

INTERPRETING CAIRN GASTRIC EMPTYING BREATH TEST RESULTS



¹³C-SPIRULINA GASTRIC EMPTYING BREATH TEST

CAIRN ¹³C-SPIRULINA GASTRIC EMPTYING BREATH TEST RESULTS

The Cairn Gastric Emptying Breath Test (GEBT) measures the rate of ¹³CO₂ excretion after consumption of a ¹³C-enriched test meal.

The patient's ¹³CO₂ excretion rate at any measurement time "t" is calculated and reported using the GEBT metric "kPCD." The acronym kPCD stands for "1000 X Percent Carbon-13 Dose (PCD) excreted per minute." A kPCD value is calculated at each GEBT measurement time. Calculations incorporate the patient's gender, age, height and weight.

PRINCIPLES OF INTERPRETING GEBT RESULTS

A. kPCD Values:

At any measurement time t, the kPCD value (¹³CO₂ excretion rate) is proportional to the rate of gastric emptying. Increasing kPCD values represent increasing rates of gastric emptying.

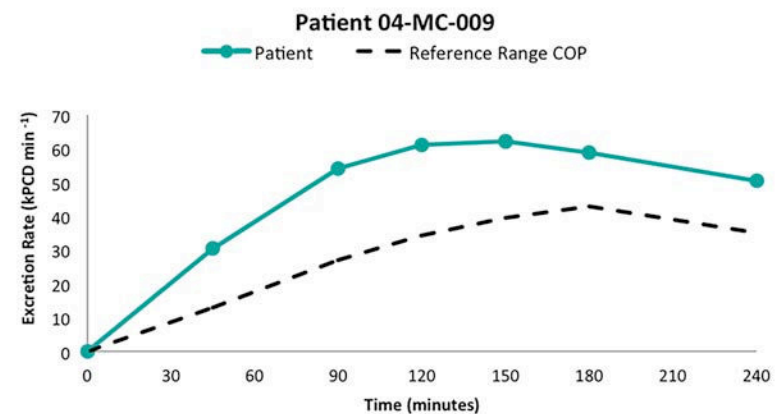
B. Graphical Display of kPCD Values:

The kPCD value (¹³CO₂ excretion rate) is calculated for each of the patient's breath collection time points. The values are tabulated and reported relative to time-specific cutoff points (COPs). A plot of the patient's kPCD values vs. time is graphically displayed.

C. Interpretation of Graphical Display:

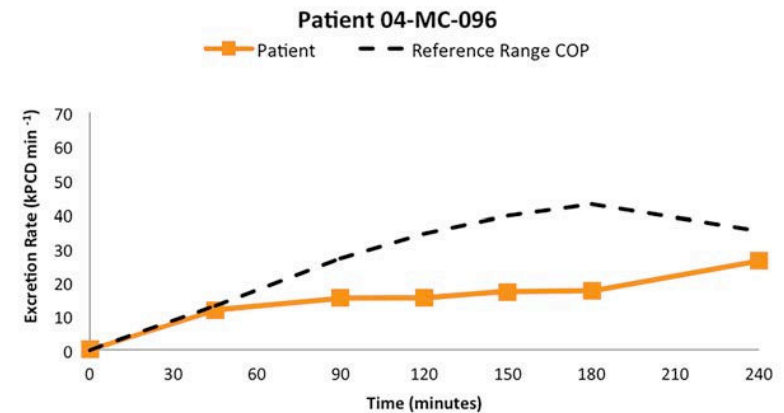
1. Subjects with NORMAL rates of gastric emptying (Exhibit I) typically display kPCD values that exceed time-specific COPs, reach a maximum kPCD value between 120 – 180 minutes, and then decline.

Exhibit I: Subject with NORMAL Rate of Gastric Emptying



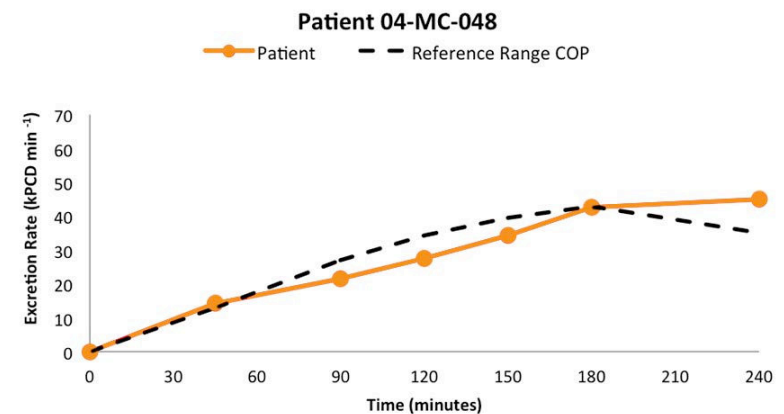
- In contrast, kPCD values of DELAYED patients (Exhibit II) are lower and typically rise continuously throughout the four-hour evaluation period. As a result, their highest kPCD value will occur at four hours.

Exhibit II: Subject with VERY DELAYED Rate of Gastric Emptying



- Because excretion curves of patients with NORMAL rates of emptying are typically declining at 180 - 240 minutes (as is the reference range derived from healthy subjects) and those of DELAYED patients are still rising at 180 and 240 minutes, kPCD values of MODERATELY DELAYED patients (Exhibit III) may rise through the cutoff points at 180 and 240 minutes. Nevertheless, the continuously rising curve with peak excretion occurring at 240 minutes is indicative of delayed emptying as verified by scintigraphy in the GEBT validation study.

Exhibit III: Subject with MODERATELY DELAYED Gastric Emptying



Gastroparesis is best identified by observing if the patient's kPCD values at either the 90, 120 or 150 minute time points are below the respective COPs, and/or if the patient's maximum kPCD value occurs at 240 minutes.

Following are the respective Test Reports for the NORMAL, Very DELAYED, and Moderately DELAYED subjects depicted above. Note that each report contains an INTERPRETATIVE GUIDELINE for reference.

SAMPLE TEST REPORT FOR SUBJECT WITH NORMAL RATE OF GASTRIC EMPTYING

CAIRN DIAGNOSTICS

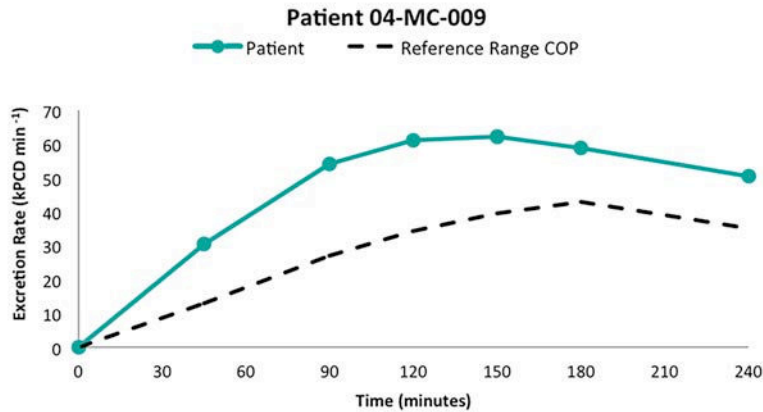
GEBT Laboratory Report

Patient ID: 04-MC-009

Customer ID: A00001

Test Administration Date: 6-Oct-2015

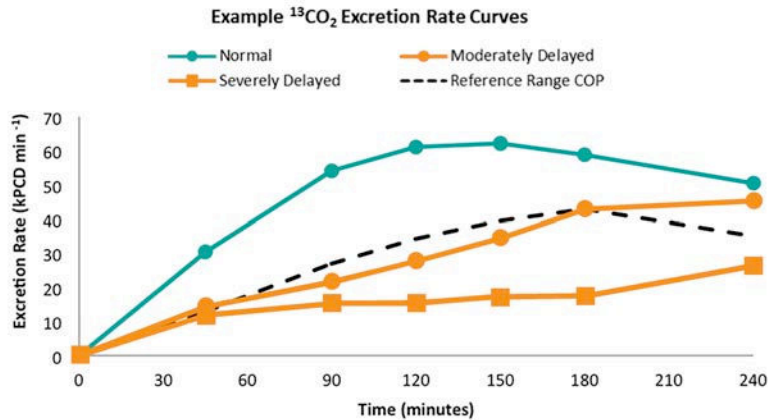
Patient Results



Time Point (minutes)	Patient ¹³ CO ₂ Excretion Rate (kPCD min ⁻¹)	Delayed Cutoff (kPCD min ⁻¹)	Patient Status
45	30.4	<12.9	Normal
90	54.2	<26.9	Normal
120	61.2	<34.4	Normal
150	62.2	<39.5	Normal
180	58.9	<43.0	Normal
240	50.4	<35.0	Normal

The maximum kPCD value occurs at 150 minutes

Interpretative Guidelines



- Increasing kPCD values (¹³CO₂ excretion rates) reflect increasing rates of gastric emptying.
- Subjects with NORMAL rates of gastric emptying typically display kPCD values that exceed cutoff points, reach a maximum between 120 – 180 minutes and then decline.
- Subjects with DELAYED rates of gastric emptying do not decline; they display lower kPCD values, typically (but not always) lower than the cutoff points, rise continuously and reach maximum excretion at 240 minutes.
- Some MODERATELY DELAYED subjects will have kPCD values that appear to be "NORMAL" at the 180 and 240 minute time points because their excretion curves are still rising at these times.

Laboratory Director

Date

Quality Assurance

Date

SAMPLE TEST REPORT FOR SUBJECT WITH VERY DELAYED RATE OF GASTRIC EMPTYING

CAIRN DIAGNOSTICS

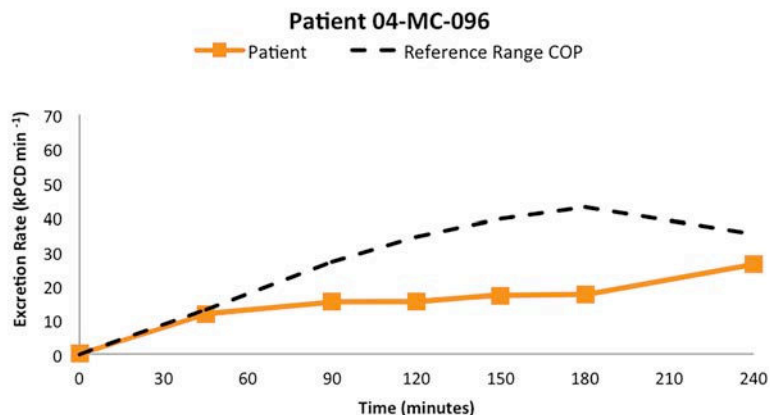
GEBT Laboratory Report

Patient ID: 04-MC-096

Customer ID: A00001

Test Administration Date: 6-Oct-2015

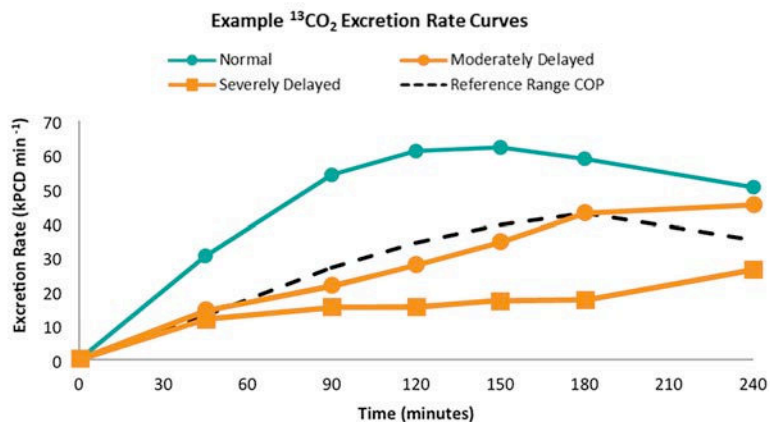
Patient Results



Time Point (minutes)	Patient ¹³ CO ₂ Excretion Rate (kPCD min ⁻¹)	Delayed Cutoff (kPCD min ⁻¹)	Patient Status
45	11.6	<12.9	Delayed
90	15.2	<26.9	Delayed
120	15.4	<34.4	Delayed
150	17.2	<39.5	Delayed
180	17.4	<43.0	Delayed
240	26.3	<35.0	Delayed

The maximum kPCD value occurs at 240 minutes

Interpretative Guidelines



- Increasing kPCD values (¹³CO₂ excretion rates) reflect increasing rates of gastric emptying.
- Subjects with NORMAL rates of gastric emptying typically display kPCD values that exceed cutoff points, reach a maximum between 120 – 180 minutes and then decline.
- Subjects with DELAYED rates of gastric emptying do not decline; they display lower kPCD values, typically (but not always) lower than the cutoff points, rise continuously and reach maximum excretion at 240 minutes.
- Some MODERATELY DELAYED subjects will have kPCD values that appear to be "NORMAL" at the 180 and 240 minute time points because their excretion curves are still rising at these times.

Laboratory Director

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SAMPLE TEST REPORT FOR SUBJECT WITH MODERATELY DELAYED RATE OF GASTRIC EMPTYING

CAIRN DIAGNOSTICS

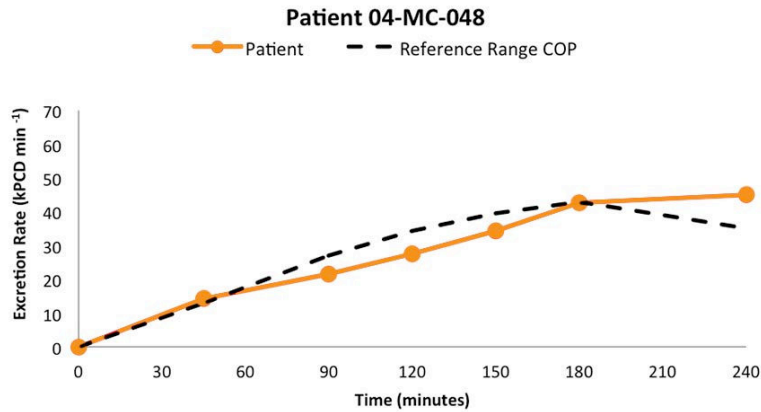
GEBT Laboratory Report

Patient ID: 04-MC-0048

Customer ID: A00001

Test Administration Date: 6-Oct-2015

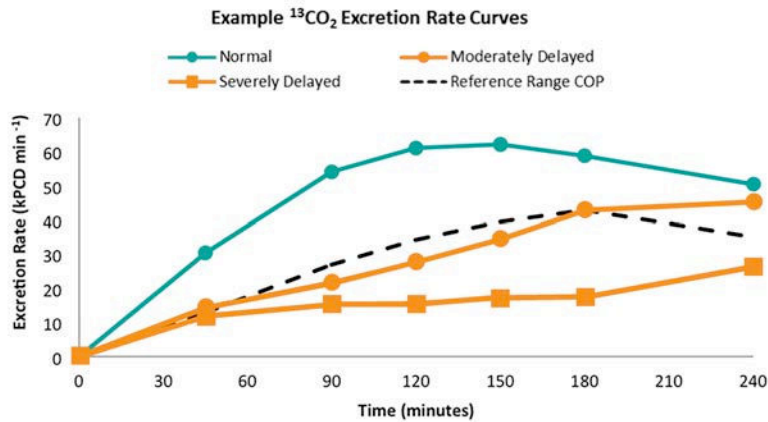
Patient Results



Time Point (minutes)	Patient ¹³ CO ₂ Excretion Rate (kPCD min ⁻¹)	Delayed Cutoff (kPCD min ⁻¹)	Patient Status
45	14.4	<12.9	Normal
90	21.5	<26.9	Delayed
120	27.5	<34.4	Delayed
150	34.3	<39.5	Delayed
180	42.6	<43.0	Delayed
240	45.0	<35.0	Normal

The maximum kPCD value occurs at 240 minutes

Interpretative Guidelines



- Increasing kPCD values (¹³CO₂ excretion rates) reflect increasing rates of gastric emptying.
- Subjects with NORMAL rates of gastric emptying typically display kPCD values that exceed cutoff points, reach a maximum between 120 – 180 minutes and then decline.
- Subjects with DELAYED rates of gastric emptying do not decline; they display lower kPCD values, typically (but not always) lower than the cutoff points, rise continuously and reach maximum excretion at 240 minutes.
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