



Geneoscopy's New FDA-Approved Stool Collection Method Simplifies At-Home Colorectal Cancer Screening

*Pairing diagnostic innovation with improved patient experience,
ColoSense aims to streamline the screening process and increase compliance*

ST. LOUIS, Mo.—July 24, 2025—Geneoscopy, Inc., a life sciences company focused on developing diagnostic tests for the advancement of gastrointestinal health, received FDA approval to streamline the stool collection process for ColoSense®, its RNA-based colorectal cancer (CRC) screening test. The newly approved collection kit no longer requires patients to separate their sample into multiple containers. This improves ease of use and reduces barriers to at-home screening,¹ while maintaining clinical performance.

“We’ve taken a critical step toward improving the at-home colorectal cancer screening experience by removing one of the most burdensome aspects for patients—the scraping of stool,” said Dr. Erica Barnell, Chief Medical & Science Officer of Geneoscopy. “The new collection kit simplifies the process for collecting a patient’s stool sample. By eliminating the most confusing and undesirable step, we believe ColoSense will drive higher adherence and better outcomes.”

ColoSense is indicated for individuals aged 45 and older who are at average risk for CRC. It uses advanced RNA technology to detect biomarkers associated with CRC and advanced adenomas (AA)—precancerous growths that can develop into cancer if left untreated. As the only FDA-approved RNA-based test for CRC screening, ColoSense demonstrated 93% sensitivity for CRC and 45% sensitivity for AA in average-risk individuals. Among average-risk individuals aged 45 to 49, where CRC incidence is on the rise, the test demonstrated 100% sensitivity for CRC and 44% sensitivity for AA*.

Despite the availability of multiple screening options, an estimated 44 million people aged 45-75 remain unscreened for CRC.² To help address a common barrier to stool-based screening, the updated ColoSense collection kit removes the need to scrape the sample. This improvement is expected to increase patient compliance, lower the rate of collection errors, and reduce the frequency of invalid samples. This ease of use can translate into fewer missed screenings and a greater overall impact on population health.

“To exceed 80% compliance for colorectal cancer screening, the patient experience for stool-based screening must be improved,” said Andrew Barnell, Chief Executive Officer of Geneoscopy. “The new ColoSense test does that, offering patients everything they like about at-home, high-sensitivity screening, but now, with an easier collection process.”

ColoSense is included in National Comprehensive Cancer Network (NCCN) guidelines, based on an evaluation of the strength of its clinical evidence and the robust science behind the technology. The test will be available through Geneoscopy’s strategic collaboration with Labcorp, expanding access for providers and patients across the United States. ColoSense represents a significant advancement in noninvasive stool testing options, reinforcing the importance of accessible tools that help reach individuals who are less likely to undergo colonoscopy.

**Exhibit
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About ColoSense

ColoSense is intended for the qualitative detection of colorectal neoplasia-associated RNA markers and for the presence of occult hemoglobin in human stool. ColoSense is for use with the ColoSense Collection Kit, the ColoSense Test Kit, the ColoSense Software, and the following instruments: Polymedco iFOBT Analyzer; bioMérieux EMAG Nucleic Acid Extraction System; and Bio-Rad QX Dx ddPCR System. ColoSense is a single-site test performed at Geneoscopy, Inc.

A positive ColoSense result may indicate the presence of colorectal cancer (CRC), advanced adenomas (AA), or serrated precancerous lesions (SPL) and should be followed by a colonoscopy. ColoSense is indicated as a screening test for adults aged 45 years or older who are at the typical average risk for developing CRC. ColoSense is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high-risk individuals.

Results from Geneoscopy's pivotal CRC-PREVENT trial were published in *The Journal of the American Medical Association (JAMA)*. For more information, visit www.colosense.com.

About Geneoscopy, Inc.

Geneoscopy, Inc. is a life sciences company focused on developing diagnostic tests for gastrointestinal health. Leveraging its proprietary, patented stool-derived eukaryotic RNA (seRNA) biomarker platform, Geneoscopy's mission is to empower patients and providers to transform gastrointestinal health through innovative diagnostics. The company's FDA-approved ColoSense test uses a proprietary RNA-based platform to screen for colorectal cancer and advanced adenomas for average-risk individuals over the age of 45. In partnership with leading universities and biopharmaceutical companies, Geneoscopy is also developing diagnostic tests for treatment selection and therapy monitoring in other areas of gastrointestinal health. For more information, visit www.geneoscopy.com and follow the company on [LinkedIn](#).

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*ColoSense identified 5/5 colorectal cancers and 37/84 advanced adenomas.