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July 2014

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Cairn launches non-invasive Gastric Emptying Breath Test for measuring rate of gastroparesis in adults

Published on March 30, 2016 at 9:59 AM

Cairn Diagnostics, formerly known as Advanced Breath Diagnostics (ABDiagnostics), has launched the ^{13}C-Spirulina Gastric Emptying Breath Test (GEBT). The GEBT is intended for measurements of the rate of solid-phase gastric emptying and as an aid in the diagnosis of delayed gastric emptying (gastroparesis) in symptomatic adults. The Cairn GEBT was approved by the U.S. Food and Drug Administration (FDA) on April 6, 2015. The GEBT has been validated against the method of gastric scintigraphy.

The Cairn GEBT enables the rapid and accurate diagnosis of gastroparesis, is non-radioactive and non-invasive and can be administered conveniently at a physician's office, a laboratory collection center or in a tertiary care setting.

A kit containing the specially labeled test meal and all components necessary to administer the test meal and collect breath samples is provided to the test administration site by Cairn Diagnostics. Collected breath samples are returned to Cairn's CLIA-certified clinical laboratory for analysis by gas isotope ratio mass spectrometry (GIRMS). The GIRMS platform is a validated, FDA-approved analytical system for conducting GEBT breath analyses. GEBT test results are presented in a comprehensive gastric emptying profile report and provided to the ordering clinician.

"While scintigraphy has historically been used to confirm the diagnosis of gastroparesis, it requires referral to specialized outpatient centers and exposes patients to radiation," said Kerry Bush, president and chief operating officer, Cairn Diagnostics. "As a result, scintigraphy is frequently used later in the diagnostic pathway, if at all. Diagnosis is challenging because symptomology is a poor predictor of the presence or absence of gastroparesis. Symptoms may be the same for different itiologies of gastroparesis and other conditions such as dyspepsia, GERD and peptic ulcer disease often present with the same constellation of complaints that accompany gastroparesis. This challenging pathway contributes to patients often being treated empirically.However,without confirmation of delayed gastric emptying, clinical outcomes may be uncertain and add additional burden to the patient."

Gastroparesis

It is estimated that there are 5.8 million patients with suspected gastroparesis in the United States. The most common forms are diabetic, idiopathic and post-surgical gastroparesis, which is sometimes associated with vagotomy and vagus nerve injury. Some pharmacologic agents, especially narcotic opiate analgesics, anticholinergic agents and some diabetic medications cause gastroparesis. In diabetics, glycemic control is important as glucose levels greater than 200 mg/dl may induce gastroparesis. Post-viral infection gastroparesis may occur. Other rarer causes of gastroparesis include diseases affecting neural control (such as Parkinson's, amyloidosis and paraneoplastic disease).

Principles of GEBT

The Cairn GEBT helps to identify gastroparesis by measuring the rate of excretion of a special form of carbon dioxide in the patient's breath. Patients consume a precisely-formulated egg mixture containing pharmaceutical-grade Spirulina platensis, a safe and nutritional blue green algae, that has been enriched with carbon-13. Carbon-13 is a rare and naturally occurring, safe, non-radioactive form of carbon. Consuming the ^{13}C-enriched test meal gives rise to $^{13}CO_2$. The rate of $^{13}CO_2$ excretion at any measurement time t is proportional to the rate of gastric emptying.

Cairn GEBT Manufacturing Process

The Cairn GEBT is a product that has both medical device and drug components. Manufacturing activities are conducted in strict compliance with FDA regulations as mandated in the Code of Federal Regulations, Title 21 - Food and Drugs. Specifically, manufacturing is conducted consistent with the applicable requirements of 21 CFR Part 4 - cGMP for Combination Products, 21 CFR Parts 210 & 211 - cGMP in Manufacturing, Processing, Packing or Holding of Drugs and Finished Pharmaceuticals and 21 CFR Part 820, Quality System Regulation.

Source:

http://www.cairndiagnostics.com/