

A blood test for colon cancer performed well in a study, expanding options for screening

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This image provided by Guardant Health in March 2024, shows packaging for their colon cancer blood test, Shield. According to a study published Wednesday, March 13, 2024, in the *New England Journal of Medicine* and sponsored by Guardant Health, the test performed well, further expanding screening options for a leading cause of cancer deaths. The test missed some cancers and won't replace colonoscopy, the gold standard test. Credit: Guardant Health via AP



A blood test for colon cancer performed well in a study published Wednesday, offering a new kind of screening for a leading cause of cancer deaths.

The test looks for DNA fragments shed by tumor cells and precancerous growths. It's already for sale in the U.S. for \$895, but has not been approved by the Food and Drug Administration and most insurers do not cover it. The maker of the test, Guardant Health, anticipates an FDA decision this year.

In the study, the test caught 83% of the cancers but very few of the precancerous growths found by <u>colonoscopy</u>, the gold standard for <u>colon</u> <u>cancer screening</u>. Besides spotting tumors, colonoscopies can prevent the disease by removing precancerous growths called polyps.

But some people avoid the exam because of the hassle of getting time off work or the day-ahead preparation that involves drinking a strong laxative to empty the bowels.

A convenient alternative is an annual stool test, where people send a stool sample to a lab for analysis.

"The best test is the one someone will actually complete," said Dr. Douglas Corley, chief research officer for Kaiser Permanente, Northern California, who was not involved in the study. "Giving people a choice increases the number of people who will get screened."

In the U.S., screening is recommended for <u>healthy adults</u> ages 45 to 75 at average risk for <u>colon cancer</u>. Frequency depends on the test: a routine colonoscopy is every 10 years. Screening is inching up but falls well short of the 80% of age-eligible adults goal set by the American Cancer Society and other groups.



Guardant recommends testing with its blood test called Shield every three years. Like a stool test, the blood test requires a follow-up colonoscopy if there's an abnormal result, which could lead to more outof-pocket costs.

The study, sponsored by Guardant and published in the *New England Journal of Medicine*, involved 7,861 people in the U.S. who had both a colonoscopy and a blood test.



This image provided by Guardant Health in March 13, 2024, shows a vial for their colon cancer blood test, Shield. According to a study published Wednesday, March 13, 2024, in the *New England Journal of Medicine* and sponsored by Guardant Health, the test performed well, further expanding screening options for a leading cause of cancer deaths. The test missed some cancers and won't replace colonoscopy, the gold standard test. Credit: Guardant Health via AP



While the blood test caught 83% of the cancers found by colonoscopy, it missed 17%. That's on par with stool-based tests.

There were also <u>false alarms</u>: For 10% of the people where the colonoscopy found nothing, the blood test falsely indicated they might have colon cancer. That means a sizeable number of people would face the anxiety of follow-up colonoscopies.

The blood test is tuned to pick up the signature of colon cancer but more research is needed to determine if it might pick up other cancers as well and give misleading results, Corley said.

<u>Colorectal cancer</u> is the second leading cause of cancer deaths in the United States and the third worldwide. In the U.S., more than 153,000 new cases and 53,000 deaths from the disease are expected this year.

More screening should result in fewer cancer deaths, said study coauthor Dr. William Grady of the Fred Hutchinson Cancer Center in Seattle and a paid member of Guardant's scientific advisory board.

In a separate study published Wednesday in the same journal, an updated version of the Cologuard stool test, which also looks for DNA fragments, seemed to improve its performance on false alarms, possibly leading to fewer follow-up colonoscopies. That study, involving more than 20,000 people, was sponsored by Exact Sciences, maker of the test.

"The more options we have for our patients, the better," said Dr. Nabil Mansour of Baylor College of Medicine, who was not involved in either study. He'll continue to recommend a colonoscopy for his patients but "I'm excited there will be a pretty good <u>blood test</u> option available."



More information: A Cell-free DNA Blood-Based Test for Colorectal Cancer Screening, *New England Journal of Medicine* (2024). DOI: <u>10.1056/NEJMoa2304714</u>

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