

FDA Update Product News

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## **<sup>13</sup>C-Spirulina Gastric Emptying Breath Test Aids in Gastroparesis Diagnosis**

A new, in-office test consisting of powdered eggs, blue-green algae and a breath analysis can now help gastroenterologists diagnose gastroparesis safer and more quickly than by scintigraphy.

The <sup>13</sup>C-Spirulina Gastric Emptying Breath Test (GEBT) requires no special training, according to Cairn Diagnostics, which manufactures the noninvasive test. Gastroenterologists can administer the test in the office, obtain laboratory results faster and, most notably, diagnose gastroparesis accurately without using radioactive equipment unlike the scintigraphy method, the company said in a press release.

“While scintigraphy has historically been used to confirm the diagnosis of gastroparesis, it requires referral to specialized outpatient centers and exposes patients to radiation,” Kerry Bush, president and chief operating officer of Cairn Diagnostics, said in a press release.

The test, which was approved by the FDA in April 2015, takes about 20-25 minutes to administer. Patients are given a test meal consisting of a mixture of formulated eggs; *Spirulina platensis*, a blue-green algae rich in naturally occurring carbon-13; saltines; and water. “You come in for breakfast, so to speak,” Mr. Bush said. Three breath samples are collected over a four-hour period and shipped to Cairn’s clinical laboratory for analysis. Results are returned to physicians within two to three days, he said.

Gastroenterologists can use the GEBT for a wide range of patients with delayed gastric emptying, such as those with diabetes, reflux disease and peptic ulcers. However, people who are allergic to eggs or have serious conditions, such as chronic pulmonary disease or celiac disease, should not be administered the test. Patients with inflammation or serious lung disease may generate inadequate breath samples for gastroparesis diagnosis, Mr. Bush added.

Cairn is scheduled to debut the GEBT at this year’s Digestive Disease Week, in San Diego.

—Mia Garchitorena