Shield™ Colorectal Cancer Screening Blood Test Fact Sheet for Patients

This Fact Sheet contains information to help you understand the Shield test for colorectal cancer screening. Please speak with your healthcare provider If you have additional questions after reading this Fact Sheet.

What is the Intended Use / Indications for Use of Shield?

The Shield test is a qualitative, in vitro diagnostic test intended to detect colorectal cancer derived alterations in cell-free DNA from blood collected in the Guardant Shield Blood Collection Kit. Shield is indicated for colorectal cancer screening in individuals at average risk for the disease, age 45 years or older. Patients with a positive result should be followed by colonoscopy. Shield is not a replacement for diagnostic colonoscopy or for surveillance colonoscopy of high-risk individuals. This test is performed at Guardant Health, Inc.

Precaution

Based on data from clinical studies, Shield has limited detection (55%-65%) of Stage I colorectal cancer and does not detect 87% of precancerous lesions. One out of 10 patients with a negative Shield result may have a precancer that would have been detected by a screening colonoscopy. Shield demonstrated high detection of Stage II, III, and IV colorectal cancer.

What is colorectal cancer?

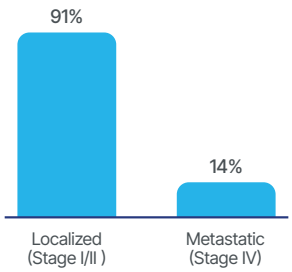
Colorectal cancer is a type of cancer that develops in the colon or rectum. CRC is the second-leading cause of cancer-related death in the United States (US).

Screening for colorectal cancer in healthy individuals age 45 years or older, who do not have any symptoms of colorectal cancer and are not at high risk for colorectal cancer is recommended by multiple healthcare organizations including the US Preventive Services Task Force (USPSTF) and the American Cancer Society (ACS). The goal of screening is to reduce deaths from colorectal cancer through early detection and treatment.

Why is colorectal cancer screening important?

CRC is the second leading cause of cancer related death for both men and women in the United States.[1] CRC survival rates dramatically increase when the disease is detected early, when there are often no clinical symptoms of colorectal cancer. The 5-year relative survival rate is 91% in those with early, localized disease (Stage I or II), dropping to 14% in those with metastatic disease (Stage IV).2 (Figure 1)

Figure 1. 5-year Relative Survival



What is the Shield test and is it right for you?

Shield is a blood-based colorectal cancer screening test that can detect fragments of colorectal tumor DNA that are released, or shed, into the blood. DNA shedding is a normal process that happens as a tumor grows. By determining if signals from these DNA fragments are present in a blood sample, Shield can screen for colorectal cancer.

Shield is intended as a screening test for individuals at average risk and not intended for individuals at high risk for colorectal cancer.

'Average-risk' in the context of colorectal cancer screening are those individuals who do not have symptoms of colorectal cancer and do not have increased risk factors for developing colorectal cancer, such as:

- Prior diagnosis of colorectal cancer or inflammatory bowel disease;
- Family history of colorectal cancer in a parent, brother, sister, or child;
- An inherited risk to develop colorectal cancer , for example Lynch Syndrome or Familial Adenomatous Polyposis (these are rare inherited conditions)

Shield is not indicated in individuals who have a positive result on another colorectal cancer screening method within the last six months, or completed a fecal occult blood test (FOBT) or fecal immunochemical test (FIT) within the last 12 months, or FIT-DNA Test within the last 36 months

In a large clinical study, Shield accurately detected colorectal cancer in 54 of 65 individuals. This means Shield has a colorectal cancer sensitivity of 83% (54 of out 65; Figure 2A).

Shield did a better job identifying Stage II, III, and IV colorectal cancer (approximately 100% of individuals with these cancers were correctly identified) than Stage I colorectal cancer (55%-65% of individuals with these cancers were correctly identified; Figure 2A).

Shield has a 90% specificity for advanced neoplasia (AN), which means that one out of 10 people who do not have Advanced Neoplasia (colorectal cancer or advanced adenoma) will have a false positive test result (Figure 2B).

Shield has limited ability to detect precancer (i.e., pre-cancerous lesions that have the potential to develop into colorectal cancer called advanced adenomas). This impacts the opportunity to prevent the development of colorectal cancer. Only a colonoscopy can confirm the presence of colorectal cancer or precancer and prevent colorectal cancer development.

- In the same clinical study, Shield accurately detected 147 of the 1,116 people with advanced adenoma (precancer). This means Shield has an advanced adenoma sensitivity of 13% (Figure 2B).

Shield is not a replacement for diagnostic colonoscopy or for surveillance colonoscopy in high-risk individuals.

Figure 2A.
Shield CRC Sensitivity

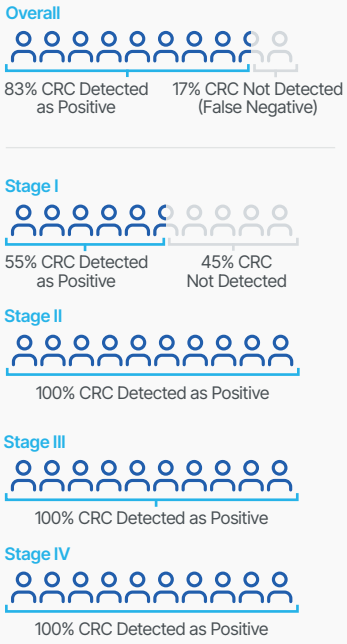
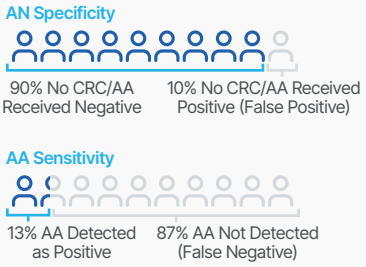


Figure 2B.
Shield AN Specificity and AA Sensitivity



How is the Shield test completed?

Your healthcare provider will draw up to 4 tubes of blood, about 3 tablespoons, using the Guardant Shield Blood Collection Kit. There is no special preparation needed prior to your blood sample collection.

Your blood sample will be sent to the Guardant Health Clinical Laboratory for testing.

Once your testing is completed, you and your healthcare provider will receive the Shield test results which will be "positive" or "negative".

What does a "positive" result mean?

This result does not mean you have colorectal cancer but raises concern that colorectal cancer or precancer could be present. Additional follow-up is needed.

- You should discuss these results with your healthcare provider who will recommend a colonoscopy to determine if colorectal cancer is present.

Shield has a false positive rate of 10%. This means that of 10 people who do NOT have colorectal cancer or advance adenoma, one of them will incorrectly receive a "positive" result.

What does a "negative" result mean?

A "negative" result indicates a signal associated with colorectal cancer was not detected.

- A "negative" Shield result does not guarantee that colorectal cancer is not present. Patients who receive a "negative" result should continue participating in colorectal cancer screening programs.

Shield has a colorectal cancer false negative rate of 17%. This means out of 100 people who have CRC, 17 of them will incorrectly receive a Shield result of "negative". While Shield accurately detected 100% of Stage II, III, and IV colorectal cancer, it failed to detect up to 45% of Stage I colorectal cancer.

Shield has an advanced adenoma false negative rate of 87%. This means that out of 100 people who have precancer, 87 of them will incorrectly receive a Shield result of "negative".

What should I know about colorectal cancer screening tests?

There are several colorectal cancer screening tests available today. No colorectal cancer screening test is perfect. Each test has different sensitivity (the tests ability to accurately identify those individuals with the disease) for colorectal cancer or precancer and specificity (the tests ability to accurately identify those individuals who do not have the disease). Evaluation of all appropriate screening options should be part of every colorectal cancer screening discussion.

How can I learn more?

- Talk to your healthcare provider
- Visit Patient FAQs at www.ShieldCancerScreen.com

Talk to your healthcare provider about the benefits and risks of screening for colorectal cancer with Shield

References

1. Siegel RL, Wagle NS, et al. Colorectal Cancer Statistics, 2023. CA Cancer J Clin. 2023;73(3):233-254.

2. Siegel RL, Gianquinto AN, et al. Cancer Statistics, 2024. CA Cancer J Clin. 2024;74(1):12-49.

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