# FDA Approves ColoSense™ – Geneoscopy's Noninvasive Multi-target Stool RNA (mt-sRNA) Colorectal Cancer Screening Test

- *In average-risk individuals, ColoSense demonstrated 93% sensitivity for detecting colorectal cancer (CRC) and 45% sensitivity for detecting advanced adenomas (AA).*
- *The CRC-PREVENT study evaluated more than 1,800 average-risk individuals aged 45-49, representing over 20% of participants. Results in this subgroup showed 100% sensitivity in detecting CRC and 44% sensitivity for AA, offering a promising new tool to combat early-age onset CRC.*

**ST. LOUIS, MO – MAY 6, 2024** – Geneoscopy, Inc., a life sciences company focused on developing diagnostic tests for the advancement of gastrointestinal health, today announced that the U.S. Food and Drug Administration (FDA) approved its noninvasive colorectal cancer screening test, ColoSense. ColoSense is indicated as a screening test for adults, 45 years of age or older, who are at typical average risk for developing CRC.

Designated as a Breakthrough Device by the FDA, ColoSense is the first noninvasive colorectal cancer screening test to provide a dynamic view of disease activity by using RNA biomarkers. RNA biomarkers are not subject to age-related methylation patterns that can lead to variability in test performance across different age groups.[1-2]

"Securing FDA approval for ColoSense marks a significant milestone for Geneoscopy and demonstrates that our patented RNA technology can provide millions of eligible adults with a safe and effective option for detecting CRC and advanced adenomas," said Andrew Barnell, CEO and co-founder of Geneoscopy. "This achievement is a testament to our deep dedication and commitment to bringing innovative technology to market that will improve outcomes for this deadly, yet preventable, disease."

Geneoscopy's CRC-PREVENT trial evaluated participants aged 45 and older from various racial, ethnic, and socioeconomic backgrounds. Using a novel decentralized enrollment approach, 64% of participants had never been screened for colorectal cancer, and 68% of participants had not scheduled a colonoscopy at the time of enrollment. This is unlike traditional centralized trials, in which patients are typically already engaged in healthcare screening programs. In average-risk individuals, ColoSense successfully demonstrated 93% sensitivity for CRC and importantly identified 100% of CRC in Stage I, when the disease is most curable. Additionally, ColoSense detected 45% of advanced adenomas, when the disease is most preventable. Notably, the study reported 100% CRC sensitivity and 44% AA sensitivity in patients aged 45-49, a critically important screening demographic.

Colorectal cancer is the second deadliest cancer in the United States. However, millions of eligible Americans do not get screened due to a lack of access to or avoidance of invasive options like colonoscopies. CRC incidence rates are also rising among younger populations under 50 years old, prompting a recent shift in the United States Preventive Services Task Force's guidelines to recommend initiation of CRC screening at age 45.[3] Underscoring the critical nature of this issue, the American Cancer Society recently reported that colorectal cancer is now the leading cause of cancer death for males and the second leading cause of death for females under 50.[4] Further compounding this challenge, approximately 40% of unscreened and eligible Americans are ages 45-49.[5,6]

“The growing number of adults diagnosed with colorectal cancer underscores the urgent need for innovative approaches in screening. It's essential to eliminate obstacles and broaden the availability of screening methods for healthcare providers and patients,” said Anjee Davis, president of Fight CRC. “We hope that introducing new FDA-approved diagnostic tools, including stool-based tests like ColoSense, will help to advance access and increase screening rates, ultimately reducing the impact of late-stage colorectal cancer diagnoses.”

FDA approval of ColoSense is a significant step in making this important screening tool available to patients. Geneoscopy is working with payors, professional societies, and advocacy partners to support a commercial launch later this year or early in 2025 to ensure patients have timely access to ColoSense to support CRC screening. Geneoscopy will launch ColoSense in collaboration with Labcorp (NYSE: LH), a global leader of innovative and comprehensive laboratory services.

**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 QXDx 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, 45 years of age or older, who are at 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)* in October 2023. 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. Beyond colorectal cancer screening, Geneoscopy is developing diagnostic tests for treatment selection and therapy monitoring in other disease areas in partnership with leading universities and biopharmaceutical companies. For more information, visit www.geneoscopy.com and follow the company on LinkedIn.

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