Freenome's SimpleScreen™ CRC Blood-Based Test Included in Updated ACS Colorectal Cancer Screening Guideline

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– Guideline includes new category – blood-based tests – that represents a broader shift in cancer screening toward minimally invasive approaches that may improve screening rates

– SimpleScreen CRC is under FDA review with approval anticipated in mid 2026

Brisbane, CA (May 27, 2026) — Freenome, an early cancer detection company developing blood-based screening tests, welcomes the inclusion of blood-based testing in the American Cancer Society (ACS) Guideline for Colorectal Cancer Screening, marking an important milestone in expanding patient access to non-invasive colorectal cancer screening options. As part of its guideline update, the ACS Guideline Development Group reviewed the available clinical performance and modeling data for blood-based testing, including Freenome's SimpleScreen™ CRC screening test. The update:

- Recognizes blood-based testing as an option for individuals who decline or do not complete other recommended screening approaches;
- Notes that offering multiple screening options may improve participation and adherence because "the most effective screening test is the one that the patient completes;"
- Highlights the potential for blood-based screening to help reach individuals who otherwise may avoid screening altogether;
- Emphasizes that patients should be informed about the pros and cons of other screening options and the limitations of blood-based testing, and that a positive non-invasive test should be followed by a colonoscopy.

"Too many eligible individuals remain unscreened for CRC despite the proven benefits of early detection," said Aaron Elliott, Ph.D., chief executive officer of Freenome. "The inclusion of blood-based testing in the ACS screening guidelines marks an important step toward expanding patient access to testing. We're encouraged by the growing momentum behind blood-based screening and remain focused on advancing clinically validated tools that can help improve screening participation and patient outcomes."

SimpleScreen CRC was submitted for FDA review in August 2025. Approval is expected in mid 2026, and Abbott (formerly Exact Sciences) will lead the broad commercialization of SimpleScreen CRC. The test is currently available at select pilot sites as a laboratory-developed test (LDT).

"Expanding colorectal cancer screening means meeting patients with options that work for them," said Jake Orville, senior vice president, cancer diagnostics, at Abbott. "With Abbott's portfolio of screening solutions — from Cologuard to blood-based screening with SimpleScreen CRC — we can responsibly support ACS guidelines and help more people get screened earlier, when colorectal cancer is most treatable. The addition of blood tests as an option in the ACS guideline will help reach people who might otherwise go unscreened and reflects the continued evolution of the screening landscape."

Freenome continues to develop an updated version of SimpleScreen CRC, including an independent clinical validation study that is expected to be completed in Q3 2026. This study is a follow-up to case-control validation data presented at the 2026 ASCO Gastrointestinal Cancers Symposium in January.

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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