Geneoscopy Receives New York State Department of Health Permit, Expanding Ability to Provide Laboratory Services Nationwide

ST. LOUIS, Mo. – Oct. 1, 2024 – Geneoscopy, Inc., a life sciences company focused on developing diagnostic tests for the advancement of gastrointestinal health, received its laboratory permit from the New York State Department of Health. Geneoscopy is now able to provide laboratory services in all 50 states and the District of Columbia. The company's first commercially available laboratory test will be ColoSense™, an FDA-approved, noninvasive multi-target stool RNA (mt-sRNA) screening test for colorectal cancer (CRC) and advanced adenomas.

The New York State Department of Health's Clinical Laboratory Evaluation Program (CLEP) regulates and oversees laboratories that accept clinical specimens originating in New York State. The CLEP seeks to ensure the accuracy and reliability of test results in clinical laboratories located in or accepting specimens from New York State.

"New York's CLEP is known to have the most rigorous review process and standards for clinical laboratories, and we believe that this permit reflects the high standard of quality and precision of our laboratory," said Julie LaRocca, Senior Vice President of Quality Assurance and Regulatory Affairs at Geneoscopy. "Our goal at Geneoscopy is to provide patients with a reliable, accessible, noninvasive option for early detection of CRC. Receiving this permit marks a key milestone in our efforts to offer ColoSense to patients nationwide."

Colorectal cancer is the second deadliest cancer in the US; however, millions of eligible patients avoid screening due to unpleasant procedures or the perceived low risk of developing CRC. Expanding access to new screening tools will enhance the ability to detect disease early and provide valuable information to guide personalized treatment options. Geneoscopy's CRC screening test, ColoSense, is the first noninvasive option to use an RNA-based assay, offering a dynamic view of disease activity without dependence on age-related methylation patterns.

Geneoscopy is a Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists (CAP) accredited laboratory. In total, CLIA oversees approximately 320,000 laboratory entities, and the CAP Laboratory Accreditation Program is considered a benchmark for excellence in clinical laboratory accreditations, ensuring that laboratories adhere to strict guidelines for quality, safety, and accuracy. Additionally, Geneoscopy's CLIA/CAP laboratory is the only facility approved by the US FDA to process ColoSense.

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. A positive ColoSense result may indicate the presence of colorectal cancer (CRC), advanced adenomas, or serrated

precancerous lesions 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.

Geneoscopy's pivotal CRC-PREVENT trial results 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. 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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