US FDA approves new blood test for detecting colon cancer

The US FDA has approved a new blood test, Shield, for detecting colorectal cancer, offering a significant advancement in early cancer screening.

The Shield blood test results from over 10 years of research and development.

In Short

- Shield is the first FDA-approved blood test for primary colon cancer screening
- Clinical studies showed Shield detected colon cancer in 83% of average-risk individuals
- However, it limitations in detecting Stage I cancer and precancerous lesions

The US Food and Drug Administration (FDA) has approved a blood test that can help detect colorectal or colon cancer. This expands options for screening one of the most deadly diseases affecting younger populations worldwide.

The blood test is called Shield, manufactured by the pharmaceutical company Guardant Health, Inc. The approval by FDA follows the promising results from a clinical study earlier this year, published in the New England Journal of Medicine in March.

The study found that the test correctly detected colon cancer in 83% of people confirmed to have the disease. These participants were at average risk and did not experience any symptoms. The Shield blood test results from over 10 years of research and development.

"The FDA approval of the Shield test is a significant victory for patients and an important milestone in Guardant Health's mission to conquer cancer with data," Guardant Health co-CEO AmirAli Talasaz said in a news release.

"Shield can help improve colorectal cancer screening rates so we can detect more cancers at an early stage, when they are treatable," Talasaz added.

As per the official statement, Shield is the first blood test to be approved by the FDA as a primary screening option for colon cancer, meaning healthcare providers can offer Shield in a manner similar to all other non-invasive methods recommended in screening guidelines.

The study found that the test correctly detected colon cancer in 83% of people confirmed to have the disease.

"The persistent gap in colorectal cancer screening rates shows that the existing screening options do not appeal to millions of people. The FDA's approval of the Shield blood test marks a tremendous leap forward, offering a compelling new solution to close this gap," said Daniel Chung, MD, gastroenterologist at Massachusetts General Hospital and Professor of Medicine at Harvard Medical School.

The test uses blood collected in the Guardant Shield Blood Collection Kit, for individuals 45 years of age or older.

Patients with positive test results should have a colonoscopy since the test is not a replacement for diagnostic colonoscopy or for surveillance colonoscopy in high-risk individuals.

However, Shield has limited detection (55%-65%) of Stage I colorectal cancer and does not detect 87% of precancerous lesions.

John Gormly, a 77-year-old business executive in Newport Beach, California, US, used the Shield blood test and found his test positive. "A few days later the result came back positive, so [the doctor] referred me for a colonoscopy. It turned out I had stage II colon cancer. The tumor was removed, and I recovered very quickly. Thank God I had taken that blood test," he said.

News Source:

https://www.indiatoday.in/health/story/us-fda-approves-new-blood-test-for-detecting-colon-cancer-2574290-2024-07-31