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**New Method for Detection of Precancerous Cells in Heartburn Patients
Can Help to Prevent Esophageal Adenocarcinoma, the Most Rapidly Growing Form
of Cancer in the U.S.**

NEW YORK – March 24, 2011 – An important advance in the fight against esophageal adenocarcinoma is being reported in the March issue of *Digestive Diseases and Sciences*, the official journal of the Gastroenterology Research Group. Two large nationwide multi-center studies found that the addition of a specialized brush biopsy with computer-assisted laboratory analysis of the specimen (EndoCDx®) to the standard upper endoscopy procedure already performed on over 8 million Americans with heartburn each year, increased the detection of both Barrett’s esophagus and esophageal dysplasia (still-harmless, but precancerous cells) by over 40%. This large increase in detection was found in both academic centers and in community-based gastroenterology practices.

This large increase in detection of both Barrett’s and dysplasia was accomplished in just a few minutes, and with no increase in false positives or risk to the patient. When detected at this early, precancerous stage, development of esophageal cancer can typically be prevented.

"Seeking dysplasia in a segment of Barrett's esophagus is like looking for the proverbial needle in a haystack. Academic centers tend to perform numerous forceps biopsies on each of the high risk patients that they follow. The fact that the brush biopsy with computer-assisted tissue analysis was found to increase detection by over 40% in even these highly experienced esophageal GI specialty centers demonstrates the potential of this technique," said Sharmila Anandasabapathy, MD, Chief of Endoscopy at The Mount Sinai Medical Center in New York and lead author of the academic study.

“If you have frequent heartburn and have never had an upper endoscopy you should make an appointment for one today, especially if you are over 50. If you have had an upper endoscopy and no Barrett’s or dysplasia was found, but your heartburn symptoms have persisted, our study teams have found that the new brush biopsy technique may discover abnormal cells which may have been missed by standard biopsy procedures.” said Jerome D. Waye, MD, former President of the American College of Gastroenterology and of the American Society for Gastrointestinal Endoscopy, and a study author.

“These two large studies demonstrating the same high degree of benefit from addition of the brush biopsy in two very different patient populations are extremely convincing. There is no reason not to include this test as part of every upper endoscopy with biopsy,

and it will soon be available through all of our member hospitals and GI ambulatory surgery centers” said Bruce Wenig, MD, Chairman of Pathology at Continuum Health Partners (Beth Israel Medical Center Hospital, Roosevelt Hospital, and St Luke’s Hospital in New York). Dr. Wenig was not a participant in the study.

The number of Americans diagnosed with esophageal adenocarcinoma has increased 600% over the last 25 years. It is now the fastest growing form of cancer in the U.S., and its incidence is rising faster than breast cancer, prostate cancer, or melanoma. Esophageal adenocarcinoma is also one of the most lethal of cancers, with a five year survival rate of less than 20%.

Background on Esophageal Adenocarcinoma (EA) and Why Standard Upper Endoscopy Often Fails to Detect its Precancerous Precursors:

Many cases of esophageal adenocarcinoma (EA) are preceded by chronic heartburn. About 30 million Americans report having heartburn at least twice a week. This condition, also known as GastroEsophageal Reflux Disease or GERD, is not only uncomfortable but potentially dangerous. About 10% of patients with GERD, or 3 million Americans, will develop small areas of altered cells in their esophagus. This condition, known as Barrett’s esophagus, is not harmful in itself. However, each year about 0.5% of people with Barrett’s will develop esophageal cancer from the Barrett’s area of their esophagus.

The current standard of care for preventing EA is for patients with chronic heartburn to see a gastroenterologist every three years for an upper endoscopy of their esophagus. During this procedure, which is typically performed under sedation in the doctor’s office or ambulatory surgery center, the doctor will biopsy any areas that appear suspicious for Barrett’s esophagus using a small forceps that is passed down the endoscope. Patients who are found to have Barrett’s esophagus may then have this procedure performed annually during which the Barrett’s area is now repeatedly biopsied to try to detect any precancerous cells (known as dysplasia) that may be within it. As is true with many other cancers, detection and removal of these precancerous (dysplastic) cells can prevent esophageal cancer before it can actually start. For this reason upper endoscopy is performed on over 8 million Americans with heartburn each year.

Gastroenterologists have long known that the very small forceps that they can pass through the narrow biopsy channel of an endoscope can take only a limited, and often random, tissue sample; hence many cases of Barrett’s esophagus and dysplasia are currently being missed.

“A long segment of Barrett’s esophagus is usually appreciated during endoscopy, however, previous studies have shown that a very short segment of Barrett’s, which is often not suspected visually is also typically missed by the forceps biopsy”, said Dr. Wayne.

These two studies tested the esophageal brush biopsy on two widely different patient populations and practice settings to determine its benefit at both points where the current forceps biopsy can fail to detect precancerous disease. In one study performed at eight primary care GI centers, the brush biopsy was tested for its ability to increase the detection of Barrett's esophagus in patients whose only symptom was chronic heartburn or GERD. In the other study, conducted at four academic referral centers on high risk patients, the brush biopsy was tested for its ability to increase the detection of precancerous dysplasia. In both studies the large increase in detection provided by addition of the brush biopsy was approximately the same.

About CDx Diagnostics

CDx Diagnostics (www.cdxdiagnostics.com) is the world's leader in the prevention of cancer of the oral cavity, pharynx, larynx and esophagus through early detection of their pre-cancerous precursors. Clinicians use CDx patented brush biopsy instruments to non-invasively collect a wide area, disaggregated tissue specimen of the entire thickness of the suspect epithelium. This unique tissue specimen is then subjected to specialized, computer-assisted laboratory analysis. These life-saving tests are nationally available to gastroenterologists, otolaryngologists, oral surgeons, periodontists, and dentists. CDx Diagnostics includes tests developed and provided by CDx Laboratories, Inc., Oral Cancer Prevention International, Inc., and its U.S. and international laboratory affiliates. For further information please call (201) 843-5600.