FDA-Approved

epi pro colon®

Colon Cancer Screening Blood Test

Epi proColon is for the 1 in 3 people who remain unwilling or unable to be screened by other recommended methods.[1]

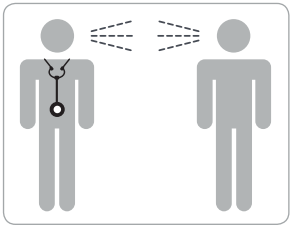
As a patient-accepted method of testing, a blood test for CRC screening can be easily integrated into your patient's annual wellness exam.

Rx Only

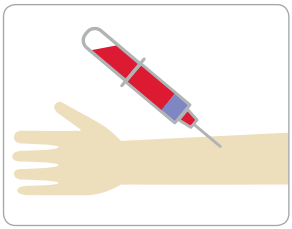
epigenomics
DETECTING CANCER IN BLOOD

How Do My Patients Get Tested?

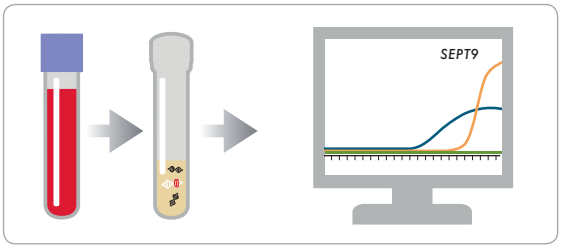
1 **Provider-Patient Discussion**



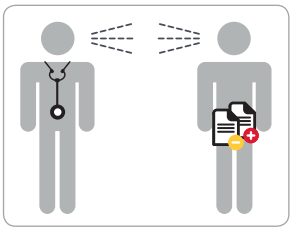
2 **Routine Blood Draw**



3 **Plasma-based Testing by 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.

Impact of CRC Screening Non-Adherence

37%

U.S. population non-adherent to any form of screening[1]

43%

New colorectal cancer cases attributed to the unscreened[2]

Ten-year NCQA data review, persons of screening age 50–75

76%

Percent of patients who died from colorectal cancer who were not up-to-date with screening.[3]

99.5%

Percent of twice-non-compliant patients who were offered and completed the Epi proColon blood test for CRC screening.[4]

* Higher rates have been shown in organized, navigated screening programs.

A blood test provides the best opportunity for an unscreened patient to participate in a screening program.

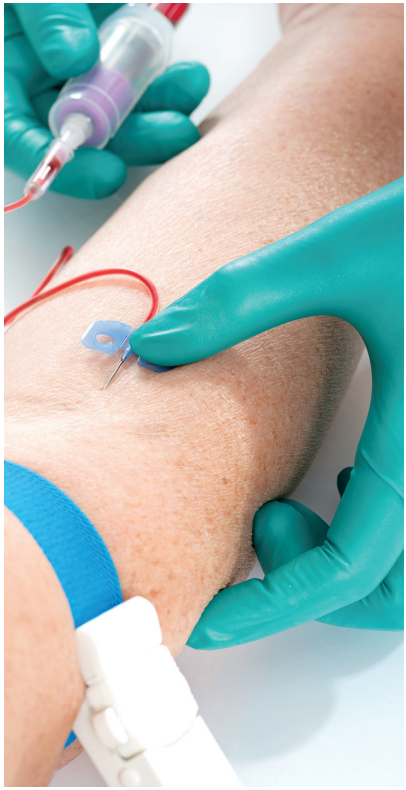
The best screening test is the one that your patient will complete.

FIND OUT MORE @ epiprocolon.com

Where Do My Patients Get Tested?

A routine blood draw may be performed at a regional or national clinical laboratory as designated by your patient's health plan.

- ARUP Laboratories (2013906)
- LabCorp (481160)
- Quest (16983)
- Sonic Healthcare Laboratories (X700)
- Sunrise Medical Laboratories (F693)



Important Coding Information

- CPT Code: 81327
- DEX Z Code™ Identifier: ZB2FC
- ICD-10-CM Diagnosis Codes: Z12.11, Z12.12, Z91.19

NOTE: Coverage is not guaranteed; Patients may incur out-of-pocket costs.

Clinical Trial Summary

Epi proColon vs Colonoscopy[5]

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.

Epi proColon vs FIT[6]

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.

Screening Participation in the Repeatedly Non-Adherent[4]

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

- 99.5% (202/203) of people offered the blood test, completed the test
- 30 people had a positive Epi proColon test result
- 59% (10/17) of people who completed a colonoscopy had a polyp or adenoma removed

FIT

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

Indications for 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.

REFERENCES

[1] American Cancer Society Colorectal Cancer Facts and Figures, 2017–2019. American Cancer Society, 2017.

[2] Kaur A et al. (2016) Recognizing diagnostic gap in colorectal cancer. Intern Med 6:3. DOI: org/10.4172/2165–8048.1000219

[3] Doubeni C et al. Modifiable failures in the colorectal cancer screening process and their association with risk of death. Gastro. 2019, 156:63–74.

[4] Liles E et al. (2017) Uptake of a colorectal cancer screening blood test is higher than of a fecal test offered in clinic: A randomized trial. Cancer Treatment and Research Communications 10:27–31.

[5] Potter N et al. (2014) Validation of a real-time PCR-based qualitative assay for the detection of methylated *SEPT9* DNA in human plasma. Clin Chem 60(9):1183–1191.

[6] Johnson D et al. (2014) Plasma Septin 9 versus fecal immunochemical testing for colorectal cancer screening: a prospective multicenter study. PLOS ONE 9(6) e98238.

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