



Peer-Reviewed Study Confirms Reliability of ColoSense, Geneoscopy’s Noninvasive Multi-target Stool RNA Colorectal Cancer Screening Test

ST. LOUIS, Mo. – July 10, 2024 – Geneoscopy, Inc., a life sciences company focused on developing diagnostic tests for the advancement of gastrointestinal health, announced the publication of a study in *The Journal of Molecular Diagnostics*, highlighting the analytical validation of ColoSense™, a noninvasive, multi-target stool RNA (mt-sRNA) screening test for colorectal cancer (CRC) and advanced adenomas (AAs) in average-risk individuals aged 45 and older.

“ColoSense is the first FDA-approved CRC screening test to leverage stool-based RNA biomarkers, providing a consistent sensitivity profile for all average-risk patients from the youngest to the older population – a challenge for methylation-based assays,” said Dr. Erica Barnell, Chief Science and Medical Officer at Geneoscopy. “These study results position us to continue advancing diagnostic technologies that will help meet the growing demand for reliable and accessible cancer screening solutions for the 44 million Americans at average risk for CRC.”

The study, "Analytical Validation of the Multitarget Stool RNA Test for Colorectal Cancer Screening," demonstrated ColoSense's high stability, precision, and reproducibility. Researchers evaluated 12 analytical validation studies as part of the pre-market approval application to the FDA to determine analytical sensitivity, linearity, precision, and robustness, among other parameters. Key findings indicated that the test detects low levels of specific RNA markers and maintains accuracy across a wide range of testing conditions. The study's data further validates ColoSense’s assay robustness, which obtained 93% sensitivity for CRC and 45% sensitivity for AAs in average-risk individuals.

CRC is the second most common cause of cancer death in the United States. However, millions of Americans do not get screened due to a lack of access to or avoidance of invasive options like colonoscopies. While traditional colonoscopy is the gold standard for detecting CRC and AAs, noninvasive tests like ColoSense offer an essential alternative for patients who are noncompliant with colonoscopy recommendations. The recent lowering of the recommended screening age from 50 to 45 years by the United States Preventive Services Task Force and the American Cancer Society has expanded the need for effective CRC screening methods.

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 GI disease areas. For more information, visit www.geneoscopy.com and follow the company on [LinkedIn](#).

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Media

Andrea Sampson
Sampson Public Relations Group
asampson@sampsonprgroup.com

Investor Relations

Carrie Mendivil / Ji-Yon Yi
Gilmartin Group
investors@geneoscopy.com