

Abbott Launches SimpleScreen™ CRC Blood Test, Joining Cologuard Plus® In Its Colorectal Cancer Screening Portfolio

- Only Abbott offers a complete screening solution combining end-to-end support with both stool- and blood-based colorectal cancer screening options, giving healthcare providers more ways to help eligible patients get screened¹⁻³
- SimpleScreen CRC expands screening options for adults age 45 and older, providing another way to help reach people who otherwise may remain unscreened
- SimpleScreen CRC is covered by Medicare, with no out-of-pocket costs for eligible patients with Medicare Part B

ABBOTT PARK, Ill., Sept. 30, 2026 /PRNewswire/ -- Abbott (NYSE: ABT) today announced the U.S. commercial launch of SimpleScreen™ CRC, an FDA-approved blood-based colorectal cancer (CRC) screening test for adults age 45 and older who are at average risk for the disease. Developed and manufactured by Freenome and exclusively commercialized by Abbott, SimpleScreen CRC joins the Cologuard Plus® test in Abbott's colorectal cancer screening portfolio, providing another way to help reach people who otherwise may remain unscreened.

Colorectal cancer is the second-leading cause of cancer-related death in the U.S., yet it is preventable and highly treatable when detected early through screening.⁴ Up to 60 million Americans remain due for recommended screening, emphasizing the need for more ways to help eligible people complete screening.⁵

With Cologuard Plus, an American Cancer Society (ACS)-preferred stool-based screening option, and SimpleScreen CRC, a blood-based option for eligible adults who decline or do not complete preferred screening, Abbott provides tests that help healthcare providers match more patients with an appropriate screening option while keeping prevention and early detection at the forefront.

"We still see too many eligible patients who remain unscreened. Expanding the ways patients can participate in screening gives clinicians another opportunity to address those barriers," said Dr. Folasade May, director of quality in digestive diseases at UCLA Health and co-founder and board member of the Association of Black Gastroenterologists and Hepatologists. "For someone who has declined or does not complete preferred approaches, the option of a blood draw may be what helps them finally take action. It can help us keep the conversation going and offer another path to screening."

The ACS recommends several preferred CRC screening options, including stool-based tests and direct visual tests.³ All blood-based screening should be recommended only for individuals who decline or do not complete a preferred screening option. For those patients, SimpleScreen CRC provides a convenient way to get screened through a simple blood draw.

"More screening options for colorectal cancer only matter if we help more people get screened," said Jake Orville, senior vice president of Abbott's cancer diagnostics business. "Our goal is to help connect each person with an appropriate screening test that is right for them and support them through completion. That means prioritizing the Cologuard Plus test for average-risk patients, colonoscopy for those who need it, and now offering SimpleScreen CRC as a blood-based option for appropriate patients who decline or do not complete a preferred screening test. With our portfolio, Abbott can help healthcare providers and patients prioritize screening and prevention while providing another path to screening for people who might otherwise go unscreened."

Clinically validated in more than 48,000 adults

SimpleScreen CRC detects signals associated with colorectal cancer, utilizing circulating cell-free DNA (cfDNA) in the blood. The test was evaluated in PREEMPT CRC, the largest prospective clinical validation study conducted for a blood-based colorectal cancer screening test. The study enrolled more than 48,000 asymptomatic, average-risk adults ages 45 to 85 who were scheduled for screening colonoscopy.⁶

In a prespecified analysis adjusted to match the U.S. Census, SimpleScreen CRC demonstrated 81.1% overall sensitivity for colorectal cancer, including 63.5% sensitivity for Stage I CRC; 13.7% sensitivity for advanced precancerous lesions; and 90.4% specificity for advanced colorectal neoplasia. In practical terms, the test correctly detected about eight in 10 colorectal cancers while correctly producing negative results for nine in 10 people without colorectal cancer or advanced precancerous lesions.²

SimpleScreen CRC is covered by Medicare. Eligible patients with Medicare Part B will have no out-of-pocket costs. Medicare Advantage patients may have out-of-pocket costs.

More than a test: support designed to help patients complete screening

Choosing a screening test is only one step in the screening journey. With SimpleScreen CRC, Abbott is extending the patient support experience and infrastructure built through Cologuard to help eligible patients move from an order to a completed test and understand the next steps in the screening journey.

SimpleScreen CRC is backed by Abbott's patient navigation program, with support that includes blood-draw coordination, patient outreach and screening reminders, bilingual specialists and translation services, insurance assistance, follow-up support and repeat-screening reminders. Patients have flexible options for completing their blood draw, including at home through mobile phlebotomy or at a participating lab, helping make screening easier to fit into patients' lives.

A patient with a positive result should receive a timely follow-up colonoscopy to complete the screening process, consistent with

American Cancer Society recommendations.

About SimpleScreen CRC

SimpleScreen CRC is an FDA-approved blood-based colorectal cancer screening test for adults age 45 and older who are at average risk for the disease. Developed and manufactured by Freenome and distributed by Abbott in the U.S., the test utilizes circulating cell-free DNA from a simple blood draw to detect signals associated with colorectal cancer. SimpleScreen CRC expands Abbott's colorectal cancer screening solution, providing an additional option to help reach eligible patients who may otherwise remain unscreened.

The American Cancer Society recommends blood-based CRC screening for eligible individuals who decline or do not complete a preferred stool-based or visual screening test. SimpleScreen CRC is intended to serve as an alternative for these patients, alongside Abbott's Cologuard Plus® test, a preferred noninvasive screening option. A positive SimpleScreen CRC result should be followed by colonoscopy to complete the screening process.

About Abbott:

Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 122,000 colleagues serve people in more than 160 countries.

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1. Cologuard Plus Clinician Brochure. Exact Sciences Corporation. Madison, WI.
2. SimpleScreen CRC Provider Brochure. Freenome LLC. Brisbane, CA.
3. Wolf AMD, Hoffman RM, Walter LC, et al. Colorectal cancer screening: an update to the American Cancer Society guideline, 2026. *CA Cancer J Clin.* 2026;76(3): e70083.
4. Siegel RL, Kratzer TB, Wagle NS, et al. Cancer statistics, 2026. *CA Cancer J Clin.* 2026;e70043.
5. Ebner DW, Kisiel JB, Fendrick AM, et al. Estimated Average-Risk Colorectal Cancer Screening-Eligible Population in the US. *JAMA Netw Open.* 2024;7(3):e245537.
6. Shaukat A, Burke CA, Chan AT, et al. Clinical Validation of a Circulating Tumor DNA-Based Blood Test to Screen for Colorectal Cancer. *JAMA.* 2025;334(1):56-63.

SOURCE Abbott

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