clinical performance data for Epi proColon, the first and only FDA-approved blood test for colorectal cancer screening.

In June 2016, JAMA had published the United States Preventive Services Task Force (USPSTF) recommendation statement on colorectal cancer screening. The statement listed a number of screening tests, including serologic testing for methylated *SEPT*9 DNA (Epi proColon). However, the data cited for *SEPT*9 DNA was based on an earlier version of the assay and does not reflect the test that was granted Premarket Approval (PMA) by the U.S. Food and Drug Administration. The approved Epi proColon assay incorporated significant technology enhancements including improved DNA extraction, bisulfite conversion reagents and protocol and refined primer and probe sequences.

"We are pleased by JAMA's decision to publish this important clarification on the clinical evidence and the publication status of the FDA-approved, optimized version of Epi proColon. An effective screening test has performance as well as a high participation rate – Epi proColon provides both," said Greg Hamilton, Chief Executive Offer of Epigenomics AG. "We will continue to work closely with U.S. medical guideline bodies to further broaden the adoption of our blood-based test, which has the potential to remove the existing barriers for colorectal cancer screening and thereby save thousands of lives, as still 1 in 3 or almost 23 million Americans are not screened for colorectal cancer."

In their "letter to the editor", the study authors Klaus Mergener, MD, PhD, Digestive Health Specialists, Tacoma, WA, and Nicholas T. Potter, PhD, Molecular Pathology Laboratory Network, Inc. highlight the performance data of the FDA-approved and commercially available Epi proColon as published in peer-reviewed journals.

In the performance trial submitted to the FDA, which used the prospective PRESEPT sample collection (NCT00855348), the Epi proColon had a sensitivity* of 68% and a specificity* of 80%. In a second study, the *SEPT*9 DNA colorectal cancer detection test was non-inferior to fecal immunochemical test (FIT) with a test sensitivity of 72% compared with 68% for FIT while specificity was 81% compared with 97% for FIT. Epi proColon received FDA approval based on demonstration of safety and efficacy, as established in those clinical studies. The Epi proColon blood test has also demonstrated its potential to increase participation rates in colorectal cancer screening by eliminating the barriers of patient preparation and stool handling.

*Sensitivity: the percentage of cancer cases correctly identified; Specificity: the percentage of healthy individuals correctly identified as negative

About colorectal cancer (CRC)

The American Cancer Society projects there will be over 134,000 new diagnosed cases of colorectal cancer, and almost 50,000 deaths, from colorectal cancer in 2016 in the United States. Colorectal cancer remains the second-leading cause of cancer death in the United States. Although screening and early detection of colorectal cancer can save lives, about 35 percent of eligible U.S. patients are not being regularly screened. While the 5-year survival rate for early colorectal cancer (stage I) is 90%, only four-out-of-ten cases are diagnosed at this early stage. According to the American Cancer Society, this is in part due to the underuse of screening.

About Epi proColon

Epi proColon is a blood test indicated for colorectal cancer screening in average-risk patients who are unwilling or unable to perform colorectal cancer screening by colonoscopy and stool-based methods.

For patients, the test only requires a blood sample drawn as part of routine healthcare provider visits. There are no dietary restrictions or alterations in medication required for the test. The sample will be analyzed at a national or regional diagnostic laboratory.

Epi proColon is an in-vitro PCR (polymerase chain reaction) assay for the qualitative detection of *SEPT*9 gene methylation in DNA isolated from the patient's plasma. Cytosine residues of the *SEPT* 9 gene are methylated in colorectal cancer tissue, but not in normal colon mucosa. This tumor-specific methylation pattern can be used to detect cell-free DNA shed into the blood stream by tumor cells. Detection of colorectal cancer-derived DNA in blood plasma using the Septin9 methylation biomarker was demonstrated in multiple clinical studies, to be a reliable indicator of the presence of colorectal cancer.

Clinical evidence of Epi proColon

Epi proColon received FDA approval based on demonstration of safety and efficacy, as established in clinical studies. The test has also demonstrated its potential to increase participation rates in colorectal cancer screening.

The approval was based on multiple trials. In the performance evaluation trial using the PRESEPT prospective collection from 7.941 average risk patients (NCT00855348), samples from all patients with colorectal cancer or advanced adenomas, and a stratified random collection of patients with small polyps or no evidence of disease were blinded, randomized to batches and tested at independent laboratories. In this study, the test detected 68% of all cancer cases at 80% specificity. In a second study, conducted head-to-head against FIT, it was shown that Epi proColon is statistically non-inferior to FIT, a USPSTF recommended method in detecting colorectal cancer. Additionally, in the ADMIT (Adherence to Minimally Invasive Testing) trial, it was demonstrated that blood-based testing with Epi proColon has the potential to increase compliance with colorectal cancer screening, compared to FIT stool-based testing. In the ADMIT trial, Epi proColon reached an adherence rate of 99.5% among previously screening resistant participants.

For more information on Epi proColon, visit www.epiprocolon.com.

About Epigenomics

Epigenomics is a molecular diagnostics company focused on blood-based detection of cancers using its proprietary DNA methylation biomarker technology. The company develops and commercializes diagnostic products across multiple cancer indications with high medical need. Epigenomics' lead product, Epi proColon, is a blood-based screening test for the detection of colorectal cancer. Epi proColon has received approval from the U.S. Food and Drug Administration (FDA) and is currently marketed in the United States, Europe, and China and selected other countries. Epigenomics' second product, Epi proLung®, is in development as a blood-based test for lung cancer detection.

For more information, visit www.epigenomics.com.

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