

## DIAGNOS-TECHS GASTROINTESTINAL HEALTH PANELS AND CALPROTECTIN

### Gastrointestinal Health Panels

Diagnos-Techs Regular and Expanded Gastrointestinal Health Panels (GI-1 and GI-2) include 15-22 separate screening tests to measure overall GI health and function. Stool and saliva samples are submitted by the patient after home collection.

To ensure high sensitivity and specificity of pathogenic organism detection, Diagnos-Techs employs state-of-the-art MALDI-TOF equipment, capable of identifying over 4,000 specific microorganisms – 100 times more than standard laboratories are able to identify. This testing method is found primarily in advanced reference laboratories and provides extremely rapid and accurate results.

Diagnos-Techs GI Health Panels include comprehensive testing of three stool samples to ensure the most accurate results. We evaluate for dysbiosis, GI pathogens, inflammatory markers, mucosal immunity, occult blood, and GI functional markers. In addition, our GI Health Panels provide non-invasive, immune detection of specific parasites, bacteria, and food sensitivities via saliva markers including sIgA and IgG.

These GI Health Panels strike a balance between comprehensive screening and economy by bundling appropriate individual tests that would otherwise cost over \$900 at current prices. All the tests are insurer reimbursable with the appropriate provider documentation and coverage. In addition, follow up modular testing via Diagnos-Techs Flexi-Matrix test kits will allow for retesting of one or several abnormal findings without repeating an entire panel.

The GI Health Panels can be incredibly valuable in the assessment of patients with abdominal distress. Due to the ease of administration and modest cost, both the Regular and Expanded GI Health Panels might well be considered before other more cumbersome investigations.

### Fecal Calprotectin

Calprotectin is a sensitive and specific marker for inflammation in the gastrointestinal tract. Elevated fecal calprotectin may occur in inflammatory bowel disease, diverticulitis, celiac disease, acute gastroenteritis, NSAID-induced enteropathy, and colon cancer. In patients with symptoms of more severe irritable bowel syndrome, calprotectin is useful to help differentiate IBS from IBD. Calprotectin also may be used to monitor



treatment efficacy for patients diagnosed with IBD.

Calprotectin can be ordered as a stand-alone test, or combined with a GI Health Panel.

### About DiagnosTechs™

Established in 1987, Diagnos-Techs™ Clinical & Research Laboratory is considered the leading international salivary based testing and research laboratory. In 1989, Diagnos-Techs was the first laboratory to introduce saliva hormone testing into routine clinical practice, creating a powerful tool for evaluating stress and hormone related disease and illness. In 1995, Diagnos-Techs added saliva and stool based gastrointestinal and food sensitivity testing.

Diagnos-Techs continues to refine and improve our testing standards, using cutting edge technology and methods. Our commitment to assisting health care professionals in restoring patients' health and wellness is unsurpassed with over 1.2 million specimens tested per year. Diagnos-Techs tests are considered the platinum standard for salivary testing worldwide. In addition, Diagnos-Techs offers other non-invasive laboratory testing, including stool testing for digestive health and urine testing for bone health.

### FIRST PATIENTS AT VANDERBILT UNIVERSITY MEDICAL CENTER IMPLANTED IN ENDOSTIM'S LESS GERD CLINICAL TRIAL FOR GASTROESOPHAGEAL REFLUX DISEASE (GERD)

NASHVILLE, TN and DALLAS, TX – Vanderbilt University Medical Center (VUMC) and EndoStim, Inc., announced that the first patients in Nashville, Tennessee have been implanted with the EndoStim

*(continued on page 66)*

(continued from page 64)

device in the Lower Esophageal Sphincter Stimulation for GERD (LESS GERD) trial. The EndoStim system is a minimally-invasive implantable device designed to provide long-term reflux control by restoring normal function to the esophagus through neurostimulation.

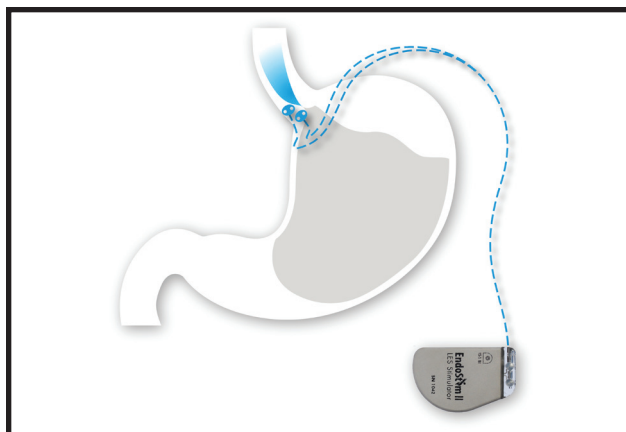
**EndoStim(R)LES Stimulation Therapy  
(PRNewsFoto/EndoStim)**

GERD affects nearly 65 million people in the United States<sup>1</sup>. It occurs when stomach acid or other stomach contents flow back into esophagus, often caused by a weak valve, or sphincter, between the esophagus and the stomach called the lower esophageal sphincter (LES). Frequent and troublesome symptoms can include heartburn, regurgitation, sleep disruption, vocal impairment and respiratory complications. Most GERD is successfully treated with acid blocking medications such as proton pump inhibitors (PPI). However, nearly 30 percent of patients on PPI medication continue to suffer from symptoms. The traditional anti-reflux surgery is laparoscopic fundoplication surgery, a procedure in which the surgeon wraps the top of the stomach around the lower esophagus to reinforce the lower esophageal sphincter. While typically effective, fundoplication can cause significant side effects.

The LESS GERD trial will evaluate the safety and efficacy of the EndoStim Lower Esophageal Sphincter (LES) Stimulation System in patients with gastroesophageal reflux disease (GERD) who experience symptoms despite taking high-dose proton pump inhibitor (PPI) medications.

“GERD disrupts the lives of millions of Americans, and many continue to suffer from symptoms like heartburn and regurgitation even when taking PPI medications,” commented Dr. Vaezi, M.D. Ph.D., Professor of Medicine at VUMC and a principal investigator in the study.

“We are excited to start the LESS GERD Clinical trial at Vanderbilt University Medical Center to generate evidence for a novel new treatment for Chronic GERD, an undertreated disease that is disrupting the lives of millions of patients worldwide,” said Rohan Hoare, Ph.D., President and Chief Executive Officer of EndoStim. “Unlike many common treatment options that work to alleviate GERD symptoms, EndoStim targets the underlying pathophysiology of GERD with the potential to restore normal function to the lower esophageal sphincter (LES).”



**About the Lower Esophageal Sphincter Stimulation for GERD (LESS GERD) Trial**

The LESS GERD trial will examine the effects of the EndoStim LES Stimulation System on GERD outcomes such as: esophageal acid exposure; GERD symptoms (heartburn and regurgitation); ability to avoid dependence on PPI medications; and the effect on overall quality of life. A minimum of 110 subjects will be implanted with the EndoStim device. The study is open to GERD patients who are between the ages of 22 and 75; have been diagnosed with GERD; have taken daily PPI medication and whose GERD symptoms are not completely resolved or have side effects from the PPI; and have had no prior surgery involving the esophagus.

**Patients seeking information on the trial should visit:  
[lessgerd.com](http://lessgerd.com)**

**About EndoStim**

EndoStim is a medical device company based in Dallas, Texas, and Nijmegen, The Netherlands, developing and commercializing a revolutionary treatment for GERD. The EndoStim LES Stimulation System is CE Marked for patients with gastroesophageal reflux disease with symptom duration of six months or longer, and is available in a number of countries throughout Europe, Latin America, and Asia Pacific. The EndoStim system is not approved for sale in the US and is limited by US federal law to investigational use only.

**For more information, visit:  
[endostim.com](http://endostim.com)**

1. National Institute of Diabetes and Digestive and Kidney Diseases, Definition and Facts for GER and GERD, <http://www.niddk.nih.gov/health-information/health-topics/digestive-diseases/ger-and-gerd-in-adults/Pages/definition-facts.aspx>. Accessed June 9, 2016.