FDA APPROVED BLOOD TEST FOR COLORECTAL CANCER SCREENING

epi pro colon®

What is Epi proColon®?

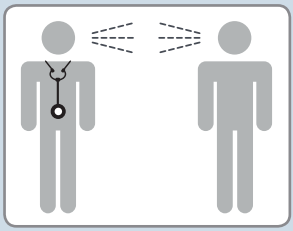
Epi proColon is a blood test for colorectal cancer screening for patients who are unwilling or unable to be screened by recommended methods.[1] The test detects methylated Septin 9 DNA, a differential blood biomarker that is methylated in colorectal cancer. Methylated Septin 9 tumor DNA shed into the bloodstream is detectable by Real-Time PCR.

Rx Only

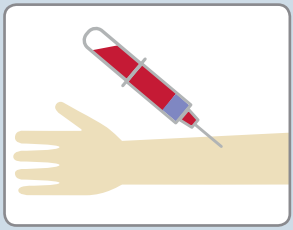
epigenomics
DETECTING CANCER IN BLOOD

How Do My Patients Get Tested?

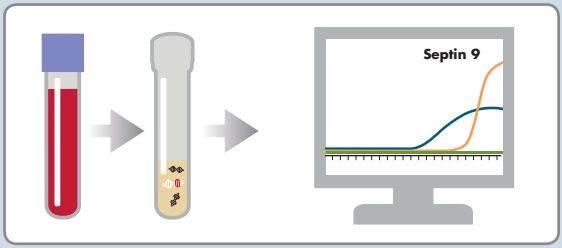
1 **Provider Patient Counseling**



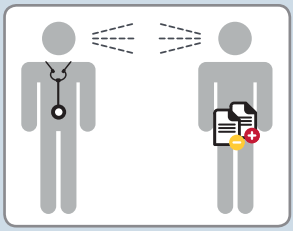
2 **Routine Blood Draw**



3 **Plasma-based testing for Real-Time PCR**



4 **Patient Management**



No pretest dietary or medication restrictions before blood draw.

Testing may take a few days to be completed.

Patients with positive results should be referred for diagnostic colonoscopy.

Clinical Trial Overview

Trial One[3]

The first study compared the accuracy of Epi proColon to colonoscopy in 1,544 samples from men and women, 50–85 years of age who were of average-risk for CRC.

Sensitivity (95% CI)	**Specificity** (95% CI)
68.2% (53.4–80.0)	80.0% (77.9–82.1)*

Negative Predictive Value (NPV) (95% CI)	**Positive Predictive Value (PPV)** (95% CI)
99.7% (99.6–99.8)	2.4% (2.0–3.0)

People Not Tested in the Study

- People considered at higher-risk for developing CRC.
- People with rectal bleeding, fresh blood in the stool, or with a known history of iron deficiency.

* Weighted to the Study One Population.

Trial Two[4]

The second study compared the accuracy of Epi proColon to a Fecal Immunochemical Test (FIT) using matched blood and stool samples from 290 people. Epi proColon was found to be statistically non-inferior to FIT with respect to sensitivity but not specificity.

Epi proColon (95% CI) (n=290)	
Sensitivity 72.2% (62.5–80.1) Specificity 80.8% (74.7–85.8)	NPV 99.8% (99.7–99.8) PPV 2.7% (2.0–3.7)

FIT (95% CI) (n=290)	
Sensitivity 68.0% (58.2–76.5) Specificity 97.4% (94.1–98.9)	NPV 99.8% (99.7–99.8) PPV 15.6% (7.2–30.8)

Both Tests

- Identified similar numbers of patients with CRC.
- Identified CRC in all cancer stages and throughout the colon and rectum.

NOTE: Assumes a prevalence of 0.7% based on Study One for Positive and Negative Predictive Values with 95% CI. Predictive values inform how likely disease is given the test result. PPV indicates how likely disease is given a positive test result. NPV indicates how likely absence of disease is given a negative test result.

Trial Three[5]

The third study compared participation in CRC screening between people who were offered either a stool test or a blood test. All people in the study had at least two screening recommendations in the past and were not up to date.

Epi proColon

- 203 people were offered the blood test for CRC screening and 202 completed it (99.5%).
- 30 people had a positive Epi proColon test result; of those, 10 out of the 17 people who completed a colonoscopy had a polyp or adenoma removed.

FIT

- 210 people were offered the stool test for CRC screening and 185 completed it (88.1%).
- 3 people had a positive FIT test result; of those, 1 completed a colonoscopy and had a polyp removed.

REFERENCES

1 United States Preventive Services Task Force (USPSTF). Screening for colorectal cancer recommendations statement. Oct 2008.

2 deVos T et al. Circulating methylated *SEPT9* DNA in plasma is a biomarker for colorectal cancer. Clin Chem. 2009, 55(7):1337-1346.

3 Potter N et. al. Validation of a Real-Time PCR-based qualitative assay for the detection of methylated *SEPT9* DNA in human plasma. Clin Chem. 2014, 60(9):1183-1191.

4 Johnson D et al. Plasma Septin9 versus fecal immunochemical testing for colorectal cancer screening: a prospective multicenter study. PLOS ONE. 2014, 9(6):1-8. E98238.

5 Epi proColon Instructions for Use (IFU 0008) and Epigenomics data on file, P130001.

How Do My Patients Benefit?

For your patients who have been counseled and offered but declined screening by recommended methods, Epi proColon® is another test choice that may be considered for CRC screening.

- Simple, routine blood test
- Methylated Septin 9 DNA is associated with colorectal cancer[2]
- Providing test choices and considering patient preferences have been cited as key factors that influence patient behavior

Using Epi proColon

- Your patient's blood sample may be drawn at your office laboratory or other local or US clinical laboratories as designated by your patient's healthcare plan.
- Epi proColon has been validated for use ONLY with the BD Vacutainer® K2EDTA blood collection tube.
- Epi proColon is not intended to replace colorectal cancer screening by colonoscopy, sigmoidoscopy or high-sensitivity fecal tests.

When CRC is detected early, cure may still be possible.

A good prognosis is more likely with early diagnosis.

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Intended Use

The Epi proColon test is a qualitative in vitro diagnostic test for the detection of methylated Septin 9 DNA in EDTA plasma derived from patient whole blood specimens. Methylation of the target DNA sequence in the promoter region of the SEPT9_v2 transcript has been associated with the occurrence of colorectal cancer (CRC). The test uses a real-time polymerase chain reaction (PCR) with a fluorescent hydrolysis probe for the methylation specific detection of the Septin 9 DNA target.

The Epi proColon test is indicated to screen adults of either sex, 50 years or older, defined as average risk for CRC, who have been offered and have a history of not completing CRC screening. Tests that are available and recommended in the USPSTF 2008 CRC screening guidelines should be offered and declined prior to offering the Epi proColon test. Patients with a positive Epi proColon test result should be referred for diagnostic colonoscopy. The Epi proColon test results should be used in combination with physician's assessment and individual risk factors in guiding patient management.

Contraindications

The Epi proColon test is not intended to replace colorectal cancer screening tests that are recommended by appropriate guidelines (e.g., 2008 USPSTF guidelines) such as colonoscopy, sigmoidoscopy and high sensitivity fecal occult blood testing.

The Epi proColon test is not intended for patients who are willing and able to undergo routine colorectal cancer screening tests that are recommended by appropriate guidelines.

The Epi proColon test is not intended for patients defined as having elevated risk for developing CRC based on previous history of colorectal polyps, CRC or related cancers, inflammatory bowel disease (IBD), chronic ulcerative colitis (CUC), Crohn's disease, familial adenomatous polyposis (FAP). People at higher risk also include those with a family history of CRC, particularly with two or more first degree relatives with CRC, or one or more first degree relative(s) less than 50 years of age with CRC.

The Epi proColon test has not been evaluated in patients who have been diagnosed with a relevant familial (hereditary) cancer syndrome, such as non-polyposis colorectal cancer (HNPCC or Lynch Syndrome), Peutz-Jeghers Syndrome, MYH-Associated Polyposis (MAP), Gardner's syndrome, Turcot's (or Crail's) syndrome, Cowden's syndrome, Juvenile Polyposis, Cronkhite-Canada syndrome, Neurofibromatosis, or Familial Hyperplastic Polyposis, or in patients with anorectal bleeding, hematochezia, or with known iron deficiency anemia.

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