



Client Communication

Helicobacter pylori Urea Breath Test Manufacturer Change

Clinical Pathology Laboratories (CPL) has implemented the Gulf Coast Scientific™ PyloPlus® Urea Breath Test (UBT) for detection of *Helicobacter pylori* to replace the Meridian/Otsuka™ BreathTek® UBT. The Meridian/Otsuka™ assay has been discontinued by the manufacturer. CPL’s validation has determined that:

- The PyloPlus® UBT and BreathTek® UBT use the same methodology, infrared spectrophotometry of CO₂ isotopes in breath samples before and after ingestion/metabolism of 75mg of ¹³C Urea in a citric acid solution.
- The performance characteristics of the PyloPlus® UBT and BreathTek® UBT tests are equivalent.
- As results are qualitative (Positive/Negative), the result reporting and reference interval are unchanged.
- There are minor changes to the collection kit and instructions. Those are given in detail below.

Effective March 1, 2023, distribution will begin transitioning to PyloPlus® UBT collection kits. Clients may be supplied with the PyloPlus® or BreathTek® UBT collection kits depending on availability of supplies. During this transition, the BreathTek® UBT collection devices will be run on the Meridian/Otsuka platform and incoming PyloPlus® UBT will be run on the Gulf Coast Scientific spectrophotometer platform without delays to testing. CPL has validated PyloPlus® UBT for the following tests.

Test Code	Name
5591	H PYLORI BREATH TEST
5653	H PYLORI (BREATH), PEDIATRIC

Pediatric Specimens

Gulf Coast Scientific™ PyloPlus® UBT is an FDA-cleared test on adult patients 18 years or older. CPL has validated the method for pediatric patients, <18 years of age. For pediatric samples, there will be an added message on the report indicating that the performance characteristics of the assay have been validated by CPL which is authorized to perform high-complexity laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Please review your report for specific method notes.



Gulf Coast Scientific™ PyloriPlus® UBT Procedure

1. Materials provided in each PyloPlus Kit:



- a. One pouch of ¹³C-urea powder
 - b. One packet of citric acid flavoring
 - c. Test instructions
 - d. One Quick Reference Instructions (QRI)
 - e. Two breath collection bags, one blue bag for the BASELINE sample and one red bag for the POST sample
 - f. One drinking straw
 - g. One sample transport bag
2. Materials needed, but not provided
- a. A 15-minute timer
 - b. Potable water
 - c. Cup able to measure 100mL of water
3. Patient Preparation
- a. The patient should have fasted at least 1 hour before administering the PyloPlus Kit.
 - b. Antimicrobials/antibiotics, Proton Pump Inhibitors (PPI), Bismuth preparations and Histamine Receptor antagonists (HRA) are also known to suppress *H. pylori* and may produce false-negative results. Any positive, while on those preparations should be considered a true positive. Upon the advice of their provider, patients should refrain from taking:
 - i. Antibiotics (e.g., Flagyl, Metronidazole): 2 weeks
 - ii. PPI's (e.g., Nexium, Prevacid, Zegerid and Prilosec): 2 weeks
 - iii. Bismuth preparations (e.g., Pepto-Bismol, Kaopectate and Pink Bismuth): 2 weeks
 - iv. HRA's (e.g., Pepcid, Zantac, Axid, Tagamet): 2 days

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4. Step-By-Step Procedure

- a.** Time intervals listed in the following step-by-step procedure are critical.
- b.** Verify that the patient has been prepared for the test as specified above. If the patient is not appropriately prepared, contact the ordering clinician for further instructions.
- c.** Open the PyloPlus Kit, which should contain all the materials listed in 2.1. Label each breath collection bag to maintain patient identification using a felt tip permanent marker. Include the specimen date and time of collection.
- d.** Collect the BASELINE breath sample according to the following steps:
 - i.** Pick up the blue breath collection bag.
 - ii.** Remove the twist-off cap from the mouthpiece of the breath collection bag.
 - iii.** Instruct the patient to: (1) breathe normally; (2) take a deep breath then hold their breath for 10 seconds; (3) partially exhale into the room, before fully exhaling into the mouthpiece of the bag.
 - iv.** Replace the cap firmly on the mouthpiece of the bag.
 - v.** NOTE: if the patient has not held their breath for 10 seconds, or does not fill the bag completely, there is a possibility a test result will not be obtained.
 - vi.** 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 leak, invalidating the result.
- e.** Prepare the ¹³C-urea solution no more than 50 minutes before administering it to the patient. Urea slowly decomposes in water.
 - i.** Pick up the citric acid flavoring packet and tear open. Place contents of flavoring packet into ¹³C-urea pouch by tearing open the pouch and carefully pouring contents of the flavoring packet into the open ¹³C-urea pouch.
 - ii.** Add approximately 100 mL drinking water (about 1/3 full) to the ¹³C-urea pouch.
 - iii.** Close the Ziplock feature of the ¹³C-urea pouch securely and shake the mixture for 30 seconds.
 - iv.** Instruct the patient to drink all of the drug solution with the straw provided directly from the ¹³C-urea pouch, without stopping. Advise the patient NOT to 'rinse' the inside of their mouth with the drug solution before swallowing. Discard the straw after the patient has finished drinking the drug solution.
- f.** Set the timer for 15 minutes. The patient should sit quietly and should not eat, drink, or smoke during the 15-minute interval.
- g.** After 15 minutes have elapsed, pick up the red (pink) breath collection bag. Collect the POST-SAMPLE breath sample according to the instructions above.

References

PyloPlus® UBT Kit for PyloPlus® UBT System Breath Test for Detection of *H. pylori*. Package Insert. Gulf Coast Scientific™. REV_B