A BLOOD TEST FOR COLORECTAL CANCER SCREENING

epi pro colon® 2.0 CE

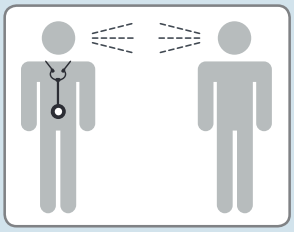
What is Epi proColon® 2.0 CE?

Epi proColon 2.0 CE is a blood test for colorectal cancer screening. The test detects methylated *SEPT9* DNA, a differential blood biomarker that is altered in colorectal cancer. Methylated *SEPT9* tumor DNA shed into the bloodstream is detectable by Real-Time PCR. The presence of methylated *SEPT9* in plasma is associated with and may aid in the detection of colorectal cancer (CRC).[1–3] Epi proColon 2.0 CE offers a non-invasive screening method to people who are unwilling to be screened by colonoscopy.

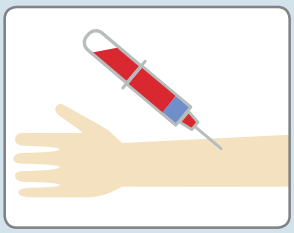
epigenomics
DETECTING CANCER IN BLOOD

How Do My Patients Get Tested?

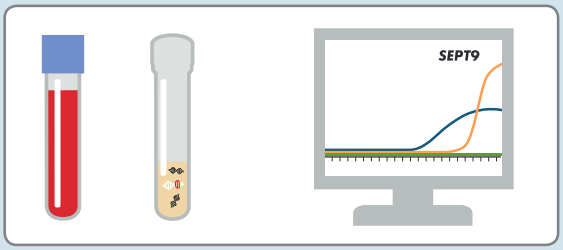
1 **Provider Patient Counseling**



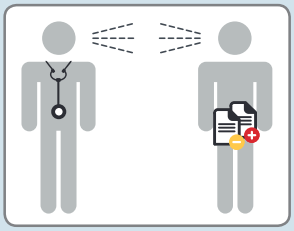
2 **Routine Blood Draw**



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.

How Do My Patients Benefit?

For your average-risk patients who have been counseled but do not complete CRC screening, Epi proColon® 2.0 CE is a simple test choice that may be considered for CRC screening.

- Simple, routine blood test.
- Methylated *SEPT9* DNA is associated with colorectal cancer.[1–3]
- Providing test choices and considering patient preferences have been cited as key factors that influence patient behavior.[5,6]

Using Epi proColon 2.0 CE

- Your patient's blood sample may be drawn at your office laboratory or diagnostic laboratory collection center.
- The following blood collection tubes have been validated with Epi proColon 2.0 CE for use: BD Vacutainer® 10 ml K2EDTA (Becton Dickinson), S-Monovette® 9 mL K3E (Sarstedt) and the S-Monovette® 8,5 mL CPDA tubes (Sarstedt).

Important Considerations

- Positive test results have been observed in patients diagnosed with chronic gastritis, esophagitis, and non-rheumatoid arthritis.[3]
- Positive test results were observed in clinically diagnosed patients with lung, breast and prostate cancers.
- Positive test results have been observed in pregnant women.[7]
- Test results should be interpreted by a healthcare professional.

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

A good prognosis is more likely with early diagnosis.

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Clinical Performance and Adherence Overview

Clinical Performance[3]

From an average-risk screening population, prospectively collected clinical samples from 149 patients with no evidence of disease (NED) were enrolled to evaluate the clinical performance of Epi proColon 2.0 CE. Additionally, in a case-control design, 197 clinical samples from 99 colonoscopy-verified negative NED patients and 98 histologically-confirmed colorectal carcinoma patients (all CRC stages) were collected and evaluated.

	Screening Cohort	Case-Control Cohort	CRC Cases
Valid Results	149	99	98
Epi proColon 2.0 CE Positive	1	3	79
Epi proColon 2.0 CE Negative	148	96	19
Specificity	99,3% (95,0% CI, 96,3–100,0)	96,9% (95,0% CI, 91,5–99,0)	N/A
Sensitivity	N/A	N/A	80,6% (95,0% CI, 71,7–87,2)
NPV*	99,9%	99,9%	N/A
PPV*	28,9%	11,9%	N/A

NPV and PPV were calculated with a presumed prevalence of 0,5% for CRC in the average-risk population

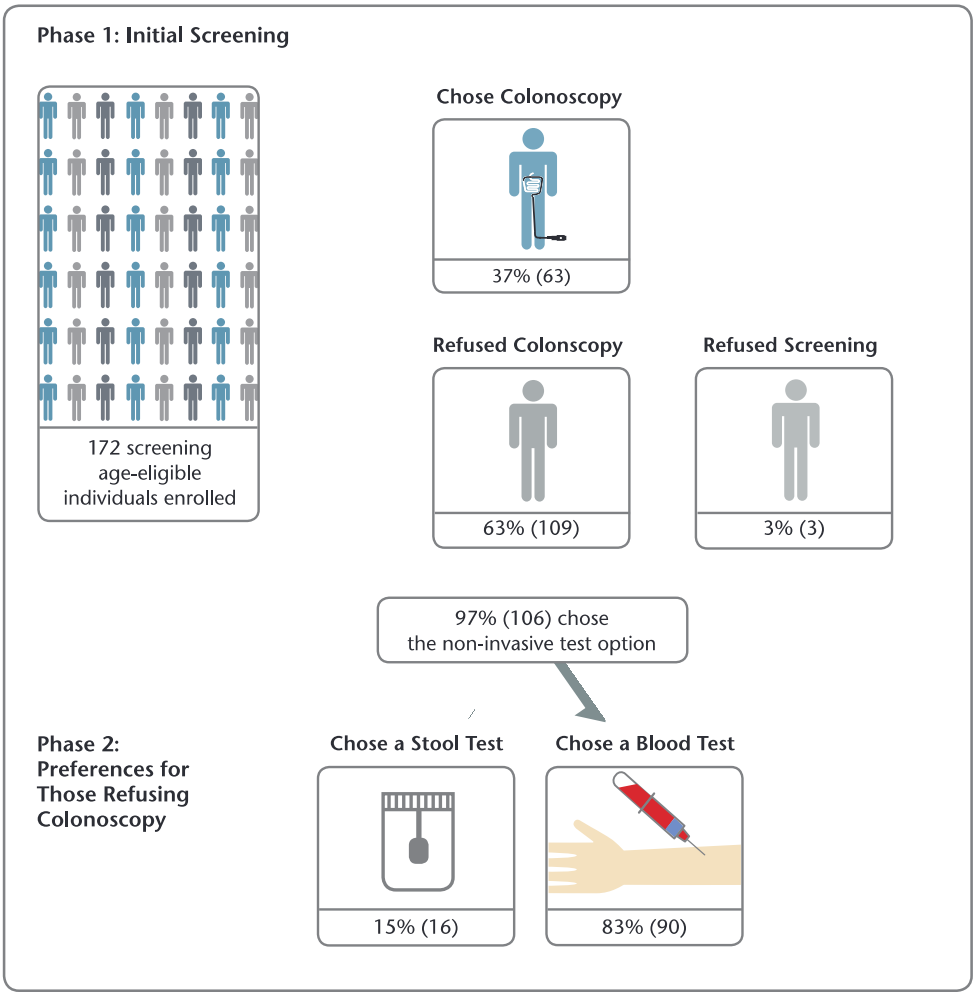
PPV (Positive Predictive Value) = percent probability that a person with a positive test result has CRC

NPV (Negative Predictive Value) = percent probability that a person with a negative test result does not have CRC

Adherence[4]

In a CRC screening adherence study, 172 people eligible for CRC screening were enrolled and advised to undergo screening by colonoscopy. People unwilling to be screened by colonoscopy were subsequently offered non-invasive blood and stool test options for screening. Of the 109 (63%) people refusing screening colonoscopy, 90 (83%) chose the blood test and 16 (15%), the stool test. This study highlights the importance of offering a non-invasive blood test alternative to increase the acceptance of CRC screening in non-adherent patients, Figure 1.

FIGURE 1: Adherence to CRC screening



More about Epi proColon 2.0 CE

The Epi proColon 2.0 CE test is a qualitative *in vitro* diagnostic test for the detection of methylated *SEPT9* DNA in EDTA plasma derived from patients 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 *SEPT9* DNA target.

The Epi proColon 2.0 CE test is indicated to screen adults of either sex, 50 years or older, defined as average risk for CRC. Patients with a positive Epi proColon 2.0 CE test result should be referred for diagnostic colonoscopy. The Epi proColon 2.0 CE test results should be used in combination with physician's assessment and individual risk factors in guiding patient management.

The Epi proColon 2.0 CE 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.

The Epi proColon 2.0 CE 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.

REFERENCES

1 deVos T et al. Circulating methylated *SEPT9* DNA in plasma is a biomarker for colorectal cancer. Clin Chem. 2009, 55(7):1337-1346.
2 Lofton-Day C et al. DNA methylation biomarkers for blood-based colorectal cancer screening. Clin Chem. 2008, 54(2):414-423.
3 Epi proColon 2.0 CE Instructions for Use (IFU 0009) and Epigenomics data on file.
4 Adler A et al. Improving compliance to colorectal cancer screening using blood and stool based tests in patients refusing screening colonoscopy in Germany. BMC Gastroenterol. 2014, 14:183.
5 Inadomi J et al. Adherence to colorectal cancer screening, a randomized clinical trial of competing strategies. Arch Intern Med. 2012, 172(7): 575-582. doi:10.1001/archinternmed.2012.332.
6 O'Farrell C et al. Physician-patient colorectal cancer screening discussions by physicians' screening rates. JABFM. 2013, 25(6)771-781. doi: 10.3122/jabfm.2012.06.110279
7 Warren J et al. Septin 9 methylated DNA is a sensitive and specific blood test for colorectal cancer. BMC Med. 2011, 133 (9):1-9.

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