INTERPRETING CAIRN GASTRIC EMPTYING BREATH TEST RESULTS
CAIRN $^{13}$C-SPRULINA GASTRIC EMPTYING BREATH TEST RESULTS

The Cairn Gastric Emptying Breath Test (GEBT) measures the rate of $^{13}$CO$_2$ excretion after consumption of a $^{13}$C-enriched test meal.

The patient’s $^{13}$CO$_2$ 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 ($^{13}$CO$_2$ 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 ($^{13}$CO$_2$ 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

Patient 04-MC-009

- Patient
- Reference Range COP

Excretion Rate (kPCD rate ¥ per min) vs. Time (minutes)
2. 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.

3. 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.

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

<table>
<thead>
<tr>
<th>Time Point (minutes)</th>
<th>Patient $^{13}$CO$_2$ Excretion Rate (kPCD min$^{-1}$)</th>
<th>Delayed Cutoff (kPCD min$^{-1}$)</th>
<th>Patient Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>45</td>
<td>30.4</td>
<td>&lt;12.9</td>
<td>Normal</td>
</tr>
<tr>
<td>90</td>
<td>54.2</td>
<td>&lt;26.9</td>
<td>Normal</td>
</tr>
<tr>
<td>120</td>
<td>61.2</td>
<td>&lt;34.4</td>
<td>Normal</td>
</tr>
<tr>
<td>150</td>
<td>62.2</td>
<td>&lt;39.5</td>
<td>Normal</td>
</tr>
<tr>
<td>180</td>
<td>58.9</td>
<td>&lt;43.0</td>
<td>Normal</td>
</tr>
<tr>
<td>240</td>
<td>50.4</td>
<td>&lt;35.0</td>
<td>Normal</td>
</tr>
</tbody>
</table>

The maximum kPCD value occurs at 150 minutes.

Interpretative Guidelines

- Increasing kPCD values ($^{13}$CO$_2$ 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.
Sample Test Report for Subject with Very Delayed Rate of Gastric Emptying

Cairn Diagnostics

Patient ID: 04-MC-096

Customer ID: A00001

Test Administration Date: 6-Oct-2015

Patient Results

<table>
<thead>
<tr>
<th>Time Point (minutes)</th>
<th>Patient $^{13}$CO$_2$ Excretion Rate (kPCD min$^{-1}$)</th>
<th>Delayed Cutoff (kPCD min$^{-1}$)</th>
<th>Patient Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>45</td>
<td>11.6</td>
<td>&lt;12.9</td>
<td>Delayed</td>
</tr>
<tr>
<td>90</td>
<td>15.2</td>
<td>&lt;26.9</td>
<td>Delayed</td>
</tr>
<tr>
<td>120</td>
<td>15.4</td>
<td>&lt;34.4</td>
<td>Delayed</td>
</tr>
<tr>
<td>150</td>
<td>17.2</td>
<td>&lt;39.5</td>
<td>Delayed</td>
</tr>
<tr>
<td>180</td>
<td>17.4</td>
<td>&lt;43.0</td>
<td>Delayed</td>
</tr>
<tr>
<td>240</td>
<td>26.3</td>
<td>&lt;35.0</td>
<td>Delayed</td>
</tr>
</tbody>
</table>

The maximum kPCD value occurs at 240 minutes.

Interpretative Guidelines

- Increasing kPCD values ($^{13}$CO$_2$ 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.
# 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 ($^{13}$CO$_2$ 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.