PATIENT BROCHURE

epi pro colon®

Epi proColon® is an FDA-approved blood test for colorectal cancer screening. This test is intended for persons age 50 and older who are unwilling or unable to be screened by recommended methods.

Rx Only

What is Epi proColon? 2
What is Colorectal Cancer Screening? 2
Who Should Be Screened for Colorectal Cancer? 2
Colorectal Cancer Screening Tests 2
Is Epi proColon Right for You? 3
How Do You Get Tested? 3
How Accurate is Epi proColon? 4
What are the Benefits and Risks of Screening with Epi proColon? 6
Understanding Your Epi proColon Results 7
More About Risk Factors for Colorectal Cancer 7
Find Out More 8
References 8

epigenomics

Colorectal cancer is one of the most preventable and treatable cancers when it's found early.

What is Epi proColon®?

Epi proColon is a blood test for colorectal cancer screening that can be ordered by your doctor. The test is for people who are unwilling or unable to use screening tests recommended in the 2008 United States Preventive Services Task Force (USPSTF) guidelines.[1] About 7 out of 10 patients who have colorectal cancer have a positive Epi proColon test result. About 2 out of 10 people without cancer have a positive Epi proColon test result.

The Epi proColon test is performed by a clinical laboratory. It detects a specific type of DNA called Septin 9. Septin 9 DNA is altered in colorectal cancer tumor cells more often than in normal cells. The tumor cells release altered Septin 9 DNA into the bloodstream. The altered DNA can be detected in a blood sample. Altered Septin 9 DNA is often found in blood samples from people with colorectal cancer.[3,4]

What is Colorectal Cancer Screening?

Screening is looking for colorectal cancer before there are symptoms. Screening is necessary to find cancer early. When colorectal cancer is found early, successful treatment is more likely. About 9 out of 10 people will survive when it is found early.[2] There are different screening tests to choose from. You and your doctor can work together to find the test that works best for you.

Colorectal Cancer in the United States

- No. 3 cancer
- No. 3 cause of death from cancer
- Only 4 out of 10 people are diagnosed early before it has spread outside the colon

Who Should Be Screened for Colorectal Cancer?

Anyone can get colorectal cancer. Today, 1 out of 3 people are not screened. It is recommended that people of "average-risk" should start screening at age 50.[1] Average-risk means that there is about a 1 in 20 chance of getting colorectal cancer in your lifetime. This risk increases as you age. If you have risk factors for colorectal cancer, you should talk to your doctor about what screening plan is right for you. See page 7 to learn more about risk factors.

Colorectal Cancer Screening Tests

There are two types of screening tests recommended by the United States Preventive Services Task Force (USPSTF) guidelines.

- Invasive imaging tests that may find and prevent cancer.

  These include colonoscopy and flexible sigmoidoscopy. CT colonography is not included in these guidelines.

- Non-Invasive tests that may tell you about your risk for cancer.

  These include high-sensitivity stool tests that detect blood in stool. Stool DNA and blood tests are not included in these guidelines.

It might be hard to decide what test you should have. Before choosing, you should understand the benefits and risks for each test. Talk to your doctor about which test would be best for you.

Is Epi proColon Right for You?

You should talk with your doctor about recommended screening tests so that you can choose the test that is best for you. Recommended methods include colonoscopy and FIT stool tests.

This test might be an option for you if:

- You are age 50 or older
- You are considered average-risk for getting colorectal cancer*
- You are out-of-date with recommended screening tests
- You decline recommended screening tests after talking with your doctor

NOTE: If you are over age 75, you should talk with your doctor about whether getting screened is right for you.

This test is NOT an option for you if:

- You are less than age 50
- You are considered higher-risk for getting colorectal cancer*
- You are up-to-date with recommended screening
- You are willing and able to be screened with recommended screening tests

* More information about risks is found on page 7 of this brochure.

How Do You Get Tested with Epi proColon?

Your blood test can be ordered by your doctor during your routine office visit. Your blood can be drawn at your doctor's office or the blood collection center. You do not have to change your diet or medicine before getting your blood drawn.

What Do You Need To Do?

1. Make an appointment with your doctor to discuss colorectal cancer screening. If you both decide this test is right for you, your doctor will write a lab order for the test.
2. Get your blood drawn. It might take a few days for the laboratory to send your test result to your doctor.
3. Talk with your doctor about your test result.

If your test result is positive, your doctor will recommend a colonoscopy. If your test result is negative, discuss your future screening plan with your doctor.

How Accurate is Epi proColon?

Epi proColon finds cancer in about 7 out of 10 (70%) people with the disease. Epi proColon also has positive results in people who do not have cancer. These are called false-positive results. Positive results were found in about 2 out of 10 (20%) people who do not have cancer.

Epi proColon was studied for accuracy in three studies:

Study One[5]

The first study compared Epi proColon to colonoscopy. The study included 1,544 men and women, age 50 to 85 years who were average-risk for colorectal cancer. The study was conducted at 32 sites in the United States and Germany.

Epi proColon Sensitivity = 68.2%	Epi proColon False-Positive Rate = 20.0%	Negative Predictive Value (NPV) = 99.7%	Positive Predictive Value (PPV) = 2.4%
This means that the blood test was positive in about 7 out of 10 people with colorectal cancer.	**This means that the blood test was positive in about 2 out of 10 people who did not have colorectal cancer.**	**This means that a person with a negative result has a very low chance of having colorectal cancer.**	**This means a person with a positive test has a 2.4% chance of having colorectal cancer.**

People Not Tested in Study One

- **People at higher-risk for colorectal cancer**
- **People with rectal bleeding or fresh blood in the stool**
- **People with a known history of iron deficiency**

Person with a positive result; Person with a positive result with colorectal cancer
PPV = percent chance that a person with a positive test result has colorectal cancer
NPV = percent chance that a person with a negative test result does not have colorectal cancer

Study Two[6]

The second study compared Epi proColon to a Fecal Immunochemical Test (FIT) at 61 sites in the United States. This study included 290 people. Each person gave a blood and stool sample for testing. In this study, both tests found colorectal cancer at all cancer stages. Also, both tests found cancer in different places throughout the colon and rectum.

Epi proColon Test

Epi proColon Sensitivity = 72.2%	Epi proColon False-Positive Rate = 19.2%	Negative Predictive Value (NPV) = 99.8%	Positive Predictive Value (PPV) = 2.7%
This means that the blood test was positive in about 7 out of 10 people with colorectal cancer.	This means that the blood test was positive in about 2 out of 10 people who did not have colorectal cancer.	This means that a person with a negative result has a very low chance of having colorectal cancer.	This means a person with a positive test has a 2.7% chance of having colorectal cancer.

FIT Stool Test

FIT Sensitivity = 68.0%	FIT False-Positive Rate = 2.6%	Negative Predictive Value (NPV) = 99.8%	Positive Predictive Value (PPV) = 15.6%
This means that the stool test was positive in about 7 out of 10 people with colorectal cancer.	This means that the stool test was positive in less than 1 out of 10 people who did not have colorectal cancer.	This means that a person with a negative result has a very low chance of having colorectal cancer.	This means a person with a positive test has a 15.6% chance of having colorectal cancer.

Person with a positive result; Person with a positive result with colorectal cancer
PPV = percent chance that a person with a positive test result has colorectal cancer
NPV = percent chance that a person with a negative test result does not have colorectal cancer

NOTE: In Study One, the chance of having colorectal cancer was found to be about 0.7%. This number was used in the formula for NPV and PPV for Study Two.

Study Three[3]

The third study compared the number of people that would take a blood or stool test for colorectal cancer screening. The study included 413 people at two health sites. All people in the study had been offered screening at least two times in the past and were not up-to-date.

Epi proColon	FIT
• 203 people were offered the blood test. 202 completed it (99.5%). • 30 people had a positive result. Of those, 17 had a colonoscopy and 10 of those had a polyp or adenoma removed.	• 210 people were offered the stool test for colorectal cancer screening. 185 completed it (88.1%). • 3 people had a positive test result. Of those, 1 had a colonoscopy and had a polyp removed.

NOTE: More information about these studies can be found at ClinicalTrials.gov. Details for Study One (NCT00855348), Study Two (NCT01580540) and Study Three (NCT02251782) may be found by looking up these study numbers.

What are the Benefits and Risks of Screening with Epi proColon?

Benefits

Getting screened for colorectal cancer is important. When colorectal cancer is found early, cure is more likely.[2] If you are not up-to-date and unwilling or unable to be screened by recommended tests, Epi proColon may be an option for you.

- Epi proColon is a blood test ordered by your doctor
- Your blood may be drawn at your doctor's office or a blood collection center
- No changes in diet or medicine are needed before your blood draw

Risks

- Epi proColon is not intended to replace colorectal screening tests that are recommended by 2008 USPSTF guidelines. These tests include colonoscopy, sigmoidoscopy and high-sensitivity stool blood tests.
- Epi proColon was positive more times in people without colorectal cancer (false-positives) than a stool test (OC-Auto® Polymedco, Inc.). Both tests were positive equally in people who had colorectal cancer.
- If your Epi proColon test is negative, you should talk with your doctor about what screening tests you should do for the next year and the years thereafter. If after talking with your doctor you still decline recommended tests, Epi proColon is an option for you.
- In clinical trials, the Epi proColon test was given to people only one time. It was not given to people who had been tested with Epi proColon before. It is not known how well the test will perform when used more than one time over a period of years.
- The chance of having a false-positive test result goes up with age. You should talk to your doctor about what a false-positive result might mean for you.
- Positive test results have been found in healthy people. Positive results have also been found in people who have chronic gastritis or lung cancer, and also in pregnant women.[3,7]

Understanding Your Epi proColon Test Results

What does a Positive Epi proColon blood test result mean?

- A positive blood test means that altered Septin 9 DNA has been found in your blood sample.
- A positive blood test result indicates an increased chance that you may have colorectal cancer. However, it does not mean that you have colorectal cancer.
- You should discuss your test result with your doctor. Your doctor should order a colonoscopy to find out if you have colorectal cancer.

What does a Negative Epi proColon blood test result mean?

- A negative blood test result means that altered Septin 9 DNA was not found in your blood sample.
- A negative test result indicates a decreased chance that you have colorectal cancer.
- Some people with colorectal cancer may have negative test results. Studies show that altered Septin 9 DNA is not found in the blood of every person with colorectal cancer.[3]
- Even if you have a negative result, you should continue to get screened for colorectal cancer on a regular basis. Talk with your doctor about your personal health history. You should consider getting a colonoscopy, sigmoidoscopy, or high-sensitivity stool blood test at your next screening.

More About Risk Factors for Colorectal Cancer

A risk factor is anything that increases your chance for getting cancer. Your personal risk factors like family history, lifestyle and ethnicity will determine when you should start screening.[1]

What are Personal Risk Factors?

- You or a close member of your family (parent, sibling, child) has had colorectal cancer. Your risk is higher when two or more family members have had colorectal cancer. It is also higher if one or more of your family members has colorectal cancer and is less than age 50.
- You have a history of benign polyps in the colon or rectum or related cancers, or have other bowel disease like inflammatory bowel disease (IBD), chronic ulcerative colitis (CUC), or Crohn's disease.
- You have inherited diseases like Lynch syndrome (hereditary non-polyposis colorectal cancer) or FAP (familial adenomatous polyposis).
- You have other inherited diseases include 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.

epi pro colon®

Find Out More

To learn more about Epigenomics and our products, please visit **epiprocolon.com**, and select the **"Q & A"** tab where you will find answers to commonly asked questions about the Epi proColon test. Please contact us in any of the other following ways:

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