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New Technology Gives Patients Access to a 5-Minute, Office-Based Test to Identify Risk for Esophageal Cancer

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Monday, June 1, 2020, by DCP Staff

EsoCheck™ and EsoGuard™

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[NCI Annual Plan & Budget Proposal for Fiscal Year 2020 \(https://www.cancer.gov/about-nci/budget/plan/2020-annual-plan-budget-proposal.pdf\)](https://www.cancer.gov/about-nci/budget/plan/2020-annual-plan-budget-proposal.pdf) (PDF, 17.4 MB)

A new technology coupled with a new biomarker test now in clinical trials are giving patients timely access to a quick, accurate and less invasive way to identify risk for one type of esophageal cancer.

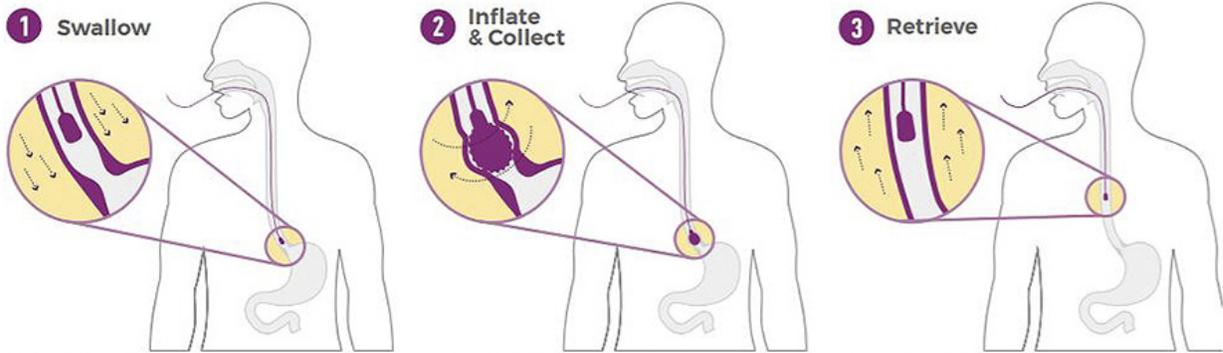
EsoCheck™ and EsoGuard™ are the device and test created for the detection of Barrett's esophagus, the benign and treatable precursor condition to esophageal adenocarcinomas (EAC). EAC are usually diagnosed at an advanced stage and are difficult to treat. Finding Barrett's esophagus, a sign of risk, could help patients by giving physicians a chance to intervene early. The technology was made more widely available with a special Food and Drug Administration (FDA) designation in February 2020.

These innovations were developed with support from programs of the National Cancer Institute (NCI) and with collaboration among oncologists, gastroenterologists, and pathologists. The EsoCheck™ device was recently named a 2020 Edison Award™ Silver Winner as one of the year's most significant innovations in the Medical Testing category.

The 15% to 30% of people in the United States who have chronic gastro-esophageal reflux disease, more commonly known as GERD, are at most risk for Barrett's esophagus. Those with chronic GERD are recommended to have an endoscopy to check for pathologic features of the condition. Endoscopy is an invasive procedure requiring sedation and a loss of a day at work for the patient and the necessary companion. After diagnosis, patients are followed longitudinally with more endoscopic exams and at the first signs of the condition worsening, the affected tissues can be removed to prevent the development of cancer.

"Only about 7% of patients who are diagnosed with esophageal adenocarcinoma have a prior diagnosis of Barrett's esophagus, indicating that most have never had that recommended endoscopy," said Ellen Richmond, MS, GNP-BC, a program director in the NCI Division of Cancer Prevention (DCP) for the Barrett's Esophagus Translational Research Network (BETRNet). "Symptoms of EAC often develop only when the cancer has reached late stages. We needed a

How the Swallowable Balloon Device Helps Detect Barrett Esophagus



Instead of undergoing standard endoscopy, patients can swallow a pill-sized capsule attached to a thin silicone catheter. The capsule passes through the esophagus and stops near the stomach.

Once the capsule nears the stomach, a balloon with a textured surface is inflated and maneuvered to swab the lower esophagus, where Barrett esophagus (BE) typically begins. A sample of the cells lining the lower esophagus is collected.

The balloon is deflated through the catheter and inverted back into the capsule, thus protecting the sample from dilution or contamination. After retrieving the capsule through the mouth, DNA is extracted from the balloon's surface for a DNA methylation test.



Device capsule and catheter in comparison to a vitamin pill and a dime.

The small dimensions of the balloon device allow clinicians to retrieve samples quickly and easily without sedation during an outpatient exam.

Source: Moirava RR et al. Sci. Transl. Med., Vol. 10, Issue 424, eaac5040 (2018). Reprinted with permission from AAS.

way to safely screen a much broader segment of the population that is quick, non-invasive, inexpensive, and easily administered to those who are currently unscreened."

[\(/sites/default/files/uploads/news_and_event/EsoCheck-vs-Gelcap-vert.png\)](https://sites/default/files/uploads/news_and_event/EsoCheck-vs-Gelcap-vert.png)

The EsoCheck device (from Top to Bottom), when swallowed, in comparison to a vitamin or capsule, and when inflated.



The conception and development of a biomarker based non-endoscopic technology for detecting Barrett's esophagus happened through support from DCP's [Early Detection Research Network \(EDRN\)](https://edrn.nci.nih.gov/) and [BETRNet programs](#), and the Division of Cancer Treatment and Diagnosis' [Translational Research Program \(SPOREs\)](https://trp.cancer.gov/).

To address the challenge of finding a better way to diagnose Barrett's esophagus, Sanford Markowitz, MD, PhD, and his co-investigators, Amitabh Chak, MD, and Joseph Willis, MD, at Case Western Reserve University in Cleveland, embarked on research on two fronts: to identify robust DNA markers of Barrett's esophagus and then to find a way to get samples for testing without endoscopy.

The team had previously discovered that the VIM gene, which codes for vimentin (a structural protein that is overexpressed in multiple cancers), is altered by methylation in the development of colon cancer. These changes in the DNA can be detected in the stool of humans with colon cancer. This discovery was proof that gastrointestinal cancers can be detected through this specific DNA change by a biomarker test, instead of through an invasive examination.

Knowing that the tissues along the gastrointestinal tract share many similarities, they tested for vimentin methylation in archived tissue samples of EAC and Barrett's esophagus. They found that the marker was present in 90% of EAC and also in 90% of Barrett's esophagus samples—an ideal biomarker of cancer development in the esophagus. Later, they demonstrated that the biomarker could be detected in samples from brushings of the esophagus taken during endoscopy in those with EAC and those with Barrett's.

In order to collect samples without requiring endoscopy, the Case Western Reserve investigators developed a "swallowable" balloon-based device to enable less invasive targeted sampling of the lower esophagus (see sidebar). The collected cells are then tested with the methylated DNA biomarker.

How EsoCheck™ Works

- [Efficacy of EsoGuard Assay on Esophageal Surface Cells Collected With EsoCheck vs EGD for the Diagnosis of BE or EAC \(ESOGUARDBE2\)\(https://clinicaltrials.gov/ct2/show/NCT04295811\)](https://clinicaltrials.gov/ct2/show/NCT04295811) by Lucid Diagnostics Inc.

Key Publications

Chen WD, Han ZJ, Skoletsy J, et al. [Detection in fecal DNA of colon cancer-specific methylation of the nonexpressed vimentin gene\(https://academic.oup.com/jnci/article/97/15/1124/2521303\)\(/external-link-policy\)](https://academic.oup.com/jnci/article/97/15/1124/2521303). J Natl Cancer Inst 97:1124-1132, 2005.

Moinova HR, Leidner RS, Ravi L, et al. [Aberrant vimentin methylation is characteristic of upper gastrointestinal pathologies\(https://cebp.aacrjournals.org/content/21/4/594.long\)\(/external-link-policy\)](https://cebp.aacrjournals.org/content/21/4/594.long). Cancer Epidemiol Biomarkers Prev. 2012 April;21(4): 594-600. Epub 2012/02/09 PNCID: PMC3454489.

Moinova HR, LaFromboise T, Lutterbaugh JD, et al. [Identifying DNA methylation biomarkers for non-endoscopic detection of Barrett's esophagus\(https://stm.sciencemag.org/content/10/424/eaao5848.short\)\(/external-link-policy\)](https://stm.sciencemag.org/content/10/424/eaao5848.short). Sci Transl Med 2018 Jan 17;10(424).

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EsoCheck™ Esophageal Cell Co



The EsoCheck™ device consists of a vitamin-sized encapsulated balloon on a silicon catheter that can be easily swallowed. The patient swallows the small balloon attached to a silicon tube and it travels down the esophagus to the stomach. Once the capsule reaches the stomach, the balloon is inflated and withdrawn through the gastro-esophageal junction and 3-5 cm (1-2 inches) into the esophagus. Surface textures on the balloon collect a gentle brushing of the lower esophagus mucosa. The balloon is collapsed back into the capsule, protecting the sample from dilution and contamination as the device is pulled back through the upper esophagus, throat, and mouth. Overall, the exam takes under 5 minutes and can be performed in a physician's office by a nurse assistant without sedation.

"One of the keys to this early detection device is the ability to sample tissue from only the lower esophagus in a noninvasive manner," said Sudhir Srivastava, PhD, MPH, chief of the NCI DCP Cancer Biomarkers Research Group, which supported this research through the EDRN. "EsoCheck fills that need."

In the first-in-human clinical trial, the combination of the balloon-based device and a DNA test of methylated vimentin plus methylated CCNA1, showed over 90% sensitivity (correctly identifying people with Barrett's esophagus) and 90% specificity (correctly identifying people without Barrett's esophagus.) This showed that the less invasive device and new DNA test were as accurate in finding the condition as testing by endoscopy.

The DNA test was further refined and moved into use at the University Hospitals Cleveland Medical Center Pathology Department. The technology and test were licensed to [Lucid Diagnostics](https://www.luciddx.com/) for commercial development with the swallowable balloon device commercialized as EsoCheck™ and the methylated DNA diagnostic test as EsoGuard™.

The EsoCheck™ device was awarded FDA 510K clearance in 2019, demonstrating it as safe and effective prior to marketing. In February 2020, FDA gave the test and device combination an FDA Breakthrough Device Designation, allowing patients faster access to the technology because it is more effective in finding a "life-threatening or irreversibly debilitating human disease or condition."

"The EsoCheck/EsoGuard combination shows how the NCI-sponsored biomarker discovery and validation process can lead to new discoveries, new technologies, and new clinical products," said Markowitz. "Ultimately, critical collaborations are vital to creating products that lead to preventing deaths through earlier detection of precancers and cancers that in later stages are largely untreatable and cause death."

Several large multicenter clinical trials are evaluating the combination's efficacy, safety, and patient tolerability in patients with Barrett's esophagus, who have had previous endoscopies, or in people with GERD who have not. The technology is also being further validated in a [LucidDx sponsored national trial](https://clinicaltrials.gov/ct2/show/NCT04293458?term=esocheck&draw=2&rank=3) aimed at winning FDA clearance for the EsoGuard DNA diagnostic assay.

Clinical Trials Under Way Using EsoCheck and EsoGuard

- [Genetic Determinants of Barrett's Esophagus and Esophageal Adenocarcinoma \(FBE\) by BETRNet](https://clinicaltrials.gov/ct2/show/NCT00288119)
- [Efficacy of EsoGuard on Samples Collected Using EsoCheck Versus EGD for the Diagnosis of BE \(ESOGUARDBE1\)](https://clinicaltrials.gov/ct2/show/NCT04293458) by Lucid Diagnostics Inc.