

New clinical trial explores novel noninvasive colon cancer screening test

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In a first-of-its-kind clinical trial, physician-scientists at University Hospitals (UH) Case Medical Center's Seidman Cancer Center and Case Western Reserve University School of Medicine are studying a promising new non-invasive technology for colon cancer screening. The five-year study is recruiting patients to compare the effectiveness of stool DNA (sDNA) testing with colonoscopy for detecting large colon polyps.

sDNA is a novel test that detects colon [cancer](#) in its earliest stages, based on analysis of stool DNA. Developed in the laboratory of Sanford Markowitz, MD, PhD, oncologist with the UH Seidman Cancer Center and Professor at Case Western Reserve University School of Medicine, sDNA is a recommended screening by the [American Cancer Society](#).

"Colon cancer is the second leading cause of cancer deaths in the United States but is a preventable disease," says Gregory Cooper, MD, Co-Program Leader for [Cancer Prevention](#) at UH Seidman Cancer Center and Professor at Case Western Reserve University School of Medicine. "Early detection through screening can prevent the development of colon cancer. This promising new test has the potential to improve [colon cancer screening](#) rates and decrease mortality from this deadly disease."

Colonoscopy is considered the gold standard for screening because of its ability to not only locate but remove [precancerous polyps](#). All adults over age 50 should undergo colonoscopy, with certain risk factors for screening at an earlier age. However, according to research conducted by

Dr. Cooper, many adults do not follow these national guidelines.

"Colonoscopy is truly the best test but it has its limitations and is vastly underutilized by the public," says Dr. Cooper, who is clinical Primary Investigator for the study. "sDNA technology is a completely non-invasive approach and a complement to colonoscopy. It is emerging as a promising alternative for patients who do not want to undergo colonoscopy or do not have access to the procedure. It also can be beneficial for patients during the years in between colonoscopies."

Dr. Markowitz, who is an alumnus investigator of the Howard Hughes Medical Institute, and his team played an intimate role in developing the new technology for DNA screening for colon cancer. They discovered a specific DNA change, methylation of the vimentin gene, which takes place in colon cancers, and then developed techniques for sensitively detecting this change in DNA shed from colon cancers in the stool. Their technology has been licensed by EXACT Sciences Corporation for commercial development and expanded to include a larger panel of genes.

"This is true translational research, bringing a discovery from the laboratory to the patient care setting," says Li Li MD, PhD, the study's basic investigator, family medicine physician at UH Case Medical Center and Associate Professor at Case Western Reserve University School of Medicine. "Information gained from this study may have significant and immediate implication for the clinical practice of screening and primary prevention of [colon cancer](#)."

The five-year study aims to recruit 1,600 patients who are scheduled for screening colonoscopy at UH Case Medical Center and UH community-based practices. Researchers will explore sDNA's efficacy in detecting large polyps, specifically advanced adenomas, which have a higher likelihood of progression to colorectal cancer.

The study is funded as part of the National Cancer Institute's Specialized Program of Research Excellence (SPORE) in Gastrointestinal (GI) Cancers award to Case Western Reserve University School of Medicine. The \$11.3 million SPORE grant focuses on translational research aimed at reducing the incidence and deaths from colon cancers and from cancers of the esophagus.

"Among our guiding principles is to pursue and implement breakthrough medical advancements and practices to deliver superior clinical outcomes for our patients," said Stanton Gerson, MD, Director, UH Seidman Cancer Center and Case Comprehensive Cancer Center, Case Western Reserve University. "Non-invasive sDNA screening is an exciting example of this principle in action and potentially can have a dramatic impact on increasing [screening](#) rates and decreasing mortality."

Provided by University Hospitals Case Medical Center

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