

epigenomics

mSept9: Why a Blood Test for Colorectal Cancer?



Colorectal cancer is highly curable. More than 90% of patients survive if the cancer is diagnosed at an early stage while it is still localized. This may be a surprising fact as this dreaded disease is amongst the most frequent causes of death in the industrialized world. In the U.S. about 150,000 people are diagnosed with the disease every year and about 50,000 people die of this cancer in the same period. This makes colorectal cancer one of the most frequent and most deadly cancers. The dilemma: The majority of colorectal cancers are diagnosed in advanced stages when they already show symptoms lowering the chances of survival to less than 10% once the cancer has already spread to distant organs. These numbers clearly show that early diagnosis can potentially save many lives.

But catching colorectal cancer in its earliest stages requires systematic screening of the asymptomatic average risk population with suitable diagnostic procedures. Screening guidelines in many countries recommend regular fecal occult blood tests (FOBT) – laboratory tests that are performed on stool samples – or invasive endoscopic procedures such colonoscopy performed on average every ten years and which requires extensive bowel preparation.

Despite these recommendations, only a minority of the target population participates in regular colorectal cancer screening. Thus, annual FOBT tests are only performed by 12% of the individuals aged 50 years and older and only about 36% attend a colonoscopy every five to ten years. The most widely accepted reason for this low compliance is the lack of convenience. The American Cancer Society identified screening compliance as the major issue in colorectal cancer and is committed to drive compliance up to 75% by 2015. Reaching this goal may be facilitated by novel screening tests that are competitive with the best available noninvasive test in the discrimination between cancer patients and healthy individuals but convenient enough to ensure broad acceptance in the guideline eligible population.

Epigenomics AG, a Berlin, Germany, based cancer molecular diagnostics company together with its partners is developing a colorectal cancer blood test that it believes is ideally positioned to address this need. The test relies on measuring the methylated DNA of a single gene, SEPT9, as a biomarker in blood plasma. In eight prospective case control studies with more than 3,250 clinical samples from cancer patients, matched healthy individuals and other critical control samples the company has created a substantial body of evidence that this DNA methylation biomarker indicates the presence of colorectal cancer at all

stages and in any part of the colon and rectum.

With the PRESEPT Study, Epigenomics together with the clinical collaborators participating in the study in the U.S. and Germany wants to evaluate whether the *m*SEPT9 blood tests under development by Epigenomics and its diagnostic industry partners meet the requirements of current screening guideline U.S. recommendations in detecting the majority of cancers in the actual target population, i.e. individuals who according to current guidelines are eligible for colorectal cancer screening. Further, the PRESEPT initiative aims at demonstrating that colorectal cancer testing with a *m*SEPT9 blood test is not only beneficial in early cancer detection but also may help reduce overall spending of healthcare systems for colorectal cancer management.

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