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TITLE PAGE

Protocol Title: Telehealth Administration of ^{13}C-Spirulina Gastric Emptying Breath Test (^{13}C-GEBT) Usability Study

Protocol Number: PRO-CD-046

Amendment Number: 01

Sponsor Name: Advanced Breath Diagnostics, LLC, dba Cairn Diagnostics

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1.0 STUDY SYNOPSIS

This study is intended to demonstrate that the ^{13}C-Spirulina Gastric Emptying Breath Test (GEBT) can be successfully administered via a telehealth platform. Telehealth administration of GEBT is where a trained Cairn employee uses a video link to remotely supervise the completion of the test request form, collection of breath samples, cooking and consumption of the test meal and return of breath samples by the patient to Cairn. In the FDA approved method of test administration, these activities are conducted in a clinician's facility, by an appropriately trained healthcare professional (although licensed personnel are not required).

The study will include participants from the intended use population (adults symptomatic for gastroparesis) and subsets of older and less educated participants who may be less familiar with technology, to ensure that the test is suitable for use by the people most likely to be administered the test via telehealth. All study participants will be naïve to GEBT (i.e., have never administered or been administered a GEBT before).

The study will show that there is no increased risk of adverse events when administering GEBT remotely, and that telehealth supervision of the test is adequate to allow proper collection of breath samples, preparation of the test meal, completion of the test request form and return of breath samples to Cairn and is comparable to in-office administration of the GEBT.

2.0 DEFINITIONS

Term/Abbreviation	Definition
Carbon-13	Carbon-13, denoted as ^{13}C, is a stable, non-radioactive, safe, naturally occurring form of carbon. Carbon-13 occurs in nature in a natural abundance of approximately 1%.
Carbon-12	Carbon-12 (^{12}C) is the most abundant, non-radioactive form of carbon in nature. Natural abundance is approximately 99%.
ABCA GIRMS	Automated Carbon Breath Analyzer Gas Isotope Ratio Mass Spectrometer. Used to analyze stable, non-radioactive isotopes of carbon, ^{13}C and ^{12}C, in QC gases and human breath samples. The ABCA GIRMS is an FDA-approved instrument for use with Cairn Diagnostics' ^{13}C-Spirulina Gastric Emptying Breath Test ("GEBT"). For these purposes, the instrument measures the ratio of $^{13}CO_2/^{12}CO_2$ in QC gases and human breath.
AE	Adverse Event
Delta values (δ^{13}C)	Amount of ^{13}C in a sample expressed as a ratio of carbon-13 to carbon-12: $\delta^{13}C(‰) = \frac{R_B - R_S}{R_S} * 1000$ Where R_B is the ratio of $^{13}C/^{12}C$ of the sample and R_s is the ratio of $^{13}C/^{12}C$ in Pee Dee Belemnite (PDB), the reference standard for these measurements.
DOB	Delta Over Baseline i.e. the difference in delta value at any given time point and the pre-meal/baseline delta value

Term/Abbreviation	Definition
GEBT	Gastric Emptying Breath Test. The ^{13}C-Spirulina Gastric Emptying Breath Test ("GEBT") is an FDA-PMA approved, Class III combination drug medical device in vitro diagnostic product intended for measurements of the rate of solid phase gastric emptying and identification of gastroparesis (delayed gastric emptying).
GES	Gastric Emptying Scintigraphy
PHI	Personal Health Information
SAE	Serious Adverse Event

3.0 BACKGROUND

3.1 Intended Use

The Gastric Emptying Breath Test (GEBT), to be used with the GEBT test meal, is a quantitative test intended for use in the measurement of the rate of gastric emptying of solids and to aid in the diagnosis of delayed gastric emptying (gastroparesis) in adults who are symptomatic for gastroparesis. For these purposes, the test system utilizes a Gas Isotope Ratio Mass Spectrometer (GIRMS) for the measurement of the ratio of $^{13}CO_2$ to $^{12}CO_2$ in breath samples.

The GEBT should be administered under supervision of a health care professional although no specialized facilities or specially licensed personnel are required.

3.2 Principle of the GEBT

After an overnight fast, a test meal containing non-radioactive ^{13}C-labeled Spirulina is administered to the patient. As the test meal is emptied from the stomach it is rapidly absorbed across the duodenum and metabolized giving rise to exogenous ^{13}C-labeled CO_2 which is excreted in the breath. The rate of $^{13}CO_2$ excretion in breath at any given GEBT measurement time is directly proportional to the rate of gastric emptying.

3.3 Description of the GEBT Device

Cairn's ^{13}C-Spirulina GEBT is a Class III in vitro diagnostic medical device that consists of three FDA regulated components:

- A diagnostic drug (^{13}C-Spirulina/Egg mix) that contains the active pharmaceutical ingredient (^{13}C-Spirulina) that gives rise to ^{13}C-labeled CO_2 in patients' breath when taking the test.
- A kit containing the diagnostic drug, repackaged saltine crackers, consumables used to prepare the meal, a breath collection kit (screw capped glass tubes and a straw), materials to allow return of breath samples and approved labeling (instructions for use/package insert).
- An Automated Breath Carbon Analyzer Gas Isotope Ratio Mass Spectrometer (ABCA-GIRMS) used to determine the ratio of $^{13}CO_2$ to $^{12}CO_2$ in breath samples.

3.4 Components and Pictures of ^{13}C-Spirulina GEBT Kit, Prepared Test Meal and ABCA GIRMS Instruments

The components of the ^{13}C-Spirulina GEBT are addressed below.

- ^{13}C-Spirulina Gastric Emptying Breath Test (GEBT) – Test Meal (^{13}C-Spirulina/Egg)

Ingredients: Desugared whole eggs, Dry non-fat milk solids, Salt, Smoke Flavoring (Char Oil), ^{13}C-labeled Spirulina

Nutritional value: Fat 8.8 g; Carb 4 g; Fiber 0 g; Protein 12 g

Energy value: 150 kCal

Net weight: 27 g

- ^{13}C-Spirulina Gastric Emptying Breath Test (GEBT) – Saltine Crackers (3 packages of 2 crackers)

Ingredients: Unbleached enriched wheat flour (wheat flour, niacin, reduced iron, thiamine mononitrate, riboflavin, folic acid), canola oil, palm oil, sea salt, malted barley flour, baking soda, yeast

Nutritional value: Fat 1 g; Carb 14 g; Fiber 0 g; Protein 1g

Energy value: 80 kCal

Net weight: 18g

- Overall Meal Nutritional/Energy Values

Fat 9.8 g; Carb 18 g; Fiber 0 g; Protein 13 g; 230 kCal

Table 1. Contents of ^{13}C-Spirulina GEBT Kit

Meal preparation components of Kit	Breath Sample Collection Components of Kit
1 Instructions for Use/Package Insert	1 Test Request Form
1 ^{13}C-Spirulina/Egg Meal packaged in a foil pouch with oxygen absorber	2 Blue-Capped Exetainer tubes labeled for pre-meal collection
3 packages of 2 saltine crackers re-packaged in a foil pouch with oxygen absorber	6 White-Capped Exetainer tubes labeled for post-meal collection
1 large (~13 fl oz/390 mL) microwaveable cooking cup	2 drinking straws
1 filling cup (small (~3.5 fl oz/~100 mL) plastic cup with pour spout for transferring water)	1 Breath tube holder
1 plastic cutlery kit (knife, fork and spoon)	1 Pre-labeled Bubble Mailer

Figure 1. Contents of ^{13}C-Spirulina GEBT Kit Displayed

Figure 2. Prepared ^{13}C-Spirulina GEBT Test Meal and Breath Sample Collection Components

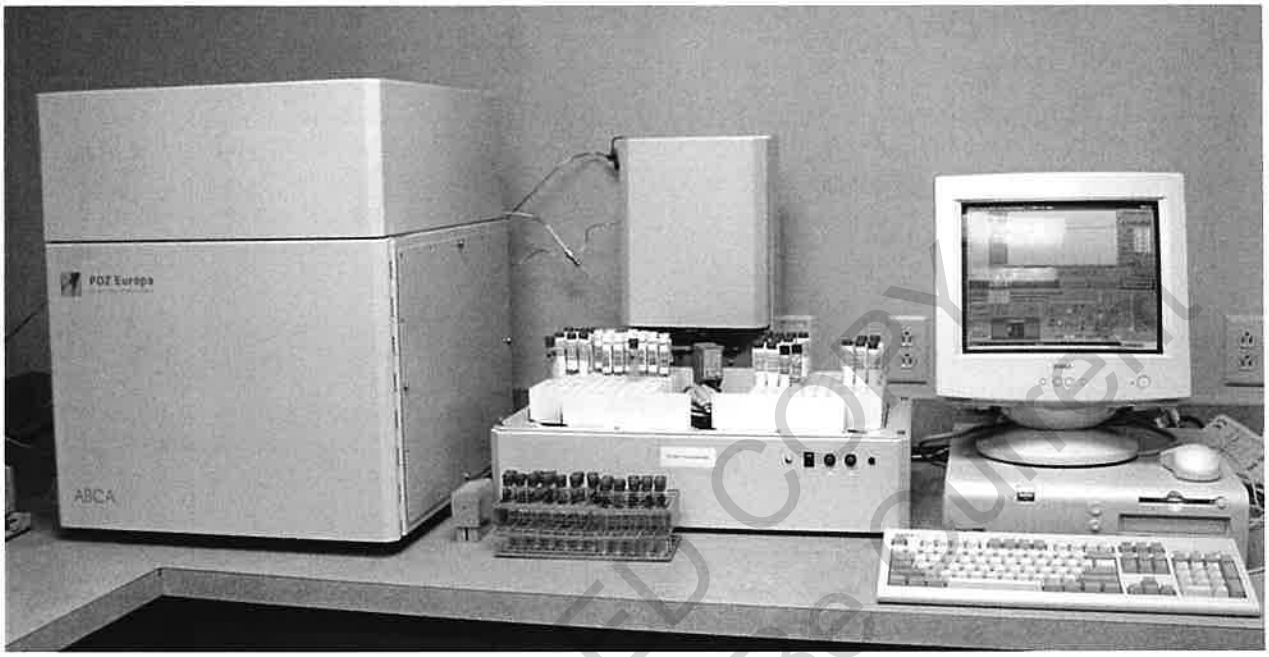

Figure 3. ABCA GIRMS instrument Approved by FDA for Use with GEBT

3.5 Summary of Relevant Clinical Studies

The GEBT was validated in FDA-approved dual-labeled validation studies. The comparative method was a nuclear medicine procedure known as Gastric Emptying Scintigraphy ("GES"). GES is conducted by administering a radionuclide-labeled test meal to a fasting patient and measuring the rate of radiation decline with time as the stomach empties the labeled test meal. In the validation studies GEBT and GES were conducted concurrently (Mayo Clinic). GEBT demonstrated excellent agreement with diagnosis by GEBT vs. GES.

The FDA approved GEBT for commercial use in April 2015 (Pre-Market Approval PMA P110015: Gastric Emptying Breath Test). Exhibit A includes the FDA's public announcement of the approval and a copy of PMA 110015 Gastric Emptying Breath Test Letter of Approval.

GEBT has an excellent safety profile with no serious adverse events reported in pre-validation, validation and post validation studies. There have been no medical device reportable (MDR) events post approval (> 5,000 GEBT).

A recent international consensus statement recommended GEBT for use in the evaluation of gastroparesis "because of its careful validation, high concordance with scintigraphic data and FDA approval" (INTERNATIONAL CONSENSUS STATEMENT: Advances in the diagnosis and classification of gastric and intestinal motility disorders. Gastroenterology and Hepatology, Volume 15, May 2018).

GEBT is currently used in the majority of Phase II, and III pharmaceutical studies for new drugs for gastroparesis. In these studies, GEBT is used to identify gastroparetic patients for enrollment and to assess physiologic effects of new pharmacologic agents (U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER); Gastroparesis: Clinical Evaluation of Drugs for Treatment; Guidance for Industry. July 2015, August 2019. Clinical/Medical).

Table 2 below summarizes key peer-reviewed literature regarding ^{13}C-Spirulina GEBT.

Table 2. Summary of Key Peer-Reviewed Literature

Publication	Brief Description
J S Lee, M Camilleri, A R Zinsmeister, D Burton, L J Kost, P D Klein. A valid, accurate, office based non-radioactive test for gastric emptying of solids Gut 2000;46:768–773	Proof of principal study in healthy subjects showing the excellent correlation of simultaneous ^{13}C-Spirulina GEBT measurements with GES.
Viramontes B, Kim M, Camilleri M, et al. Validation of a stable isotope gastric emptying test for normal, accelerated or delayed gastric emptying. Neurogastroenterology and Motility 2001; 13:567-574	In this study GEBT and GES were conducted simultaneously in subjects with conditions of delayed, normal and accelerated emptying. Data presented in this study showed a very high correlation between GES and GEBT values ($r = 0.86$; $P < 0.0001$). GEBT had a sensitivity of 86% and specificity of 80% for detecting abnormal emptying (delayed and accelerated).
Szarka L, Camilleri M, Vella A, et al. A stable Isotope Breath Test with a Standard Meal for Abnormal Gastric Emptying of Solids in the Clinic and in Research. Clinical Gastroenterology and Hepatology 2008; 8: 635-643. (Pivotal Validation Study and basis of FDA approval)	This study validated the ^{13}C-spirulina GEBT in a prospective manner among 129 symptomatic subjects meeting the criteria for referral to GES in a tertiary clinical setting This study also demonstrated that the normal, day-to-day intra-patient biologic variability of gastric emptying is the same as measured by GES or GEBT.

4.0 STUDY GOALS AND OBJECTIVES

The purpose of this study is to establish the usability of a telehealth platform for the administration of GEBT. The objectives of this study are as follows:

- To demonstrate the safety of administering the ^{13}C-Spirulina GEBT by telehealth by showing that there is no more than expected frequency of adverse events during administration of GEBT by a telehealth professional, than would be expected during administration of GEBT in a clinician's facility
- To demonstrate patient ability to prepare and administer the ^{13}C-Spirulina GEBT, under the supervision of a telehealth professional, according to instructions
- To demonstrate patient ability to complete the GEBT test request form, under the supervision of a telehealth professional, according to instructions
- To demonstrate patient ability to collect GEBT breath samples under the supervision of a telehealth professional
- To demonstrate the ability to successfully ship kits/breath samples to/from home
- To demonstrate the ability of a telehealth platform to function correctly and be used correctly by virtually supervised patients

- **Note**: The steps and order of steps for tele-supervised GEBT administration is the same as that currently conducted in doctors' offices according to approved GEBT labeling.

5.0 SUBJECT SELECTION

Cairn personnel and their family and friends may volunteer to be a participant in this study provided they are not familiar with the GEBT test administration procedure and have never been administered a GEBT test.

Participants may also be recruited from gastroenterology, multi-disciplinary, primary care or clinical research practices knowledgeable and experienced in the evaluation and treatment of patients suspected of gastroparesis (intended use population for GEBT). Participants should not have previously undergone a gastric emptying breath test.

This study requires a minimum of thirty (30) and up to fifty (50) participants. Of the participants required for this study, at least fifteen (15) must be symptomatic for gastroparesis, at least fifteen (15) must be over the age of 55, and at least fifteen (15) must have no higher than a high school education or equivalent.

5.1 Inclusion criteria

Participants are eligible to be included in the study if they meet the following criteria:

- Males and females, ≥18 years of age at the time of signing the consent form, from healthy and intended use population (i.e. symptomatic for gastroparesis). Women of childbearing potential must not be pregnant at the time of GEBT administration.
- Ability to eat test meal and provide breath samples.
- Access to a microwave oven at home
- Internet connection and telehealth accessible device (smart phone/tablet/computer with visual and voice capability) at home
- Environment to sit comfortably and quietly at home.

5.2 Exclusion criteria

Participants are **not** eligible to be included in the study if they meet any of the following criteria:

- History or physical exam suggestive of systemic disease such as pathophysiologic disorders such as renal failure, chronic heart disease, chronic respiratory disease, liver disease, or malabsorption syndrome
- History of abdominal surgery except appendectomy
- Pregnancy

- Intolerance or allergy to any component of GEBT meal
- History of neurologic or psychiatric disorders

5.3 Participant Meal and Dietary Restrictions

The participant will fast for at least 8 hours (preferably overnight) prior to administration of the GEBT. Alcohol should not be consumed within 8 hours prior to testing. The participant may consume a small amount of water up to 1 hour before the test, but not more than 4 fl oz.

Subjects should not smoke/use tobacco products (e.g. chewing tobacco, nicotine gum) before or during administration of the GEBT.

5.4 Participant Activity Restrictions

The participant will abstain from strenuous activity for at least 8 hours prior to administration of the GEBT. Participants may participate in light activities during administration of the GEBT (e.g. watching television, reading, using restroom) but otherwise will remain comfortably seated in the test administration location.

6.0 STUDY PROCEDURES/RESEARCH METHOD

6.1 Study Scheme

Visit 1: For each potential participant, perform a screening visit at the clinical study site or via the telehealth communications platform where the study is explained to the participant. Ensure that the participant is eligible to participate in the study. Answer any questions about the GEBT test procedure and ask the participant to provide consent to participate in the study (see SPEC-CD-036). The informed consent form will be signed in the presence of the research coordinator explaining the consent form. A copy of the signed consent form will be sent via fax, scan or email for the research coordinator to sign and return to the participant. Participants are free to leave the facility or log out upon completion of the screening visit.

Visit 2: Within two weeks of visit 1, participants will log into the telehealth platform using the information provided by a Cairn telehealth administrator at which time the GEBT will be administered under virtual supervision. After confirmation that the participant has met the fasting and dietary restriction requirements, the participant will begin to complete the test request form, provide baseline (PRE-meal) breath samples, prepare the GEBT test meal, consume the prepared GEBT test meal, and collect post meal breath samples at 45, 90, 120, 150, 180 and 240 minutes after consumption of the meal under the supervision and instruction of a Cairn telehealth administrator.

Visit 3: Follow up contact (e.g. phone call, email, in-person, etc) will be made with the participant within one week following the GEBT administration to assess whether there were any post-administration adverse events and to administer a patient questionnaire to complete the subject's participation in the study.

Table 3. Schedule of Activities (SoA)

Procedure	Screening (Visit 1)	Visit 2	Follow-up (Visit 3)	Notes
Informed Consent	X			
Inclusion and exclusion criteria	X			
Telehealth administration of ^{13}C-Spirulina GEBT		X		
Completion of post-test questionnaire			X	
AE review			X	
SAE review			X	

6.2 Administration of ^{13}C-Spirulina GEBT

Administer the ^{13}C-Spirulina GEBT to participants according to the instructions enclosed in the GEBT kit in the approved package insert and modified labeling under the supervision of a Cairn telehealth administrator as described in SOP-CD-028, Telehealth Administration Procedures (Exhibit E).

6.3 Analysis of breath samples

Accession samples, analyze breath samples, and generate reports using Cairn's approved ABCA GIRMS instrument according to SOP-CD-005, Breath Test Processing. Patient reports from ^{13}C-Spirulina GEBT administered according to telehealth procedures will NOT be provided to participants or referring clinicians prior to FDA approval of telehealth procedures.

6.4 Experimental Design and Analyses

6.4.1 Study population

The current intended use population for ^{13}C-Spirulina GEBT is adults, symptomatic for gastroparesis. A recent US study Syed et al., 2020 determined an overall prevalence of gastroparesis at ~0.16%. In this study, over 70% of patients diagnosed with gastroparesis were also diabetic – with the majority (~55%) comprising Type II diabetics. In addition, ~66% of patients diagnosed with gastroparesis were women. Almost 69% of gastroparetic patients were aged 50 or above. It has been shown that there is a correlation between incidence of diabetes and level of education (Borrell et al., 2006), therefore it might be expected that a significant proportion of the intended use population for ^{13}C-Spirulina GEBT may have no more than a high school level of education. In order for GEBT to be able to be successfully administered via telehealth, it must therefore be demonstrated to be usable for subjects without a college education and for older subjects, who may not have the degree of familiarity with technology that might be expected from younger subjects.

In order to ensure that the study is representative of the intended use population and of a range of expected abilities, experience and understanding of the technology and procedures required for telehealth administration of GEBT, this study will include a minimum of 15 subjects each in the following subgroups (subjects may fall into more than one subgroup):

- Subjects symptomatic for gastroparesis
- Subjects aged 55 or older

- Subjects with no more than a high school education

6.4.2 Tasks and Use Scenarios

GEBT is typically administered on a single occasion and subjects administered the test by telehealth would not be expected to become experienced in its use. Therefore, usability testing will be performed where subjects are administered the GEBT via telehealth on a single occasion, and where the subjects have never previously taken a GEBT (in office) and have no prior experience of collecting breath samples.

6.4.3 Instructions for Use

GEBT kits for use via telehealth will be the same as GEBT kits for use in office. However, additional labeling (Patient Information Sheet) will be provided with GEBTs shipped to a subject's home for administration under telehealth supervision. Copies of this labeling can be found in Exhibit F. Additional instructions for use are not needed for GEBT administered via telehealth, because a healthcare professional, trained in test administration, will remotely supervise the self-administration of the GEBT.

6.4.4 Participant Training

Participants in this study who are taking the GEBT at home, under supervision of a telehealth professional will receive no prior training in how to administer the GEBT, in the same way that patients that would be administered the GEBT via telehealth would not have had prior training. Telehealth administrators, who are Cairn employees, will be trained on telehealth administration procedures (SOP-CD-028, Exhibit E) according to standard Cairn training policies. A minimum of two and up to four different individuals trained in telehealth procedures will administer the GEBT by telehealth for this study.

6.4.5 Safety of telehealth administration of ^{13}C-Spirulina GEBT

Preliminary risk analysis of the telehealth administration procedure did not identify any increased risks of adverse events associated with telehealth administration of the GEBT compared with in-office administration of the test. This usability study will confirm that there is no more than expected frequency of adverse events during administration of GEBT by a telehealth professional, than would be expected during administration of GEBT in a clinician's facility.

6.4.5.1 Cairn's medical director will review individual adverse events reported during the study to determine whether the adverse events would have been more or less likely to occur during test administration in a physician's office.

6.4.6 Patient ability to prepare and administer the ^{13}C-Spirulina GEBT, under the supervision of a telehealth professional, according to instructions

Ability to prepare GEBT will be assessed by the telehealth administrator's observation of the patient and by a patient questionnaire (Exhibit B) regarding the GEBT that will be completed at the end of the test and returned to Cairn along with the test request form and breath samples.

6.4.6.1 The patient will be asked whether the meal preparation instructions were clear and whether the instructions on meal preparation could be improved upon (Exhibit B).

6.4.6.2 The telehealth administrator will observe and record the following (Exhibit C):

- Was the patient able to transfer the meal to the cooking cup without significant spills?
- Did the patient remove the oxygen absorber?
- Did the patient add the correct amount of water to the meal?
- Did the patient cook the egg for the correct length of time?
- Did the patient flip the egg in the middle of cooking?
- Did the egg appear to be adequately cooked?

6.4.7 Patient ability to complete the GEBT test request form, under the supervision of a telehealth professional, according to instructions

Ability to complete the GEBT test request form will be assessed by Cairn accessioning personnel upon receipt of returned breath samples and by a patient questionnaire (Exhibit B) that will be completed at the end of the GEBT.

6.4.7.1 The patient will be asked whether the test request form was easy to complete (Exhibit B)

6.4.7.2 Accessioning personnel will evaluate the returned test request form and breath samples as follows (Exhibit D).

- Was the test request form returned to Cairn in the mailer with the breath samples?
- Was the patient demographic information (including units) entered correctly on the form?
- Were pre-meal breath sample collection times recorded appropriately?
- Were meal start/end times recorded appropriately?
- Were post-meal breath sample planned and actual sample collection times calculated/recorded appropriately?

6.4.8 Patient ability to collect GEBT breath samples under the supervision of a telehealth professional

Ability to collect GEBT breath samples will be assessed by examination of GEBT results for participants (ensure adequate CO_2 in each sample/delta values follow expected pattern if collected in correct order). In addition, patients will be asked about instruction on breath sample collection.

6.4.8.1 Patients will be asked whether instructions of collecting breath samples were easy to follow (Exhibit B).

6.4.8.2 Cairn Telehealth personnel will review breath samples over the telehealth platform and note whether condensate is observed in breath tubes (Exhibit C)

(Note: breath condensate is not always visible in breath tubes, even when a sample has been collected successfully, this data is being collected for information only)

6.4.8.3 Cairn Clinical Laboratory personnel will review breath tubes received and GEBT results obtained to determine whether breath samples were collected correctly as follows (Exhibit D):

- Is condensate visible in breath tubes (see note above)?

- Does each breath sample contain a minimum of 1%CO_2 (in the case of pre-meal samples, at least one sample must contain a minimum of 1% CO_2)?
- Did the breath samples appear to have been collected in the correct order? (In correctly collected samples sets, pre-meal sample delta values will (usually) be more negative than post-meal delta values and post-meal delta values tend to increase in value over time – in normal patients, they may start to decline after 120 minutes – and in delayed patients rise to a maximum at 240 minutes).

6.4.9 Ability to successfully ship kits/breath samples to/from home

Ability to ship GEBT kits/breath samples to/from home will be assessed by surveying patients regarding shipping (Exhibit B) and by recording the dates that kits were shipped and received.

6.4.9.1 Patients will be asked whether they have any problems receiving their GEBT kit (Exhibit B)

6.4.9.2 Patients will be asked whether they had any issues returning breath samples to Cairn (Exhibit B)

6.4.9.3 Cairn personnel will record dates when each kit and breath samples are shipped/received.

6.4.10 Ability of a telehealth platform to function correctly

Telehealth platform software will be validated in a separate protocol. However, this study will verify that the software is user friendly and not subject to frequent failures during use.

6.4.10.1 Patients will be asked whether they had trouble using the telehealth platform and whether their internet connection failed during the test (Exhibit B).

6.4.10.2 Telehealth administrators will be asked whether the patient had trouble using the telehealth platform and whether the software/their internet connection failed during the test (Exhibit C)

6.5 Acceptance Criteria for Demonstration of Usability of the Telehealth Administration

6.5.1 Study population

Study includes a minimum of 15 subjects each in the following subgroups (subjects may fall into more than one subgroup):

- Subjects symptomatic for gastroparesis
- Subjects aged 55 or older
- Subjects with no more than a high school education

6.5.2 Safety of telehealth administration of ^{13}C-Spirulina GEBT

There are no more/more severe adverse events than would have been expected to occur during in-office administration of ^{13}C-Spirulina GEBT.

6.5.3 Patient ability to prepare and administer the ^{13}C-Spirulina GEBT, under the supervision of a telehealth professional, according to instructions

Greater than or equal to 90% of Patient questionnaires record no issues with meal preparation (Exhibit B, Section 4)
Greater than or equal to 90% of meal preparation steps (described in Exhibit C, section 1) were completed successfully.

6.5.4 Patient ability to complete the GEBT test request form, under the supervision of a telehealth professional, according to instructions

Errors in test request forms occur at a rate of ~16% for in-office test administration. There are no more errors in test request form completion than are routinely found in test request forms returned with GEBTs administered in office.

6.5.5 Patient ability to collect GEBT breath samples under the supervision of a telehealth professional

Missing breath samples occur at a rate of ~6% for in-office test administration. There is not a higher incidence of missing breath samples in breath samples collected via telehealth than are routinely found in breath samples returned from GEBTs administered in office.

6.5.6 Ability to successfully ship kits/breath samples to/from home

Kits are delivered/received by subjects in time for the scheduled breath test and breath samples and test request form are returned to Cairn/analyzed within the 28-day stability period of breath samples.

6.5.7 Ability of a telehealth platform to function correctly

There are no significant problems with the telehealth platform: majority of users find the telehealth platform to be simple to use and do not have issues with internet access.

6.6 End of Study

- Participants may withdraw from the study at any time, without prejudice
- An authorized investigator may discontinue any test subject at any time if medically indicated or in the best interest of the individual
- Participants who do not complete all components of the testing and compliance procedures will be excluded from the statistical analysis
- Withdrawn participants may be replaced to achieve the number of subjects specified
- The trial may be terminated prematurely if, in the judgement of Cairn's Medical Director, the severity or frequency of adverse events so warrants

Each participant is considered to have completed the study when they have completed the GEBT test administrations, follow-up questionnaire and AE review follow-up and all collected breath samples have been analyzed on the ABCA GIRMS system.

The end of the study is defined as the date on which all of the participants' breath samples have been analyzed on the ABCA GIRM, all participant's study questionnaires have been returned, and all follow-up (AE review) has been completed.

7.0 RISK/SAFETY INFORMATION

7.1 Established Contraindications, Warnings and Precautions of GEBT

The following contraindications, warnings and precautions have been established for the ^{13}C-Spirulina GEBT in FDA-approved labeling:

- Individuals with known hypersensitivity to Spirulina, egg, milk or wheat allergens should avoid the GEBT
- Because the GEBT is an indirect multi-compartmental method of measuring gastric emptying, GEBT results may be inaccurate in individuals compromised with

significant small bowel, pancreatic, liver, and/or lung disease. Consequently, GEBT should not be administered to patients with pulmonary dysfunction (e.g. COPD) and/or small bowl malabsorption.

- Individuals with severe lactose intolerance may wish to avoid the GEBT, as the test meal contains a small amount of lactose, approximately 2.7 grams.
- The performance characteristics for individuals under the age of eighteen (18) years have not been established for this test.
- The performance characteristics for pregnant women have not been established for this test.
- False positive and false negative results can occur with this test.
- Follow the directions for collecting breath samples carefully. Errors in the timing and/or procedures for collecting breath samples may affect test results and necessitate retesting.
- The GEBT should not be performed in individuals who have taken medications known to influence the rate of gastric emptying (e.g. erythromycin, metoclopramide, opiates and anticholinergics) within three (3) days prior to testing. Individuals should stop such medications only after consulting with and obtaining approval from their attending physician or the physician ordering the test.
- Fasting serum glucose levels of diabetic subjects should be checked before administration of GEBT and the test should only be administered to subjects with a fasting serum glucose level of <275mg/dl.
- After 24 hours there is no residual $^{13}CO_2$ signal in the breath arising from the ^{13}C label contained in the GEBT meal; thus, the GEBT may be administered as frequently as every 24 hours.
- The GEBT should not be administered within 24 hours (or the relevant washout period) of other ^{13}C breath tests (e.g. the ^{13}C-Urea breath test for H. pylori).

7.2 Potential Risk to Participant Associated with this Study

This study involves the following risks:

- Allergic reactions such as rash, itching, hives or problems breathing are a possibility if the participant were unknowingly and severely allergic to the GEBT test meal ingredients. The ingredients are 100 mg Spirulina, 27 grams of dried scrambled eggs (with nonfat milk added), saltine crackers (containing wheat) and water.

Any unanticipated problems will be reported to the IRB within ten (10) calendar days of being reported.

8.0 MONITORING AND REPORTING OF ADVERSE EVENTS/SERIOUS ADVERSE EVENTS

An Adverse Event (AE) is any untoward medical occurrence in the participant associated with administration of GEBT, whether or not considered related to GEBT.

A Serious Adverse Event (SAE) is defined as any untoward medical occurrence that:

- Results in death
- Is life-threatening
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent disability/incapacity

AE's will be reported by the participant (or, when appropriate, by a caregiver, a surrogate of the participant or the participant's legally authorized representative).

The investigator and any qualified designees are responsible for detecting, documenting and recording events that meet the definition of an AE or SAE and remain responsible for following up AEs that are serious, considered related to the GEBT test procedure or study procedures that caused the participant to discontinue the study.

8.1 Time Period and Frequency for Collecting AE and SAE Information

All AEs or SAEs will be collected from the day of each GEBT test administration until the follow-up visit as outlined in Table 3, Schedule of Activities.

In the event any serious adverse events are reported, or observed during the GEBT administration procedure, whether or not attributable to the GEBT test procedure, the event will be reported within 24 hours to the IRB and to Cairn's medical director.

The following information will be provided in writing: study protocol number, patient's identification code, date of birth, date and nature of the serious adverse event and the causality assessment. The report of an SAE will be completed and signed by the next working day.

8.2 Intensity of an Event

The intensity/severity of an event will be classified as follows:

- Mild: that is an awareness of sign or symptom, but easily tolerated
- Moderate: that is discomfort of sign or symptom, but easily tolerated
- Severe: at least partially incapacitating (or restricting usual activity)

8.3 Relationship to Study Procedures

Adverse events will be considered associated with the study procedure if the attribution is possible, probable or very likely. The relationship can be classified as follows:

- Not related: an adverse event that is not related to the study procedure
- Doubtful: an adverse event for which an alternative explanation is more likely
- Possible: an adverse event, which might be due to the study procedure
- Very likely: an adverse event which is listed as a possible adverse reaction and cannot be reasonable explained by an alternative explanation
- Unknown: it is not possible to assign the reaction to any of the above categories because of insufficient, pending or contradictory information

8.4 Follow-up of AEs and SAEs

After the initial AE/SAE report, Cairn's medical director will follow the participant at subsequent visits, contacts, etc. All SAEs and non-serious AEs of special interest will be followed until resolution, stabilization, the event is otherwise explained, or the participant is lost to follow-up.

If an adverse event results in withdrawal, the patient will be followed up until the cause of the event is established, if possible, and the outcome resolved, or the patient's condition stabilized.

8.5 Regulatory Reporting Requirements for SAEs

Prompt notification of a SAE is essential so that legal obligations and ethical responsibilities towards the safety of participants and the safety of a study intervention under clinical investigation are met.

Cairn has a legal responsibility to notify both the local regulatory authority and other regulatory agencies about the safety of GEBT. Cairn will comply with country-specific (U.S. FDA) and IRB-specific regulatory requirements relating to safety reporting.

9.0 STUDY OVERSIGHT

Qualified Cairn personnel specifically designated by Cairn's medical director, Alex Ryder, MD, PhD, will provide oversight of this study protocol and supervise all study activities. The designee will ensure that all personnel associated with the study are adequately trained in the study protocol and delegations of study duties will be given to the appropriately trained personnel.

Cairn Quality Assurance and Compliance personnel will ensure:

- The study protocol is being followed as approved by Cairn Diagnostics and the IRB
- Informed consent is being obtained before GEBT test administration is conducted
- Accurate, complete and current records are being maintained
- Responsibilities have not been delegated to unspecified or untrained personnel

10.0 PRODUCT STORAGE AND ACCOUNTABILITY

GEBT kits will be distributed to telehealth study participants as needed for the study. Only participants enrolled in the study may receive the GEBT kits. Upon receipt, GEBT kits must be stored at room temperature and used within two weeks of receipt.

The kits have an expiry date and should not be used beyond the expiration date displayed on the GEBT test kit box. Collected breath samples should be stored at room temperature. Kit shipping, receipt, usage or destruction will be recorded in the proper GEBT kit inventories to assure all kits are accounted for during the study.

11.0 DATA MANAGEMENT

11.1 Breath Sample Analysis

Perform sample analysis on the participants breath sample using the ABCA GIRMS system according to SOP-QC-017, Operation, Calibration and Maintenance – ABCA GIRMS. Analysis will be conducted by trained and qualified clinical laboratory personnel with verified and documented training appropriate for operation of the ABCA GIRMS systems.

11.2 Sample retention

Retain all participant breath samples collected for at least 28 days after the sample collection date recorded on the GEBT test request form.

Dispose of the samples according to SOP-CD-021, GEBT Breath Sample Accessioning and Chain of Custody.

11.3 Data Retention

Maintain data as hard copies, scan and store electronic copies on Cairn's server.

Review all data generated during execution of the protocol for completeness and accuracy in accordance with SOP-QC-030, Data Generation and Review.

11.4 Statistical Analysis

Comparisons of rates of occurrence of errors in test administration procedures between telehealth and in-office administered tests will be performed according to accepted statistical techniques.

11.5 Reporting

Collate the results of the executed protocol, including all associated data, and document the completion of the protocol in a report. The report must be approved by the same individuals who approved the associated protocol.

12.0 IRB REVIEW/ETHICS/INFORMED CONSENT

12.1 Regulatory and Ethical Considerations

This study will be conducted in accordance with this protocol and in accordance with:

- Consensus ethical principles derived from international guidelines including the Declaration of Helsinki and Council for International Organization of Medical Sciences International Ethical Guidelines
- Applicable ICH Good Clinical Practice Guidelines
- Applicable U.S. laws and regulations

This protocol, protocol amendments, Informed Consent Form and other relevant documents (e.g. advertisements) must be submitted to an IRB/IEC and reviewed and approved by the IRB/IEC before initiation of this study.

Any amendments to this protocol will be submitted for IRB/IEC approval before implementation of changes made to the study design, except for changes necessary to eliminate an immediate hazard to study participants.

12.2 Informed Consent Process

Obtain a signed consent from the participant prior to any participation in study activities. Participants may ask questions and/or withdraw from the study at any time.

A copy of the Informed Consent Form (SPEC-CD-036) must be provided to the participant.

13.0 CONFIDENTIALITY

Assign the participant a unique identifier. Any participant's data sets that are transferred to any other party will contain the identifier only; participant names or any information which would make the participant identifiable will not be transferred.

The following steps to keep information about the participant confidential, and to protect it from unauthorized disclosure, tampering or damage:

- Verbal PHI Safeguards
  - Verbal discussions regarding the participant's information will be performed in locations that are as private as possible and reasonable measures, such as lower voices or asking unauthorized personnel to step away, will be taken to assure unauthorized personnel to not overhear conversation

- Written PHI Safeguards
  - All documents are stored in Cairn's GEBT accessioning room in locked file cabinets with limited accessibility and only authorized staff have access.
  - Clinical laboratory management identifies and documents issuance of keys to personnel that may be allowed access to Participant records.
- Inform the participant that his/her personal study-related data will be used by Cairn Diagnostics in accordance with local data protection law.
- Obtain a HIPAA authorization to collect, use and disclose the study subject's personal information and protected health information as needed to conduct the study (refer to SPEC-CD-036).

14.0 INTENDED USE OF DATA

Data obtained in this study will be used to demonstrate the usability of the ^{13}C-Spirulina GEBT when administered by telehealth procedures and to confirm that the level of risk associated with telehealth administration of ^{13}C-Spirulina GEBT is not greater than that associated with administration of ^{13}C-Spirulina GEBT according to the currently approved labeling.

15.0 EXHIBITS

A. FDA's public announcement of PMA approval of ^{13}C-Spirulina GEBT and a copy of PMA 110015 Gastric Emptying Breath Test Letter of Approval

B. Telehealth Administration of ^{13}C-Spirulina Gastric Emptying Breath Test (^{13}C-GEBT) Usability Study – Patient Questionnaire to be completed at end of ^{13}C-Spirulina GEBT
C. Telehealth Administration of ^{13}C-Spirulina Gastric Emptying Breath Test (^{13}C-GEBT) Usability Study – Telehealth Administrator Patient Ability/Compliance Questionnaire
D. Telehealth Administration of ^{13}C-Spirulina Gastric Emptying Breath Test (^{13}C-GEBT) Usability Study – Test Request Form and Breath Sample Evaluation
E. SOP-CD-028, Telehealth Administration Procedures
F. SPEC-CD-032, Patient Preparation Sheet

16.0 REVISION HISTORY

Revision Level	Brief Description of Revision(s)	Effective Date
00	Initial Document	11-05-2020
01	Updated section 6.1, visit 1 to include performing informed consent using telehealth platform and how to obtain a copy of the signed informed consent from the participant; Updated exclusion criteria to remove the exclusion of females on hormone replacement therapy other than birth control and receipt of investigational drugs; Updated Exhibit D, section 2.0 to add 180- and 240-minute time points to table	See first page of this document.

Principal Investigator Agreement:

By signing this protocol, I commit to conducting the clinical investigation in accordance with the procedure all requirements of the investigational plan, IDE regulations, other applicable regulations of the FDA, and any conditions of approval imposed by the Institutional Review Board (IRB) or FDA. I agree to abide by all of the responsibilities of investigators addressed un 21 CFR Part 812, Subpart E and Subpart G.

	NAME (Print)	SIGNATURE	DATE
Principal Investigator:	SEE	ATTACHED SD	12/14/20

B. Telehealth Administration of ^{13}C-Spirulina Gastric Emptying Breath Test (^{13}C-GEBT) Usability Study – Patient Questionnaire to be completed at end of ^{13}C-Spirulina GEBT
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	NAME (Print)	SIGNATURE	DATE
Principal Investigator:	Alex Ryder		12/14/20

FDA's public announcement of PMA approval of ^{13}C-Spirulina GEBT and a copy of PMA 110015 Gastric Emptying Breath Test Letter of Approval

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 6, 2015

MR. KERRY BUSH
PRESIDENT
ADVANCED BREATH DIAGNOSTICS, LLC
105 WESTPARK DRIVE, SUITE 150
BRENTWOOD, TN 37027

Re: P110015
Gastric Emptying Breath Test (GEBT)
Filed: July 11, 2012
Amended: September 18, 2012, December 26, 2012, April 5, 2013, September 19, 2013, May 15, 2014
Procode: PGE

Dear Mr. Bush:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Gastric Emptying Breath Test (GEBT). This device, to be used with the GEBT test meal, is intended for use in the measurement of the rate of gastric emptying of solids and as an aid in the diagnosis of delayed gastric emptying (gastroparesis) in adult humans who are symptomatic for gastoparesis. For these purposes, the test system utilizes a Gas Isotope Ratio Mass Spectrometer (GIRMS) for the measurement of the ratio of $^{13}CO_2$ to $^{12}CO_2$ in breath samples. The GEBT procedure should be administered under supervision of a health care professional although no specialized facilities or specially licensed personnel are required. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). FDA has determined that this restriction on sale and distribution is necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at three years for 20 °C - 25 °C (68 °F – 77 °F) with excursions permitted to 15 °C - 30 °C (59 °F - 86 °F). This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of this PMA is contingent upon the submission of periodic reports, required

under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84. This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final UDI rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. For more information on these requirements, please see the UDI website, http://www.fda.gov/udi.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA. In addition, the results from any post approval study should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm).

Before making any change affecting the safety or effectiveness of the device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm).

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR)

regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. Final printed labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the

amendment.

All required documents should be submitted in 6 copies, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Sunita Shukla at 301-796-6406.

Sincerely yours,

Alberto Gutierrez -S

Alberto Gutierrez
Director
Office of In Vitro Diagnostics and
Radiological Health
Center for Devices and
Radiological Health

Patient ID:_____ **GEBT ID:**_____

1.0 PATIENT DEMOGRAPHIC INFORMATION

What is your highest level of education? High school ☐ College ☐ Post-Graduate ☐

Do you have symptoms of gastroparesis (nausea, vomiting, bloating, feeling full)? Yes ☐ No ☐

Are you diabetic? Yes ☐ No ☐

2.0 RECEIPT OF GEBT KIT

GEBT ID (e.g. GEBT20000123) _____

Did you have any problems with the receipt of your GEBT kit? Yes ☐ No ☐

If yes, please describe:_____

3.0 COMPLETION OF TEST REQUEST FORM

Was the test request form easy to complete? Yes ☐ No ☐

If no, please describe why not:_____

4.0 BREATH SAMPLE COLLECTION

Were the instructions on how to collect breath samples easy to follow? Yes ☐ No ☐

If no, please share any ideas on how to clarify the process:_____

5.0 MEAL PREPARATION

Were the meal preparation instructions clear? Yes ☐ No ☐

If no, please share any ideas on how to clarify the process:_____

6.0 TELEHEALTH PLATFORM

Was the video link during the test easy to use? Yes ☐ No ☐

If no, please describe what was difficult to use:_____

Was texting communication easy to understand? Yes ☐ No ☐

Did you lose internet connection at any point during the test? Yes ☐ No ☐

What kind of internet connection were you using for the telehealth administration of GEBT?

Cable ☐ DSL☐ Satellite ☐ Cellular ☐ Other (Describe:_____) ☐ Don't know ☐

7.0 SAMPLE SHIPPING

Was it easy to return breath samples to Cairn? Yes ☐ No ☐

If no, please describe what was difficult about the shipping of breath samples?:_____

Form Completed by: _____ Signature:_____ Date:_____

Patient ID:_____ **GEBT ID:**_____

1.0 MEAL PREPARATION

Was the patient able to transfer the dry meal to the cooking cup without significant spills? Yes ☐ No ☐

Did the patient remove the oxygen absorber? Yes ☐ No ☐

Did the patient add the correct amount of water to the meal? Yes ☐ No ☐

Did the patient cook the egg for the correct length of time? Yes ☐ No ☐

Did the patient flip the egg in the middle of cooking? Yes ☐ No ☐

Did the egg appear to be adequately cooked? Yes ☐ No ☐

If the answer to any of the questions above was No, explain:_____

_____

2.0 BREATH SAMPLE COLLECTION

Were you able to observe breath condensate in sample tubes after collection? Yes ☐ No ☐

3.0 TELEHEALTH PLATFORM

Did the patient appear to have trouble using the telehealth platform? Yes ☐ No ☐

If no, please describe what was difficult to use:_____

_____

Did the telehealth session fail at any time during your test? Yes ☐ No ☐

If yes, please explain:_____

Did you lose internet connection at any point during the test? Yes ☐ No ☐

What kind of internet connection were you using for the telehealth administration of GEBT?

Cable ☐ DSL☐ Satellite ☐ Cellular ☐ Other (Describe:_____) ☐ Don't know ☐

Form Completed by: _____ Signature:_____ Date:_____

Patient ID:_____ **GEBT ID:**_____

1.0 TEST REQUEST FORM

Was the completed test request form returned with the GEBT breath samples? Yes ☐ No ☐

Was patient height recorded? Yes ☐ No ☐ Units entered? Yes ☐ No ☐

Was patient weight recorded? Yes ☐ No ☐ Units entered? Yes ☐ No ☐

Was patient sex recorded? Yes ☐ No ☐ Was patient age recorded ? Yes ☐ No ☐

Were the pre-meal breath sample collection times entered? Yes ☐ No ☐

Was the meal start time entered? Yes ☐ No ☐ Was the meal end time entered? Yes ☐ No ☐

Were all post-meal planned breath sample collection times calculated correctly? Yes ☐ No ☐

Were all post-meal actual breath sample collection times entered? Yes ☐ No ☐

Post-meal collection time	Post meal planned collection time	Post meal actual collection time	Actual time +/- 5 mins of planned time?
45 minutes	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
90 minutes	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
120 minutes	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
150 minutes	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
180 minutes	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
240 minutes	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐

2.0 BREATH SAMPLE COLLECTION

Was condensate visible in the breath tubes received? Yes ☐ No ☐

Did the breath samples contain sufficient CO_2 (i.e., >1% CO_2)

Breath Sample	>1% CO_2?
Pre-meal	Yes ☐ No ☐
45 minutes	Yes ☐ No ☐
90 minutes	Yes ☐ No ☐
120 minutes	Yes ☐ No ☐
150 minutes	Yes ☐ No ☐
180 minutes	Yes ☐ No ☐
240 minutes	Yes ☐ No ☐

Form Completed by: _____ Signature:_____ Date:_____

SOP-CD-028, Telehealth Administration Procedures (20 pages)

Effective Date: NOV 04 2020

1.0 PURPOSE

This document describes the procedures for requesting and administering the ^{13}C-Spirulina GEBT via the telehealth process.

2.0 RESPONSIBILITIES

The Client Services Manager (CSM) or CSM's designee is responsible for receiving faxed orders (prescriptions) for GEBT.

The CSM or designated Client Services Representative (CSR) schedules the patient's GEBT test procedure, arranges for delivery of GEBT kit and sends out pre-test administration communications to the patient.

The Tele-Administrator (TA) conducts the GEBT test administration procedure on the scheduled date. TA's must have documented and approved training. TA's documented training is approved by Cairn's Medical Director or a healthcare provider delegated by Cairn's Medical Director.

3.0 PROCEDURES

3.1 Physician Account Set-up

3.1.1 If an account has not been set up, refer to SOP-CD-009 "Commercial Accounts Setup" for instructions on establishing a customer account.

3.1.2 If an account has previously been established, proceed to Section 3.2 for instructions on participating in the telehealth process.

3.2 Telehealth Physician Welcome Packet & Order Form

3.2.1 For physicians, Nurse Practitioners or Physician Assistants participating in the telehealth process, send or allow access to the following documents:

- Commercial 13C – Spirulina GEBT Package Insert – CE Marked (SPEC-QA-322)

	NAME (Print)	SIGNATURE	DATE
Originator:	Shane Cabrice		10/30/2020
Approved By:	CATHERINE WILLIAMS		11-2-2020
Approved By:	SEE	ATTACHED SD	11-4-20
Approved By:	N/A	N/A SD	11-4-20

Effective Date:

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	NAME (Print)	SIGNATURE	DATE
Originator:			
Approved By:	Alex Ryder		11/3/20
Approved By:			
Approved By:			

SD
11-4-20

- Telehealth Patient Brochure (SPEC-CD-016)
- Telehealth Patient Preparation Sheet (SPEC-CD-032)
- Telehealth GEBT Intended Use, Contraindications, Warnings and Precautions (SPEC-CD033)
- Telehealth Physician Order Form (SPEC-CD-037)

3.2.2 After a completed Telehealth Physician Order Form has been received, verify that all necessary information has been included, and forward the order form to a Client Service Representative to process the order per SOP-CD-023, "GEBT Order Placement".

3.3 Initial Patient Contact – GEBT Scheduling

3.3.1 Once the Physician Order Form has been received and accepted, the CSM or CSR will call the patient to discuss scheduling the GEBT using the Welcome Call Script (Exhibit A).

3.3.2 The CSR/CSM will begin tracking patient contact using FORM-CD-036, Telehealth Patient Contact Form using information obtained during the call.

- Enter the patient name in the Patient Name field.
- Complete the GEBT ID once a kit has been selected for shipping.
- Enter the date of the Welcome Call.
- Enter the Client Services Representative Name (CSR) which is usually the person initially entering information in this form.
- Enter the Tele-administrator name.
- Complete the questions during the Welcome Call with the patient.
- Enter the appointment date and time for the scheduled GEBT.
- Enter the type of device that the patient proposes to use during the administration of the test.

3.3.3 Within one hour after the Welcome Call, the CSR/CSM completes the following activities:

3.3.3.1 Send an email using the Summary Email Template (Exhibit C) with the following information:

- A summary of the information discussed,
- Confirmation of the date and time for administration of the GEBT,
- Include the link to the information video and include the password "tummy." (https://cairndiagnostics.com/healthcare-providers/telehealth-resources/ SPEC-CD-038, "GEBT Informational Video").

3.3.3.2 Send the patient the following text which includes the date and time for the administration of the GEBT and a link to the informational video.

NOTE: Change the underlined portion to the appropriate day, date, and time of the patient's test.

Text Message Template 1

Your GEBT is scheduled on (Tuesday, August 4, 2020 at 8 a.m. EST). Please watch the patient information video prior (link included below and, in your email) to the morning of your scheduled test. The password to view the video is "tummy." https://cairndiagnostics.com/healthcare-providers/telehealth-resources/

3.3.3.3 Enter appointment date and time on FORM-CD-036, Telehealth Patient Contact Form and initial and date when the confirmation text and email have been sent.

3.3.4 Schedule the "24-hour before the test" text reminder as seen below (*change the underlined portion to the appropriate teleadministrator and the day, date, and time of the patient's test*).

Text Message Template 2

"REMINDER: Your GEBT test is scheduled for tomorrow, (Tuesday, August 4, 2020 at 8 a.m. EST) with (name of tele-administrator). Please review the patient preparation sheet. You must FAST a minimum of 8 hours prior to the test or overnight."

3.3.5 Record initials/date on FORM-CD-036, "Telehealth Patient Contact Form."

3.4 GEBT Shipment and Receipt Confirmation

3.4.1 Contact the shipping department to arrange shipment of the GEBT kit to the patient as described in SOP-CD-023, GEBT Order Placement. Include in the shipping box a copy of the **Telehealth Patient Brochure** (SPEC-CD0-16) and the **Telehealth GEBT Patient Preparation Sheet** (SPEC-CD-032). Include a copy of the completed internal order form from the shipping department with patient file. The shipping department will set up an email confirmation alert with shipper to include the CSR and CSM.

3.4.2 On the day the GEBT kit is shipped, the CSR/CSM will send the following text to the patient.

Text Message Template 3

"Your GEBT kit has been shipped on (date) and should arrive on (date)."

3.4.3 Record the GEBT ID, initials/date for kit shipped and kit shipped text message sent on FORM-CD-036, Telehealth Patient Contact Form.

3.4.4 On the expected delivery date, the CSR/CSM confirms with the shipper or shipping department that the kit was delivered.

3.4.5 Send the following text to the patient.

Text Message Template 4

"Please confirm that you have received the GEBT test kit. Reply with a YES or NO to this text."

3.4.5.1 If the GEBT kit has not arrived by the expected delivery date, contact the shipping department. Depending on if the kit is lost or just delayed, the tele-administration date may need to be rescheduled with the patient.

3.4.6 Record initials/date for kit delivered confirmation text and response on FORM-CD-036, "Telehealth Patient Contact Form."

3.5 GEBT Administration – Initial Video Call

3.5.1 On the day of the GEBT, five (5) minutes before the scheduled administration, the Tele-Administrator (TA) sends the patient the following text and/or email (based on the patient's preference).

Text Message Template 5

"To begin your GEBT test, please select link in the next text.

3.5.2 Once this text has been sent, start the video call in TigerConnect (see SOP-CD-033 for starting the video session) and wait for the patient to join the session.

3.5.3 Follow the Telehealth Administration Call Script (Exhibit B) and complete the Telehealth Meal Administration Questionnaire & Checklist (FORM-CD-037).

3.5.3.1 If any of the answers to the patient qualification questions are not satisfactory, then the test must be rescheduled.

3.5.3.2 File the completed Telehealth Meal Administration Questionnaire & Checklist in the patient file once the test administration is completed.

3.5.4 After the patient completes the meal and records the times for post-meal breath samples, schedule text messages to be delivered five minutes before each scheduled

breath collection time. There will be six texts total, one each for the 45, 90, 120, 150, 180 and 240-minute time points.

Text Message Template 6 - 11

"GET READY: The (XX)-minute breath sample should be collected at (Scheduled time). Record the actual collection time on your test administration form."

3.6 GEBT Administration – Final Video Call

3.6.1 Approximately 5 minutes after the 240-minute breath sample should have been collected, send the following text and start the video call in TigerConnect using Text Message Template 12 (already set up in TigerConnect).

Text Message Template 12

"To complete your GEBT, please select the secure link to video chat in the next text to speak with your tele-administrator."

3.6.2 Complete the test administration by reviewing all paperwork, covering the points below, and explaining how to package the breath samples.

- *Confirm the patient has collected all scheduled breath samples*
- *Review patient test request form*
- *Check that all information has been entered - including units of measure for height and weight*
- *Confirm Patient's Signature*
- *Confirm start and finish test-meal consumption times are recorded*
- *Confirm actual post-meal breath collection times are recorded and are within the +/- 5-minute time frame.*
- *View breath samples for condensation and sharpie check marks*
- *Proper packaging for return to lab*
- *Ensure test request form is placed into bubble mailer.*
- *Ask again if there are any questions and document questions/answers*
- *TA will need to encourage the patient to ship the samples back to us within 3 days, stressing that the quicker we receive them, the quicker we can analyze then and send the results to their physician.*

3.6.3 Inform the patient that after we receive the samples, the results should be uploaded to their physician within 2 business days.

3.6.4 Initial and date on FORM-CD-037, "Meal Administration Questionnaire & Checklist."

3.6.5 After completion of the tele-administration, the CSR/CSM will initial/date FORM-CD-036, "Telehealth Patient Contact Form."

3.6.6 After the patient has packaged the breath samples, schedule the following text for the next day (NOTE: Insert the shipping company name that is used for shipping):

Text Message Template 13

"Please confirm you dropped off the sample with (insert shipping company name) to be shipped to Cairn Diagnostic Laboratory. Reply with a YES or NO."

3.6.7 If the patient replies, yes, then initial and date "Breath Sample Shipping Confirmation Received" on FORM-CD-036, "Telehealth Patient Contact Form." If the patient replies no, call the patient to determine why the breath samples have not yet been shipped and attempt to help expedite return of the breath samples.

3.6.8 Once breath samples are received initial/date FORM-CD-036, "Telehealth Patient Contact Form."

4.0 REFERENCES

A.	SPEC-CD-037	Telehealth Physician Order Form
B.	FORM-CD-036	Telehealth Patient Contact Form
C.	FORM-CD-037	Telehealth Meal Administration Questionnaire & Checklist
D.	SOP-CD-009	Commercial Accounts Setup
E.	SOP-CD-023	GEBT Order Placement
F.	SOP-CD-033	Operation and Administration of the TigerConnect Telehealth Platform
G.	SPEC-CD-016	Telehealth Patient Brochure
H.	SPEC-CD-032	Telehealth GEBT Patient Preparation Sheet
I.	SPEC-CD-033	Telehealth GEBT Intended Use, Contraindications, Warnings and Precautions
J.	SPEC-CD-038	GEBT Informational Video

5.0 EXHIBITS

A. Patient Welcome Call Script
B. Telehealth Administration Call Script
C. Summary Email Template

6.0 REVISION HISTORY

Revision Level	Brief Description of Revision(s)	Effective Date
00	Initial revision.	See the first page of this document.

Welcome Call Script:

Phone call to patient after receiving Telehealth Physician Order Form

Good morning/afternoon. My name is "CSM/CSR Name" with Cairn Diagnostics, May I speak with Jane Doe?

Ms. Doe, I am calling to schedule your Gastric Emptying Breath Test, AKA GEBT, ordered by Dr. _____. It will take about 5 minutes to schedule your procedure.

Great! To get started, I need to verify some information (*which is found on the Physician Order Form*). Please confirm your:

- Name
- DOB
- Shipping address for kit shipment
- Mobile phone number
- Email

The GEBT test will be conducted at your home using a secure video link. I need to ask you a few questions to be sure we are able to conduct the GEBT at your home under the direction of one of Cairn Diagnostic's tele-administrators. (*Record on the Telehealth Patient Contact Form, FORM-CD-036*)

1. Is your mobile phone able to send and receive text messages?
2. Do you have a Smartphone/tablet/iPad or laptop with audio/video capabilities and internet access at home? What device do you plan on using for the tele-administration of the GEBT? (*choices are smartphone, tablet, or laptop*)? (*Ask what device will be used and enter on the form*)
3. Do you have a microwave that you can use on the day of the test?
4. If you are an insulin dependent diabetic, will someone be able to accompany you, or check on you, during the test?
5. After the test is finished you will need to send your breath samples back to us in a prepaid bubble mailer, which will be included in the GEBT kit. We usually use UPS. Do you have access to a UPS store nearby or do you live in a building which offers UPS pickup? (*CSR may have look up the nearest UPS drop-off location* https://www.ups.com/dropoff/). *If UPS dropoff/pickup is not available, contact the shipping department for an alternative method.*

(If the answer to questions 1-5 are all Yes, continue; if no to any one question, stop and reschedule.)

Ok, now let's get you scheduled. You will need to set aside approximately 5 hours to complete the test. Our next available appointment is "Day, Date and Time of appointment" *(e.g., Friday, August 3, 2020 at 7 am).*

You will receive a text message confirming your appointment. You will also receive an email that will include the Telehealth GEBT Patient Preparation Sheet that **must be reviewed prior to the morning of the test. It will also be provided with your kit. There are certain items that you are required to have to complete the test that are not included in the test kit**. Within this

same email you will receive a link to our patient informational video which discusses what to expect when taking the GEBT at home.

Your GEBT Kit will be shipped to the address we confirmed earlier. You will receive an automated text when the kit has been shipped, which will include the tracking number and an approximate delivery date. We will send a follow-up text within 2 or 3 days to verify that you have received the kit.

The day before your test you will receive a text message reminder. **Please be sure to review the patient preparation sheet and the patient informational video!** Thank you for scheduling your test. Do you have any additional questions? (notate any questions asked and answers given)

Step	Tele-Administrator	Form Location	Notes
1	Good Morning, my name is (*Tele-administrator Name*), and I will be your tele-administrator for the GEBT. Before we start, I have a few things I need to confirm.		
2	Please verify your Name and Date of Birth. I also need to verify your identity. Would you show me a picture ID such as your driver's license, etc.?	Section 1 Question 1	*Verify that the Name and DOB on the order form matches their answer. If it does not match write in the correct information on the form*
3	Did you receive the GEBT Test Kit? Would you read to me or show me the barcode number on the right-hand side of the kit box?	Section 1 Question 2	*This should have been confirmed ahead of time through shipping and patient text confirmation.*
4	What is the kit lot number and expiration date that are printed on the label on the left hand side of the kit box?	Section 1 Question 3	*If the kit has an expired lot number, do not proceed with the test*
5	Do you feel well enough to take the GEBT Test this morning?	Section 1 Question 4	*If not, reschedule the test*
6	Have you completed an 8-hour overnight fast?	Section 1 Question 5	*If not, reschedule the test*
7	Are you diabetic? (*If yes)* What is your blood glucose this morning?	Section 1 Question 6	**If patient's blood glucose level is >275 mg/dL, reschedule the test*
8	Do you have anyone assisting you with this test today?	Section 1 Question 7	**If they are diabetic and this response is NO, reschedule the test.*
9	Did your doctor advise you to stop taking any medications that could affect your gastric emptying rate prior to your test? (*If yes*) Have you done so?	Section 1 Question 8	**If NO patient must reschedule test*

Step	Tele-Administrator	Form Location	Notes
10	Have you received any other breath tests within the past 24 hours? If so, what was the test?	Section 1 Question 9	*If the patient received another ^{13}C breath test in the last 24 hours, reschedule the test.*
11	Are you able to sit in a quiet area and refrain from vigorous activity or exercise for the duration of the test?	Section 1 Question 10	*If not, reschedule the test.*
12	Remember that you may not eat, drink, or smoke while taking the GEBT.		
13	If we lose connection, I will call you to determine the reason for the lost connection. I will then send you a new video link. Please ensure that your phone, tablet, or laptop is charged or plugged into power and connected to a reliable Wi-Fi/internet connection. At the end of your last breath sample we will send you another video link to make sure you package the samples correctly for UPS. At this point you will be finished. Please plan for 5 hours.		*If the patient or administrator loses the connection and cannot regain a video connection, continue with a phone call explaining the procedure over the phone; if the test meal pouch and crackers have not been opened, then you may need to reschedule if unable to establish video connection.*
14	Let's begin the GEBT Administration		
15	Please wash your hands before beginning.		
16	Open the GEBT kit by breaking the red seal on the box.		

Step	Tele-Administrator	Form Location	Notes
17	Remove kit components from box. Can you confirm the following items are in the box? • 2 straws • Utensils (fork, knife, spoon, & napkin) • Large white cooking cup • 3 oz. pouring cup • 8 test collection tubes in test tube holder • 6 saltine crackers (foil pouch containing 3 packages of 2 crackers each) • ^{13}C Spirulina GEBT test meal (Foil pouch containing Spirulina/egg mix) • Test Request Form • Return pre-paid mailing envelope • Package insert information sheet • GEBT Administration Instructions	Section 2 Question 1	
18	Fill out the ^{13}C-GEBT Test Request Form. Be sure to complete your name, the test administrator's name which is (*tele-administrator's name*), date of the test which is (*today's date*), and your age, height, weight, and gender. Please ensure you indicate whether you measured your height and weight in inches and pounds or meters and kilograms. Please hold your insurance card up to the camera so I can verify your insurance information. Please sign and Date the Test Requisition Form.		*The insurance information should be with the order form but if it is not, then either copy the information on the front/back of the card or see if they can take a picture of the front/back of the card and send via the texts from TigerConnect.*

Step	Tele-Administrator	Form Location	Notes
19	Hold the breath collection tube holder in the upright position, open from the front and fold backwards to connect the tab of flap into the slit in the back of tube holder. This will enable the tube holder to stand upright.		*Make sure that the tube holder is upright via the video link; otherwise the tubes could fall on the floor.*
20	There are (2) pre meal breath test tubes capped in BLUE tops. There are (6) post meal "white capped" test tubes in different time slots, we will be collecting breath samples before and after you consume the meal.		
21	Next, unwrap a straw. You will use the same straw for the entirety of the test. There are two straws in case you need to use an additional straw. Please do not throw the straws away until the last breath sample has been collected.		
22	I will now demonstrate how to collect a breath sample, and you can practice before we start the test.		
23	Unscrew the first blue capped tube and insert the red straw. Inhale and hold your breath for about 5 seconds, then slowly exhale into the test tube while removing the straw at the same time. Replace the cap on the tube (ensure the cap is secure, but do not overtighten). Record the exact time that the samples were collected on the test request form		
24	Please check to see if there is condensation in the test tube. If you feel you did not get a good sample breath, you can redo the breath sample into the same test tube.		

Step	Tele-Administrator	Form Location	Notes
25	Use a marker (sharpie) to put a check mark on the top of each test tube used to collect a breath sample as soon as you have collected that sample or turn the tube upside down in the tube holder. This will help to ensure that you don't collect a breath sample in a tube that has already been used.		
26	If you have not done so, replace the breath sample back into the first slot in the breath tube holder.		
27	Repeat the process with the second "blue capped" pre meal breath sample tube, cap and replace in the second slot. Record the sample collection time. Again, you may check off the tube cap with a marker or place the tube upside down.		*Instruct the patient to make sure the breath tubes are in upright position before shipping back to us.*
28	Next, we are going to start the meal preparation. You will need the following: Provided with the GEBT kit • Cooking cup (large white cup), • 3 ounce pouring cup, • ^{13}C-Spirulina GEBT Test Meal pouch • Spoon from utensil packet • 3 packets of saltine crackers Not provided with the GEBT kit • Water • Microwave • Plate • Cup or glass with 6 ounces of water-to drink during test meal		
29	Open the GEBT meal pouch and remove the oxygen absorber.		

Step	Tele-Administrator	Form Location	Notes
30	Please empty packet into white cooking cup. The powder mix will look yellow/green in color.		
31	Add 3 ounces of water (use 3 oz pouring cup) into cooking cup		
32	Use the spoon to stir the mixture		
33	Place cooking cup into microwave Cook for 1 minute Remove from microwave. **Use Caution:** Cup may be hot. Flip the partially cooked egg with the spoon and cook for an additional 30 seconds. It is ok if the egg breaks apart while flipping. **Use Caution**: The egg will be hot.		*The egg may be cut into two pieces in order to flip it; make sure they don't flip it onto the floor.*
34	Flip the cup upside down on your plate and remove the cooking cup. You may cut the egg meal into pieces to help it cool.		
35	Open the crackers (6) and place on the plate		
36	Use the 3 oz measuring cup to measure 6 ounces of water into your cup or glass		*Make sure the patient has meal ready, utensils out, water poured before starting the meal so there is no delay during the meal ingestion.*

Step	Tele-Administrator	Form Location	Notes
37	Next, I want you to consume the test meal The whole meal (egg mix, crackers and water) needs to be consumed within 10 minutes for accurate test results.		*Encourage the patient to consume all the meal in the 10 minutes! Eat steady and don't distract them during the meal including anyone assisting them.* *TA will time the meal consumption to verify that it was completed in 10 minutes.*
38	When you are ready to begin eating, record the time from the clock, watch or other device you will use for keeping track of the time during the test on your test request form. Record the time that you finished consuming the test meal on the test request form	Section 2 Question 2	
39	Now we need to calculate the planned breath collection times.	Section 2 Question 3	*Administrator now calculates post-meal breath sample collection times using the meal finish time and the GEBT calculator; record calculated collection times on Telehealth Meal Administration Questionnaire & Checklist, FORM-CD-037)*

Step	Tele-Administrator	Form Location	Notes
40	Please record the post meal collection times that I read off to you in the planned collection times section of your test request form.		*Administrator tells patient to record the calculated post-meal collection times on the patient's test request form.*
41	I am going to set up automatic patient reminder breath collection texts for breath sample collection times. Although I will schedule the text messages, you will need to make sure to keep track as well so that you take the breath samples at the planned collections times.		*Schedule the post-meal text message reminders in TigerConnect; they should be scheduled for 5 minutes before the planned times.*
42	Collect post meal breath samples in white capped tubes in the same way as you collected the pre-meal samples in the blue capped tubes. Be sure to collect each breath sample in the correctly labeled tube (e.g., 45 minute sample in tube labeled 45 minutes) and don't forget to mark the cap with a marker when you have collected each sample or turn them upside down in the tube holder, so that you don't accidentally collect a two samples in one tube!		
43	Record the actual time at which you collect each breath sample on the test request form. Breath samples must be collected within 5 minutes of the planned collection time for the results of the test to be accurate!		
44	After you collect your final breath sample at _____time, I will send you a text message or an email containing a video link so that I can check your test request form and explain shipping instructions for your breath samples.	Section 3 Questions 1-7	*Schedule the reminder texts for collecting breath samples in TigerConnect using the text templates (see Section 3.6)*

---------- **END OF VIDEO CALL** ----------

Dear _____,

It was a pleasure speaking with you this morning. Your test is scheduled for _____(date) at _____(time). Please watch the patient information video prior (link included below) to the morning of your scheduled test. The password to view the video is "tummy." https://cairndiagnostics.com/healthcare-providers/telehealth-resources/ Please review the information below and feel free to contact us if you have any additional questions.

When you receive the kit, do not open the GEBT kit before your virtual meeting with your tele-administrator! Store the GEBT kit in a cool dry place until you are ready to take the test.

Patient Preparation

- The GEBT must be taken after an overnight (minimum eight (8) hours) fast. This means that you must not consume any food or drink, including alcohol and coffee for at least eight (8) hours prior to starting the test.
- You may consume a small amount of water up to 1 hour before the test (e.g., if you need to take your regular medication), but not more than 4 fl oz (100 mL).
- Do not smoke/use tobacco products (e.g. chewing tobacco, nicotine gum) before or during administration of GEBT.
- Do not undertake any vigorous activity within 8 hours prior to the test. During the test, limited walking is allowed, when necessary, e.g., use of restroom.
- The GEBT procedure should be performed in a comfortable environment. You should sit quietly, for the duration of the test. The whole test takes approximately 5 hours. You are allowed to read a book, watch TV, use a laptop/tablet.

Failure to follow all of these directions could result in inaccurate GEBT results!

Items/Information Required for Taking GEBT

- GEBT Kit (supplied by Cairn Diagnostics)
- Drinking Water
- Microwave
- Drinking Cup
- Plate
- Your Current Weight/Height
- 100% charged device (or plugged into power supply during the test) with internet access for telehealth administration, i.e. iPhone/Smartphone, Tablet/iPad, Laptop with audio/video capabilities
- A quiet place to sit for 5 hours
- Insurance Card and ID
- Glucometer (only if you are diabetic)

If you have any questions prior to taking your test, please refer to Cairn's website: www.cairndiagnostics.com.

You can also email or call (8am – 4pm Central Standard Time) our helpdesk:

helpdesk@cairndx.com

+1 615 376 5464 X 605

SPEC-CD-032, Patient Preparation Sheet (3 pages)

CAIRN DIAGNOSTICS	DOC No. SPEC-CD-032.00
SPEC: Telehealth GEBT Patient Preparation Sheet	**Page 1 of 2**

Effective Date: NOV 05 2020

Material Title: Telehealth GEBT Patient Preparation Sheet	**Material Code:** L109
Material Description: GEBT information sheet for patients and physicians to review prior to enrolling a patient in the telehealth program. FDA approved Telehealth Patient Preparation Sheets are made up of the following: 1. Text that matches attached example. 2. Text printed in color. 3. Form printed on front of one sheet of 8 ½" x 11", white paper (SPEC-QA-012, MatCode C010).	
Supplier: Cairn Diagnostics	**Supplier Material Code:** L109
Expiration/Retest: N/A	**Storage Conditions:** Limited Access Storage
Sampling Plan: 1. First article: inspect the first printed copy of the labeling according to SOP-QA-008, "Labeling Printing and Storage". 2. Final release/inspection: 100% inspection of printed labeling	
Acceptance Criteria: First article inspection: 1. Text to match example. Printed in color. Printed on one sheet of 8 ½" x 11", white paper (SPEC-QA-012). 2. Text is legible and does not smear. Final release/inspection: 1. Labeling is legible. 2. Quantity printed is correct.	

	NAME (Print)	SIGNATURE	DATE
Originator:	Shane Crabtree		10/24/2020
Approved By:	Alex Ryan		10/26/20
Approved By:	CATHERINE WILLIAMS		11-2-2020
Approved By:	N/A	N/A SD	11-5-20

Reference:

A. SPEC-QA-012 Label Stock 8 1/2" X 11"

Revision History:

Revision Level	Brief Description of Revision(s)	Effective Date
00	Initial document.	See the first page of this document.

CAIRN Diagnostics
GEBT

GEBT Telehealth Patient Preparation Sheet

- Do not open the GEBT Kit until your virtual meeting with the tele-administrator.
- Store the kit in a cool dry place until you are ready to take the test.

Patient Preparation

- The GEBT must be taken after an overnight (minimum eight (8) hours) fast. This means that you must non consume any food or drink, including alcohol and coffee for at least eight (8) hours prior to starting the test.
- You may consume a small amount of water up to 1 hour before the test (e.g., if you need to take your regular medication), but not more than 4 fluid ounces (100 mL).
- Do not smoke/use tobacco products (e.g., chewing tobacco, nicotine gum) before or during the test.
- Do not undertake any vigorous activity within 8 hours prior to the test.
- The GEBT procedure should be performed in a comfortable environment. You should sit quietly for the duration of the test. The whole test takes approximately 5 hours. You are allowed to read, watch tv, use a laptop or any other quiet activity.

Failure to follow all of these instructions could result in an inaccurate GEBT result!

Items/Information Required for taking GEBT

1. GEBT Kit (supplied by Cairn Diagnostics)
2. Drinking Water
3. Microwave
4. Drinking Cup
5. Plate
6. Your current weight/height
7. 100% charged device (or plugged into power supply during the test) with internet access for telehealth administration, i.e. iPhone/Smartphone, Tablet/iPad, Laptop with audio/video capabilities
8. Insurance Card and ID
9. Glucometer (only if are diabetic)

If you have any questions prior to taking your test, please refer to Cairn's website: www.cairndiagnostics.com.
If you have any questions, you may also respond to any of the test messages you receive or email (helpdesk@cairndx.com) or call (8 am – 4 pm CST) the Cairn help desk at 615-376.5464 ext. 605.