



BLOOD TEST TO DETECT COLORECTAL CANCER

In the United States, colorectal cancer (CRC) is the third most common cancer in men and women. Fortunately, it is also one of the most preventable types of cancer because we can detect and remove precancerous growths (called “polyps”) during a colonoscopy. The American Cancer Society estimates that in 2025, over 150,000 people will be diagnosed with CRC, and approximately 53,000 will die from the disease. Screening could prevent more than 90% of CRC-related deaths but 65% of eligible Americans have not had CRC screening. Until now, doctors have mostly performed CRC screening in one of two ways: colonoscopy and stool-based tests.

What's new?

In July 2024, the U.S. Food and Drug Administration (FDA) approved a new blood-based test for CRC screening. The FDA approved Guardant Health's Shield™ blood test for CRC screening in average risk adults aged 45 and older. The test detects DNA fragments which CRC cells and precancerous polyps can shed into the blood. Like all stool tests, if the Shield™ test returns a positive result, a **colonoscopy** is required to confirm the presence of CRC or precancerous polyps.

What's the evidence?

The approval of Shield™ test was based on a study of nearly 8,000 men and women aged 45 and older from across the U.S. The test correctly identified 83% of all patients with CRC (all stages). The accuracy was only 55% for patients with early stage 1, curable CRC. This means that a one-time Shield test may fail to detect 1 in 3 early-stage cancers and 1 in 6 total cancers. By comparison, studies have estimated that colonoscopy detects over 95% of colorectal cancers. The Shield test detected only 13.2% of patients with worrisome precancerous polyps, which is no better than chance.

Who could take this test?

This blood test is intended for asymptomatic, individuals aged 45 or older who are at average risk of CRC. It is not to be used in individuals at increased risk of CRC such as those with a personal or family history of CRC or precancerous polyps, Crohn's disease, colitis, or certain hereditary cancer syndromes.

What's the difference between a blood test vs. a colonoscopy?

Detection versus prevention. Blood tests are unable to detect precancerous polyps to any significant degree and are not a replacement for colonoscopy. A positive blood test must be followed by colonoscopy (a 2-step process). On the other hand, colonoscopy (a 1-step process) not only can detect cancer but also can remove precancerous polyps, and, therefore, can prevent CRC. Colonoscopy for screening is recommended every 10 years for average risk individuals.

What do the Test results mean?

A positive Shield™ test result indicates the possibility of colon or rectal cancer or advanced precancerous polyps, and you should proceed with a colonoscopy. It's important to remember that false positives and negatives of CRC can occur. Patients with negative results should expect to repeat the blood test in 3 years or could consider switching to colonoscopy for screening at that time.

What are the benefits of the test?

Some patients may be reluctant to do a stool test or colonoscopy due to inconvenience, preparation requirements, or concerns about the risks of procedure. Blood tests may increase screening rates by offering an alternative test leading to higher number of people getting screened.

Is this test covered by insurance?

The Shield™ test is covered every three years for eligible Medicare beneficiaries. Coverage varies by private insurance plans, so **contact your insurance provider** or healthcare team to confirm.

Recommendations:

Blood based CRC screening should be reserved for patients who are unwilling to undergo colonoscopy as a first test or a stool-based screening test. Patients must be willing to undergo colonoscopy if the blood test is positive.

The American College of Gastroenterology (ACG) and Multi-Society Task Force (MSTF) currently recommend colonoscopy every 10 years or annual FIT testing for CRC in average risk individuals starting at age 45.

TALK TO YOUR HEALTHCARE PROVIDER TODAY ABOUT
WHICH SCREENING TEST FOR COLORECTAL CANCER IS RIGHT FOR YOU!

References: *N Engl J Med.* 2024 Mar 14;390(11):973-983 | *Am J Gastroenterol.* 2022 Jan 1;117(1):57-69. | *Am J Gastroenterol.* 2021 Mar 1;116(3):458-479.

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