Helicobacter pylori Urea Breath Test- Manufacturer Change

Effective August 28, 2023, Clinical Labs of Hawaii (CLH) will transition to the Gulf Coast Scientific™ PyloPlus® Urea Breath Test (UBT) for detection of Helicobacter pylori, which will replace the Meridian/Otsuka™ BreathTek® UBT. The Meridian/Otsuka™ assay has been discontinued by the manufacturer. CLH's validation has determined that:

- The PyloPlus® UBT and BreathTek® UBT use the same methodology: infrared spectrophotometry of CO_2 isotopes in breath samples before and after ingestion/metabolism of 75mg of ^{13}C 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.
- The test code will remain the same.

H. PYLORI BREATH TEST: WHPYBT (1164)

- PyloPlus® UBT is an FDA-cleared test on adult patients 18 years or older. CLH 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 CLH which is authorized to perform high-complexity testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Please review your report for specific method notes.
- The test manufacturer indicates that there is insufficient data to recommend the use of this test on pregnant and lactating women.
- There are minor changes to the collection kit and instructions (outlined on page 2 for your reference)
- Patient preparation remains the same:
    - The patient should have fasted at least 1 hour before administering the PyloPlus® kit.
    - 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:
        - *Antibiotics (e.g. Flagyl, Metronidazole): 2 weeks*
        - *PPI's (e.g. Nexium, Prevacid, Zegerid, and Prilosec): 2 weeks*
        - *Bismuth preparations (e.g. Pepto Bismol, Kaopectate, and Pink Bismuth): 2 weeks*
        - *HRA's (e.g. Pepcid, Zantac, Axid, Tagamet): 2 days*
- Collection is performed at select CLH locations by appointment. Please visit our website at www.clinicallabs.com for a complete list of these locations.

Gulf CoastScientific™ PyloPlus® UBT Procedure

1. Collect baseline sample by having the patient inhale, hold their breath for 10 seconds; then slightly exhale before fully exhaling into the baseline bag. Place cap securely on the bag to prevent any loss of sample.

2. Empty the contents of the citric flavoring packet into the urea test pouch and fill about 1/3 with water. Shake for 15 seconds to thoroughly mix.

3. Have the patient drink the solution using the included straw.

4. Wait 15 minutes; then collect the second breath sample in the second breath collection bag. Place cap securely on the bag to prevent any loss of sample.

References:

1. PyloPlus® UBT Kit for PyloPlus® UBT System Breath Test for Detection of H. pylori. Package Insert. Gulf Coast Scientific™. REV_B.
2. False negative urea breath tests with H2-receptor antagonists: interactions between Helicobacter pylori density and pH - PubMed (nih.gov)

If you have any questions, please contact our Client Services Department at 808-677-7998 (toll free at 1-866-281-6816). You may also contact your CLH sales/marketing representative.

Thank you for choosing Clinical Labs of Hawaii