Freenome Reports Top-Line Readout of Updated SimpleScreen™ CRC Colorectal Cancer Screening Blood Test Met All Primary and Secondary Endpoints

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– Updated test version achieved significant performance improvement in detecting advanced precancerous lesions, including those with high-grade dysplasia

– Modeling projects the improvements would translate to 1,582 additional life-years gained (7.7%), 426 fewer CRC cases (9.5%) and 143 fewer CRC deaths (9.5%) per 100,000 individuals screened, compared to the first-generation test

Brisbane, CA (July 9, 2026) — Freenome, an early cancer detection company developing blood-based screening tests, today announced favorable results from its pivotal clinical validation study assessing the performance of assay and algorithm improvements for its updated version of the SimpleScreen™ CRC blood-based colorectal cancer (CRC) screening test.

The study successfully met its primary and secondary endpoints. The updated test showed 18.2% sensitivity for detecting advanced precancerous lesions (APLs), 41.9% sensitivity for APLs with high-grade dysplasia (HGD), and 80.4% sensitivity for detecting CRC, including 52% of Stage I cases (Stage I (T1) 39.9% and Stage I (T2) 81.2%), 100% of Stage II, 97.3% of Stage III and 100% of Stage IV. 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%.

CRC remains the second-leading cause of cancer-related death in the United States, yet more than 50 million eligible adults are not up to date on recommended screening. Blood-based screening tests have the potential to reach people who might otherwise remain unscreened.

The clinical validation of the updated SimpleScreen CRC test includes blinded, previously unevaluated samples from participants who enrolled in PREEMPT CRC[1] — a prospective, registrational study — as well as previously tested samples. Conducted a more than 200 sites, the PREEMPT CRC study enrolled 48,995 asymptomatic, average-risk adults between the ages of 45 and 85 scheduled to undergo a screening colonoscopy. The analysis included more than 85 individuals with CRC, 1,500 with APLs, and 150 with APLs with HGD.

Endpoint	Updated SimpleScreen CRC CV study[2] (US Census Weighted Endpoints)		SimpleScreen CRC in PREEMPT CRC study[1] (US Census Weighted Endpoints)	
	N	Value (95% CI)	N	Value (95% CI)
Sensitivity for CRC (Primary)	89	**80.4%** (70.2%, 87.7%)	72	81.1% (71.3%, 88.1%)
Sensitivity for APL (Primary)	1570	**18.2%** (16.3%, 20.4%)	2567	13.7% (12.4%, 15.0%)
Sensitivity for HGD (APL 2.1) (Secondary)	157	**41.9%** (34.0%, 50.3%)	110	30.5% (22.7%, 39.5%)

Detecting APLs, particularly those with HGD, is important because these lesions are more likely to progress to CRC if left untreated. The sensitivity results for APL and APL 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.

“The sensitivity for APL and APL with HGD for the updated SimpleScreen CRC test is a marked improvement and gets us closer to matching the performance of certain stool-based CRC screening tests, with potentially higher adherence,” noted 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.

With the improved detection of APLs and HGD, our published model[3] suggests that the updated test would result in 7.7% more life-years gained, 9.5% more cases of cancer prevented, and 9.5% more cancer deaths prevented, compared to the first-generation CRC test version.[4]

“This study marks a major milestone in our mission to advance blood-based colorectal cancer screening,” said Aaron Elliott, Ph.D., CEO of Freenome. “The significant improvement in detecting precancerous lesions demonstrates the critical role our SimpleScreen CRC platform can play in early detection and prevention of colon cancer. With millions of eligible Americans still not getting screened, expanding access to accurate, non-invasive screening options that patients are more likely to complete has never been more important.”

Freenome submitted its Premarket Approval (PMA) application to the U.S. Food and Drug Administration (FDA) in August 2025 for the first-generation version of its SimpleScreen CRC test. The FDA is expected to complete its review in mid 2026. Freenome intends to submit a supplemental PMA to the FDA for the next-generation SimpleScreen CRC test.

In August 2025, Freenome and Abbott entered into a commercial collaboration agreement to bring SimpleScreen CRC to market. Upon FDA approval, SimpleScreen CRC will be exclusively commercialized and made available by Abbott. Freenome will be offering a multi-cancer product consisting of SimpleScreen CRC in combination with its SimpleScreen Lung laboratory-developed test solely to patients who are eligible for both screenings.

The commercial collaboration agreement included a milestone payment tied to the outcome of this study. That intended milestone payment will be set at $70 million, pending FDA approval of the next-generation test and the successful technology transfer of the product to Abbott. Freenome and Abbott are collaborating on a multi-year R&D program focused on improving assay performance.

“These results strengthen our confidence in the role blood-based colorectal cancer screening can play in expanding screening,” said Jake Orville, senior vice president of Abbott’s cancer diagnostics business. “Combined with Abbott’s preferred, guideline-supported screening option, we’re uniquely positioned to offer healthcare providers and patients a differentiated colorectal cancer screening portfolio built on innovation, performance and choice—with one goal in mind: helping more people get screened.”

While the foundational SimpleScreen CRC test will provide a robust, clinically validated screening option for patients, Freenome continues to advance its next-generation pipeline of single- and multi-cancer tests. Through its pioneering Personalized Cancer Detection approach to screening, Freenome will be matching blood-based screening tests to the cancers most relevant to individuals based on their health profile, while leveraging its multiomics platform to optimize test performance for additional validated indications.

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.

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.
2. Data on file.
3. Meester RGS et al. JNCI J Natl Cancer Inst. 2026;118(1):113-120.
4. Data on file.

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