Freenome Delivers Improved Performance in Its Colorectal Cancer Blood Test with Sensitivity of 85% for CRC and 22% for Advanced Precancerous Lesions

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– As presented later this week at the ASCO GI conference, the large case-control validation study of nearly 1,000 samples highlights a head-to-head comparison with the test's first version, which is currently under FDA review –

– Assay upgrades led to improved detection rates, limit of detection and signal-to-noise ratio –

Brisbane, CA (Jan. 6, 2026) — Freenome, an early cancer detection company developing blood-based screening tests, today is reporting the improved clinical performance of an updated version of its SimpleScreen™ CRC test. In data being shown at this week's ASCO Gastrointestinal Cancers Symposium (ASCO GI) in San Francisco, the updated colorectal cancer (CRC) test detected 85% of CRC cases and 22% of advanced precancerous lesions (APLs) at 90% specificity.

The increased clinical sensitivity – higher than previously reported from Freenome's PREEMPT CRC® Study [1] – reflects improvements made to the assay, including optimizing key aspects of the reagents, workflow and automation of the testing platform. The original test and the updated version were compared head-to-head by evaluating all study subjects with both versions, which controls for biological variation and cohort effects. For both CRC and APL, the PREEMPT CRC clinical performance results were within the confidence intervals of the original test in this study, which helps validate the credibility of the improvements made to the underlying platform.

Additional improvements in the updated test included increased sensitivity of 44% for APLs with high-grade dysplasia, a 2.6-fold reduction in the limit of detection, and meaningful improvements in projected patient outcomes (9% reduction in lifetime CRC cases and 10% reduction in CRC deaths). A total of 966 samples were tested from an average-risk cohort, with results adjusted to the intended-use population using U.S. Census and PREEMPT CRC cohort information.

"The results Freenome is presenting at ASCO GI this week for an updated CRC screening test – utilizing our personalized multi-cancer detection platform – demonstrate that we can deliver a versioning strategy to generate significant improvements in test performance," said Aaron Elliott, Ph.D., CEO of Freenome. "As we look ahead to 2026 and the planned launch of multiple blood-based cancer screening tests, we are confident in our potential to systematically improve the detection of cancer at its earliest, most treatable stages."

Data for Freenome's updated CRC test will be presented at ASCO GI in a poster session at 7:00 a.m. PT on Saturday, Jan. 10, 2026. The presenting author will be 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.

Freenome's multiomics discovery platform evaluates multiple biomarker classes, including genomics, epigenomics and proteomics, to identify the early biological signals of disease in the bloodstream. SimpleScreen CRC was built using this platform and applies an AI/ML-based model to detect specific methylation signatures in tumor-derived cell-free DNA (cfDNA) at single-base resolution.

Freenome has also been working on upgrades to the AI/ML learning algorithm; these improvements will be described in future work.

In August, Freenome completed its Premarket Approval Application (PMA) to the U.S. Food and Drug Administration (FDA) for the initial version of its SimpleScreen CRC test. The company intends to submit a supplemental PMA application for the updated test following expected approval of SimpleScreen CRC and completion of a larger, independent clinical validation study in 2026.

About Freenome

Freenome is an early cancer detection company developing blood-based tests to detect cancer when it is most treatable. The company recognizes that no single technology can identify every cancer due to the disease's inherent heterogeneity. Freenome's approach combines a multiomics platform that analyzes multiple signals in the blood with artificial intelligence and machine learning to tune into cancer's subtlest clues, even at the earliest stages of the disease.

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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. 2025;334(1):56-63. doi:10.1001/jama.2025.7515