

## The PRESEPT Study: Overview



**PRESEPT:** A prospective multi-national, multi-center clinical study to assess the performance of the Epigenomics' *m*Septin 9 biomarker for detection of colorectal cancer in screening guideline eligible, average to increased risk individuals

PRESEPT was a multi-center clinical study sponsored by Epigenomics to prospectively evaluate the clinical performance of Epigenomics' proprietary biomarker, *m*SEPT9, for colorectal cancer detection in guideline-eligible individuals as defined by the U.S. Multisociety Task Force on Colorectal Cancer (CRC). It was one of the first studies ever to evaluate the performance of a non-invasive test to indicate presence of colorectal cancer in usually asymptomatic individuals in a standard blood sample. The study was designed to enroll up to 7,500 asymptomatic subjects aged 50 or older at average to increased risk for colorectal cancer who have been scheduled for a regular screening colonoscopy at multiple clinical sites in the U.S. and Germany. This population was expected to harbor about 50 cases with undetected colorectal cancer.

The study was intended to evaluate the performance characteristics of the *m*SEPT9 biomarker to determine whether it will meet the requirements of current U.S. guidelines for non-invasive screening tests. The study was further expected to define the health economic benefit to support future coverage by public and private health insurers worldwide.

Each subject enrolled in the study provided a blood sample prior to pre-colonoscopy bowel cleansing which was analyzed for methylated of the Sept9 gene. The primary study endpoint compared the Septin9 test results to the presence or absence of colorectal cancer as determined by colonoscopy, the diagnostic gold standard, and confirmed by histopathological analysis of tissue removed during the colonoscopic or surgical removal of tissue.

The PRESEPT Study is registered with [clinicaltrials.gov](https://clinicaltrials.gov) (Study-ID: [NCT00855348](https://clinicaltrials.gov/ct2/show/study/NCT00855348))

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