Covenant Health Laboratory Policy	FACILITY: Covenant Medical Center/Covenant Children's Hospital
	DEPARTMENT: Laboratory
	SECTION: General Laboratory
	AUTHOR: Natalie V. Najera, MS, MT(ASCP) MB, SBB
TITLE: H. Pylori Breath Test Specimen Collection	

STATEMENT OF PURPOSE:
The BreathID® Smart System is intended for us to non-invasively measure changes in the $^{13}CO_2/^{12}CO_2$ ratio of exhaled breath, which may be indicative of increased urease production associated with active *Helicobacter pylori* (*H. pylori*) infection in the stomach.
The BreathID® Smart System is indicated for use as an aid in the initial diagnosis and post treatment monitoring of *H. pylori* infection in adult patients and pediatric patients ages 3-17 years old.

SUMMARY AND EXPLANATION:
Since the initial identification of *H. pylori* in the early 1980s, the management of upper gastrointestinal disease has changed dramatically. "*Helicobacter pylori* is now recognized as an important pathogen and a causal relationship between *H. pylori* and chronic active gastritis, duodenal ulcer, and gastric ulcer is well documented."
Currently there are numerous *H. pylori* detection technologies for upper gastrointestinal disease including biopsy and serum analysis. These technologies depend on two general approaches for obtaining a sample for testing: invasive and non-invasive. 13C-urea breath tests provide a non-invasive and non-hazardous analysis of the exhaled breath. The BreathID® test measures the $^{12}CO_2$ and $^{13}CO_2$ components of the exhaled breath before and after the oral ingestion of ^{13}C-enriched urea. This establishes the baseline ratio of $^{13}CO_2/^{12}CO_2$ and the post ingestion ratio of $^{13}CO_2/^{12}CO_2$ in order to determine the Delta Over Baseline (change in the $^{13}CO_2/^{12}CO_2$ ratio).

TEXT:

1. Specimen Requirements:

Breath sample bags (One Baseline and one Post Ingestion)

i. The analysis of the breath samples should be conducted within 14 days after breath collection.
ii. The filled breath sample bags should be stored at 15° - 30°C protected from direct sunlight or sharp objects.
iii. If desired, use the provided sample transport bag for transport of the breath samples.

2. Materials Needed:

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Materials Provided

- **i.** A single BreathID® IDkit Hp® Two which contains:
  - **ii.** One package insert
  - **iii.** One tablet of ^{13}C-enriched urea, 75mg
  - **iv.** One packet of 4.3g (4g citric acid, aspartame, Tutti Frutti flavoring) of Citrica Powder
  - **v.** One straw for drinking
  - **vi.** One drinking cup
  - **vii.** One blue BASELINE Breath Sample Bag for BASELINE breath collection prior to ingestion of test substrate
  - **viii.** One gray POST INGESTION Breath Sample Bag for 15 minutes POST INGESTION breath collection
  - **ix.** One large sample transport bag provided to store/ship both Breath Sample Bags
  - **x.** Four barcode labels (one for each Breath Sample Bag and two for the requisition form)
  - **xi.** One Quick User Guide showing the basic steps of administering the test (may be printed on the inside of the box)

Materials Needed But Not Provided

Timer
Tap water

3. Shelf Life and Storage:

Store at 25°C; excursions permitted to 15-30°C. The following components of the test kit have expiration dates. Do not use either of these components beyond the expiration date stated on the respective labels:

1) The ^{13}C-urea tablet
2) The Citrica Powder

4. Entire Procedure:

i) Collecting the specimens

(1) Patient Preparation

(a) Confirm that the patient has fasted for at least one hour prior to testing.

(b) Confirm that the patient has NOT taken antimicrobials, proton pump inhibitors (PPI) or bismuth preparations within two weeks prior to administering the test.

(c) If PPIs are used within two weeks of breath testing, false negative test results may occur, and the test should be repeated two weeks after discontinuation of PPI treatment.
(d) Explain to the patient that the Citrica contains 84mg of phenylalanine per packet of Citrica Powder. Phenylketonurics restrict dietary phenylalanine.

(2) Prepare for Collecting the Sample
(a) Verify that the entire package is intact and contains all the materials necessary.
(b) Identify the two Breath Sample Bags (the blue BASELINE bag and the gray POST INGESTION bag).
(c) Label each bag with the appropriate identification information.

(3) Collection of the BASELINE breath sample:
(a) Remove the cap from the mouthpiece of the blue BASELINE bag.
(b) Instruct the patient to take a deep breath, hold their breath for 4 to 5 seconds and then exhale directly into the mouthpiece of the blue BASELINE breath bag until completely full.
(c) If the bag is not full, repeat step (b).
(d) Replace the cap on the bag of the mouthpiece and firmly press until it clicks and is securely locked into place.
(i) Note: If the patient has not held their breath for 4 to 5 seconds or does not fill the bag completely, there is a possibility a test result will not be obtainable.
(ii) Note: The bag is not fully closed if the cap does not click into place. Not fully closing the bag may cause the breath sample to slowly leak out.

(4) Preparing the test drink:
(a) Dissolve the Citrica Powder and the ^{13}C-enriched urea tablet in 5.1 to 6.8 oz. (150 to 200 ml) of tap water in the provided drinking cup.
(b) Close the lid firmly using both hands. Place fingers over lid and shake thoroughly for a few minutes, until the Citrica Powder and the ^{13}C-urea tablet are completely dissolved.
(i) Note: Tiny particles may remain visible after thoroughly mixing. However, if more substantial particulate matter is still present after five minutes of mixing, discard the solution and repeat the procedure with a new kit.
(ii) Note: Administer the test drink within two hours of preparation, as this is the maximal time for maintaining solution stability.

(5) Administering the test drink:
- (a) Give the prepared test drink to the patient.
- (b) Ensure that the patient drinks the solution through the provided straw.
- (c) The patient, including pediatric patients aged 3-17 regardless of age and body weight, must drink the solution within two minutes and consume the entire amount.
- (d) After the patient finishes drinking the solution, record the present time plus another 15 minutes in the Time to Fill field on the gray POST INGESTION bag and start the timer for 15 minutes.

(6) Collection of the POST INGESTION breath sample:
- (a) Fifteen minutes after the administration of the test drink (but not later than 20 minutes after administration) remove the cap from the mouthpiece of the gray POST INGESTION bag.
- (b) Instruct the patient to take a deep breath, hold their breath for 4 to 5 seconds and then exhale directly into the mouthpiece of the GRAY INGESTION bag until it is full.
- (c) If the bag is not full repeat step (b).
- (d) Replace the cap on the bag mouthpiece and firmly press until it clicks and is securely locked into place.
  - (i) Note: If the patient has not held their breath for 4 to 5 seconds or does not fill the bag completely, there is a possibility a test result will not be obtainable.
  - (ii) Note: The bag is not fully closed if the cap does not click into place. Not fully closing the bag may cause the breath sample to slowly leak out.

(7) Storage of Breath Sample Bags for future measurement:
- (a) Assure both filled Breath Sample Bags are correctly labeled, and all fields are complete for future identification.
- (b) Place both filled Breath Sample Bags (the blue BASELINE bag and the gray POST INGESTION bag) into the provided sample transport bag.
- (c) Until analyzed, Breath Sample Bags should be stored at room temperature (15-30°C, 59-86°F), protected from direct sunlight and sharp objects, for up to 14 days. Refrain from applying any external pressure on the Breath Sample Bags.

5. Limitations and Performance Considerations:

i) For in vitro diagnostic use only. The ^{13}C-urea tablet and Citrica Powder are dissolved

in a glass of water and the resulting solution is taken orally as part of the diagnostic procedure.

ii) Phenylketonurics: Contains Phenylalanine, 84 mg per dosage unit of Citrica Power.
iii) In the case of accidental overdose – drink water and call the physician.
iv) A negative result does not rule out the possibility of *H. pylori* infection. False negative results can occur with this procedure. If clinical signs suggest *H. pylori* infection, retest with a new sample or an alternate method.
v) A false positive test may occur due to urease associated with other gastric spiral organisms observed in humans such as *Helicobacter heilmanni.*
vi) A false positive test could occur in patients who have achlorhydria.
vii) Antimicrobials, proton pump inhibitors, and bismuth preparations are known to suppress *H. pylori*. Ingesting these medications within two weeks prior to performing the breath test may produce false negative test results.
viii) Post treatment monitoring of *H. Pylori* should be performed after at least six weeks of treatment for *H. pylori* infection. Earlier assessment may give false results.
ix) Safety and effectiveness in patients under the age of 3 years have not been established.
x) Data is insufficient for recommending the use of this test on patients with total or partial gastrectomy.
xi) Data is insufficient for recommending the use of this test on pregnant and lactating women.
xii) A correlation between the number of *H. pylori* organisms in the stomach and the BreathID® test results has not been established.

6. References

i) Meridian BioScience IDkit Hp® Two for BreathID® Hp Lab System and BreathID® Smart System package insert, Issued July 2022, Rev. 07