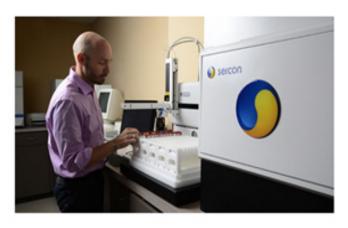


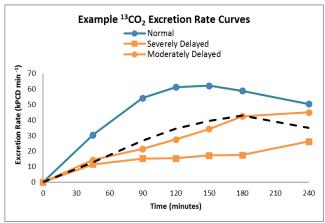
Application note 019

Monitoring Gastric Emptying via a Simple Non-invasive Breath Test

¹³C breath tests offer a non-invasive, non-radioactive alternative to many other diagnostic techniques. Gastroparesis (delayed gastric emptying) is often diagnosed via scintigraphy a costly, cumbersome procedure that must be performed in specialized outpatient centers and exposes the patient to radiation-emitting compounds. Alternatively, the rate of emptying can be much more easily determined by administering the patient with a ¹³C labeled substrate, and monitoring the expelled ¹³CO₂ in the patient's breath on a Sercon ABCA.

The Cairn ¹³C-Spirulina Gastric Emptying Breath Test (GEBT) is the only FDA-approved breath test used in the diagnosis of gastroparesis. The kit contains a specially formulated meal of dehydrated scrambled eggs containing pharmaceutical-grade spirulina, enriched in ¹³C. The Sercon ABCA is a high performance, high sample throughput isotope ratio mass spectrometer, the accepted gold standard for breath testing since 1999 and offers the highest accuracy and performance available for ¹³C breath testing.





Breath samples are collected from the patient, before and after eating Cairn's GEBT meal, and analysed via isotope ratio mass spectrometry on a Sercon ABCA. After administration of the meal, the labeled by-products of the ¹³C-Spirulina (proteins, carbohydrates and fats) are absorbed and metabolized, giving rise to ¹³CO₂ which is expelled in the breath. The rate of ¹³CO₂ excretion is proportional to the rate of gastric emptying. This simple non-invasive test is an effective means of measuring gastric emptyting, and has been validated against scintigraphy.

Cairn Diagnostics GEBT using Sercon's ABCA is FDA approved and both the GEBT kit and Sercon's ABCA are CE marked medical devices. Cairn Diagnostics analyses breath samples in a CLIA certified lab.

¹³ C	Sample	Specification (Standard Deviation)
Ref Gas Injection Precision	100% CO ₂ (n=5)	≤0.05‰
Ref gas in tubes precision	10ml 5% CO ₂ (n=5)	≤0.05‰
Breath Precision	Breath in Exetainer (n=5)	≤0.1‰
Linearity	10 to 20ml 5% CO ₂ in Exetainer	≤0.3‰ change



