



Freenome to Present New Validation Data for Next-Generation CRC Screening Test in Late-Breaking Oral Presentation at ACG 2026

October 11, 2026

- *Significant performance improvement seen across all subtypes of advanced precancerous lesions, which are important to detect for potential colorectal cancer prevention –*
- *Overall detection of colorectal cancer remained consistent with test's first version, achieving 80.4% sensitivity at 90% specificity*

BRISBANE, Calif., Oct. 11, 2026 (GLOBE NEWSWIRE) -- Freenome, Inc. (Nasdaq: FRNM), an early cancer detection company developing blood-based tests, today announced the company will present late-breaking data on an updated version of its SimpleScreen™ CRC blood-based screening test at the American College of Gastroenterology (ACG) 2026 Annual Meeting in Nashville.

Freenome conducted a pivotal clinical validation study to assess the performance of assay and algorithm improvements for the updated version of SimpleScreen CRC. The FDA approved the first-generation version of SimpleScreen CRC in July 2026, and the test was commercially launched in late September in the United States by Freenome's partner Abbott Cancer Diagnostics.

The updated test demonstrated 18.2% sensitivity for detecting advanced precancerous lesions (APLs), a significant improvement compared to the 13.7% sensitivity in the original PREEMPT CRC® study.¹ Sensitivity for APLs with high-grade dysplasia (HGD) improved to 41.9% in the updated test, compared to 30.5% reported previously. The sensitivity results for APLs and APLs with HGD demonstrated in this study are the highest reported to date for any non-invasive screening blood test in a prospective registrational pivotal clinical study.

Sensitivity was also improved for all APL subtypes, including villous or tubulovillous; adenomas ≥ 10 mm; sessile serrated lesions/polyps ≥ 10 mm; and traditional serrated adenomas.

Overall, 80.4% sensitivity was demonstrated for detecting CRC. The results were adjusted to the age and sex distribution of the U.S. Census to better reflect the intended use population, and specificity for no findings on colonoscopy was 90%.

"These results suggest that our blood-based screening test may detect precancerous lesions with clinically meaningful sensitivity," said Aaron Elliott, Ph.D., CEO of Freenome. "The ability to continually improve performance through refinements to our assay and algorithm, as seen with these results, is a fundamental part of our up-versioning strategy. We believe this iterative methodology not only improves CRC APL performance but is also applicable across our multi-cancer pipeline. Combined with our personalized cancer detection approach, this is how we continue to expand blood-based screening into an accessible option for the millions of Americans who remain unscreened."

Aasma Shaukat, M.D., M.P.H., professor of medicine at NYU Grossman School of Medicine and a co-lead principal investigator on the PREEMPT CRC study, will present the detailed results.

Presentation title: Improved Sensitivity for Advanced Precancerous Lesions (APLs) Demonstrated in Clinical Validation of an Updated Colorectal Cancer (CRC) Screening Blood Test in an Average-Risk Population.

Date: Wednesday, Oct. 14

Time: 9:10-9:20 am

Session: Plenary Session 4B: Liver, Esophagus, CRC, IBD

About Freenome

Freenome is an early cancer detection company developing blood-based screening tests to identify cancer in its earliest, most treatable stages. The company's proprietary multiomics discovery platform analyzes circulating cell-free DNA methylation patterns at single-base resolution alongside additional biomarkers to detect multiple cancers. Freenome's development of SimpleScreen™ CRC for colorectal cancer screening and a pipeline of tests for lung cancer and additional indications is designed to increase cancer detection among millions of at-risk individuals. For more information, visit www.freenome.com.

Forward-Looking Statements

Statements we make in this press release may include statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, which are usually identified by the use of words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans,"

“projects,” “seeks,” “should,” “will” and variations of such words or similar expressions. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and are making this statement for purposes of complying with those safe harbor provisions. Any statements in this press release that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking statements include, without limitation, express or implied statements regarding SimpleScreen CRC’s impact and ability to reach additional patients; the impact of FDA approval including with respect to Medicare and ACS guidelines; Freenome’s partnership with Abbott and the expected results and benefits thereof; and Freenome’s business and strategy, including its plans with respect to its broader SimpleScreen portfolio and multiomics platform. These forward-looking statements reflect our current views about our plans, intentions, expectations, strategies and prospects, which are based on the information currently available to us and on assumptions we have made. Although we believe that our plans, intentions, expectations, strategies and prospects as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a variety of risks and factors that are beyond our control including, without limitation, risks related to the approval of Freenome’s products and tests and the timing of expected regulatory and business milestones; ability to negotiate definitive contractual arrangements with potential customers; the impact of competitive products and tests; ability to obtain sufficient supply of materials; ability to obtain additional financing; ability to attract and retain qualified personnel; global economic and political conditions; legal and regulatory changes; the outcome of any legal proceedings that may be instituted against Freenome; the effects of competition on Freenome’s future business; as well as those set forth in Freenome’s most recent filings with the SEC, including our Form S-1. We assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

References

1. Shaukat A, Burke CA, Chan AT, et al. Clinical Validation of a Circulating Tumor DNA-Based Blood Test to Screen for Colorectal Cancer. JAMA. Published online June 2, 2025. doi: 10.1001/jama.2025.7515.

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