# FDA approves second blood test to help close colorectal cancer screening gap

- **Despite colorectal cancer being one of the most preventable and treatable cancers when detected early through routine screening, millions of eligible Americans remain overdue for screening.**
- **Existing screening methods, such as colonoscopy and stool-based tests, are highly effective, but many people avoid them because of preparation difficulties, discomfort, embarrassment, inconvenience, or fear of the results.**
- **The FDA approval of Freenome's SimpleScreen CRC blood test provides a new screening option for average-risk adults, complementing current options.**
- **In clinical studies, the test detected roughly 8 in 10 colorectal cancers.**

At present, colorectal cancer is the second leadingTrusted Source cause of cancer-related deaths worldwide, and early-onset colorectal cancer is the leading causeTrusted Source of cancer-related death among males and females under age 50.

Current colorectal cancer screening guidelinesTrusted Source advise that average-risk adults ages 45 years and older should undergo regular screening. However, despite this recommendation and colorectal cancer being one of the most preventable cancers through screening, an estimated 60 million eligible individuals in the U.S. do not participate.

For many years, experts have considered colonoscopies as the gold standardTrusted Source for colorectal cancer screening. Stool-based tests have also become increasingly popular because they can be completed at home. Yet, many eligible adults are reluctant to undergo screening.

People may consider screening a taboo or stigmatized topic. Potential barriers may include preparation, fear, discomfort, embarrassment, taking time off work, limited access to healthcare, cost concerns, lack of awareness of screening recommendations, and a tendency to delay preventive care when no symptoms are present.

Recognizing that no single screening method appeals to everyone, researchers have developed blood-based screening tests designed to make colorectal cancer screening more convenient. In 2024, the U.S. Food and Drug Administration (FDA) approved the Shield blood testTrusted Source. In July 2026, the FDA also approved Freenome's SimpleScreen colorectal cancer blood-based screening test.

In the large PREEMPT CRC clinical studyTrusted Source, which involved more than 48,000 participants, the SimpleScreen blood test correctly identified roughly 8 out of 10 colorectal cancers and produced negative results for about 9 out of 10 people without colorectal cancer or advanced precancerous lesions.

The approval offers another screening option, which some people may find significantly less intimidating than scheduling a colonoscopy or completing a stool test at home. This convenience may encourage previously unscreened people to participate, potentially leading to more cancers being detected earlier, when treatment is most effective.

*Medical News Today* spoke with Paul Limburg, MD, MPH, Chief Screening Medical Officer, Screening, Abbott Cancer Diagnostics, about how blood-based colorectal cancer screening works and compares to other options, if it can help close the screening gap, and how it fits into routine cancer screening.

**How does this new blood test compare with colonoscopies and stool-based screening tests such as Cologuard?**

"Colorectal cancer (CRC) screening is not one-size-fits-all, and different patients have different preferences. The current American Cancer Society guideline identifies stool-based testing, including the Cologuard Plus test, and visual examinations such as colonoscopy as preferred screening options," Limburg told *Medical News Today*.

Earlier research found that most people prefer stool-based screening to colonoscopy. However, more recent evidence suggests that many would generally prefer blood-based screening tests over other options, which may help to improve CRC screening uptake, particularly among those who are unscreened or overdue for screening.

"Ultimately, screening decisions should be made between patients and their healthcare providers based on each individual's circumstances and preferences," Limburg added.

A healthcare professional's recommendation plays a vital role in screening. Framing CRC screening as a routine, effective, and manageable preventive health measure and emphasizing that the best screening test is the one they are willing and able to complete can help increase screening uptake.

**How does this blood test actually detect signs of colorectal cancer?**

"SimpleScreen CRC is a blood-based screening test that detects signals associated with CRC," Limburg said.

After a simple blood draw, the sample is sent to a laboratory, where it is tested for specific DNA changes that may indicate the presence of cancer or precancerous cells.

In particular, the SimpleScreen test detects patterns of cytosine-phosphate-guanine (CpG) methylation. These changes often occur early in cancer development, making them useful biomarkers for cancer screening.

"Results are generally available within approximately two weeks and are shared with the ordering healthcare provider, who can review the findings and discuss appropriate next steps. To complete the screening process, a positive result requires a follow-up colonoscopy," Limburg explained.

**With nearly 60 million eligible Americans remaining unscreened, what are the biggest barriers preventing people from doing so?**

"No single screening option will reach every patient, which is why offering multiple evidence-based screening options is important," Limburg emphasized.

Research indicates that blood-based screening tests are a promising method that may help to improve CRC screening.

Organizations such as the American Gastroenterological Association (AGA) and the American Society for Gastrointestinal Endoscopy (ASGE) both acknowledge that blood tests could help to increase participation, particularly among those who decline other screening methods.

However, both organizations conclude that, although blood tests are better than no screening, current blood-based tests are less effective than established screening options and should generally be reserved for individuals who are otherwise unwilling to undergo recommended screening with colonoscopy or stool-based tests.

"With the addition of the SimpleScreen CRC test, healthcare providers have another option for eligible patients who may decline or not complete a guideline-preferred screening test, creating more opportunities to engage people who otherwise might not get screened," Limburg said.

**How should patients decide between a blood test, a stool test, and a colonoscopy?**

"Screening decisions should be made between patients and their healthcare providers," Limburg reiterated.

"The current American Cancer Society guideline identifies stool-based testing and colonoscopy as preferred screening options. Blood-based screening tests are recommended for individuals who decline or have not completed a preferred screening option."

Research suggests that most participants are willing to complete CRC blood screening tests, particularly if the test is free or covered by health insurance. Similarly, a real-world study suggests that adherence to blood-based screening could reach 95%.

"Ultimately, the most appropriate screening approach depends on each patient's individual circumstances and should be determined in partnership with their healthcare provider," Limburg accentuated.

**Do you expect blood-based screening to become a more common option for colorectal cancer prevention?**

"The American Cancer Society recently updated its colorectal cancer screening guideline for average-risk individuals to include blood-based screening tests for individuals who decline or do not complete a preferred screening option," Limburg said.

At present, research reflects that blood-based screening is likely to improve participation rates, but remains a less effective option. Still, it offers another option for healthcare professionals to provide for individuals who are unwilling to undergo other screening modalities.

"CRC screening is not one-size-fits-all, and expanding choice gives healthcare providers additional opportunities for informed decision-making with patients and to identify the highest-performing option that allows more people to complete screening," Limburg concluded.

## News Source:

https://www.medicalnewstoday.com/articles/fda-approves-second-blood-test-help-close-colorectal-cancer-screening-gap#7