Test Definition: UBT

H. pylori C Urea Breath Test

Overview

Useful For

Diagnostic testing for *Helicobacter pylori* infection in patients suspected to have active *H pylori* infection

Monitoring response to therapy

This test **is not appropriate** for asymptomatic people.

Testing Algorithm

See Helicobacter pylori Diagnostic Algorithm in Special Instructions

Special Instructions

- Helicobacter pylori Diagnostic Algorithm
- Pediatric UHR Calculation Information

Method Name

Infrared Spectrophotometry (SP)

NY State Available

Yes

Specimen

Specimen Type

Breath

Ordering Guidance

An alternative test for the diagnosis of active *Helicobacter pylori* infection in patients is the HPFRP / *Helicobacter pylori* with Clarithromycin Resistance Prediction, Molecular Detection, PCR, Feces, which requires a different collection.

Necessary Information

A completed Pediatric UHR Calculation Information card **is required** for patients between 3 and 17 years old. Testing may be delayed if this information is not received with the specimen.

Specimen Required

Patient Preparation:

1. Patient should be fasting for 1 hour.

2. Patients should not have taken bismuth/Tritec, antibiotics, proton-pump inhibitors (eg, Prilosec, Prevacid, Aciphex, Protonix, and Nexium) or Pepto-Bismol for 2 weeks prior to testing. If these instructions are not followed, test results may be inaccurate.

3. Histamine 2-receptor antagonists (H[2]RAs) such as Pepcid, Tagamet, Axid, or Zantac should be discontinued for 24 to 48 hours before the BreathTek UBT test is administered. If these instructions are not followed, test results may be inaccurate.

4. Carafate (sucralfate) does not interfere with the test. Use of antacids does not affect the accuracy of this assay.

Supplies: H. Pylori Breath Kit (T375: fees apply)

Collection Instructions:

1. **Do not** collect if patient is younger than 3 years of age.

2. Follow instructions included with kit.

Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:

-Microbiology Test Request (T244)

-Gastroenterology and Hepatology Client Test Request (T728)

-General Request (T239)

Specimen Minimum Volume

Bag of "breath" must be full

Reject Due To

No specimen should be rejected.

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Breath	Ambient	7 days	BREATH TEST BAG

Clinical and Interpretive

Clinical Information

The causal relationship between the urease-producing bacterium, *Helicobacter pylori*, and chronic active gastritis, duodenal ulcer, and nonulcer dyspepsia is well established. Conventional methods for the diagnosis of active *H pylori* infection include evaluation of biopsied gastric tissue by histopathology and culture. Less invasive assays include testing for the presence of *H pylori* by polymerase chain reaction (PCR) in stool specimens and detection of *H pylori* urease production by the urea breath test (UBT). Serologic testing for the presence of IgM/IgG/IgA-class antibodies to *H pylori* is also performed; however, this is not recommended by either the American College of Gastroenterologists nor the American Gastroenterological Association (AGA) as an accurate marker for active disease. These serologic markers can remain elevated despite resolution of active disease and may lead to misdiagnosis and inappropriate treatment.

Recommendations for use of the (13)C-UBT (Meretek) were recently provided by the Digestive Health Initiative, a joint committee assembled with representatives from the AGA, the American Society for Gastrointestinal Endoscopy (ASGE), and the American Association for the Study of Liver Diseases (AASLD).(1) These recommendations include the following statements:

"When endoscopy is not clinically indicated, the primary diagnosis of *H pylori* infection can be made serologically or

with the UBT. When endoscopy is clinically indicated, the primary diagnosis should be established by biopsy urease testing and/or histology. Available evidence suggests that confirmation of *H pylori* eradication is not mandatory in most situations because of costs associated with testing. However, for selected patients with complicated ulcer disease, low-grade gastric mucosa-associated lymphoid tissue lymphoma, and following resection of early gastric cancer, it is appropriate to confirm eradication. In other situations, the decision to confirm *H pylori* eradication should be made on a case-by-case basis."

This consensus group further specifies that there is no indication to test asymptomatic people and that testing for *H pylori* is only recommended if treatment is planned.

The (13)C-UBT) is a highly sensitive and specific noninvasive, nonradioactive test for diagnosing *H pylori* infection prior to antimicrobial treatment and for assessing whether the organism has been successfully eradicated following antimicrobial therapy.

In 2 recent large prospective studies, the (13)C-UBT was shown to be as, or more, sensitive and specific for diagnosing *H pylori* active infection than culture, stain, rapid urease testing of biopsy tissue, or serology.

When the test is used to assess eradication, it should be performed 4 to 6 weeks after completion of antimicrobial treatment.

See *Helicobacter pylori* Diagnostic Algorithm in Special Instructions.

Reference Values

Negative

Reference values apply to all ages.

Interpretation

The *Helicobacter pylori* urea breath test can detect very low levels of *H pylori* and, by assessing the entire gastric mucosa, avoids the risk of sampling errors inherent in biopsy-based methods. In the absence of gastric *H pylori*, the (13)C-urea does not produce (13)CO2 in the stomach.

A negative result does not rule out the possibility of *H pylori* infection. If clinical signs are suggestive of *H pylori* infection, retest with a new specimen or by using an alternative method.

A false-positive test may occur due to urease associated with other gastric spiral organisms observed in humans such as *Helicobacter heilmannii*.

A false-positive test could occur in patients who have achlorhydria.

Cautions

Testing for *Helicobacter pylori* is only recommended if treatment is planned.

For patients with phenylketonuria (PKU), the Pranactin-Citric solution contains phenylalanine (75 mg/dose; for reference, 12 ounces of a typical diet cola contains approximately 80 mg).

The patient should not have taken antibiotics, proton pump inhibitors (PPIs) or bismuth preparations for 2 weeks prior to the test. If PPIs are used within 2 weeks of BreathTek urea breath test (UBT) testing, false-negative test results may occur. Premature collection time can lead to a false-negative diagnosis for a patient with a marginally positive result.

If particulate matter is visible in the reconstituted Pranactin-Citric solution after thorough mixing, the solution should

not be used.

The breath test should not be used until 4 weeks or more after the end of treatment for the eradication of *H pylori* as earlier posttreatment assessment may give false-negative results.

A correlation between the number of *H pylori* organisms in the stomach and the breath test result has not been established.

The safety of using the BreathTek UBT kit during pregnancy and lactation is not established.

Clinical Reference

1. Talley NJ, Vakil NB, Moayyedi P: American Gastroenterological Association technical review on the evaluation of dyspepsia. Gastroenterology. 2005;129:1756-1780

2. Chey WD, Leontiadis GI, Howden CW, Moss SF: ACG Clinical Guideline: Treatment of Helicobacter pylori infection. Am J Gastroenterol. 2017 Feb;112(2):212-239. doi: 10.1038/ajg.2016.563

3. Talley NJ, Ford AC: Functional dyspepsia. N Engl J Med. 2015 Nov 5;373(19):1853-63. doi: 10.1056/NEJMra1501505

Performance

Method Description

In the *Helicobacter pylori* urea breath test, 3 g of reconstituted Pranactin-Citric solution containing 75 mg of (13)C-urea is ingested by the patient. In the presence of urease associated with gastric *H pylori*, (13)C-urea is decomposed to (13)CO2 and NH4(+) according to the following equation:

	HPUrease	
(NH2)(2) (13)CO + H2O + 2H	---------->	(13)CO2 + 2NH4+(13)C-urea

The (13)CO2 is absorbed in the blood, then exhaled in the breath. This results in an increase in the ratio of (13)CO2 to (12)CO2 in a TEST breath specimen compared to a BASELINE specimen taken before the Pranactin-Citric solution was consumed. Analysis of the breath specimen is performed by infrared spectrophotometry.(Package insert: BreathTek UBT for *H.pylori* Kit. Otsuka America Pharmaceutical, Inc; Revision 08/2019)

PDF Report

No

Day(s) Performed

Monday through Friday, Sunday

Report Available

Same day/1 to 2 days

Specimen Retention Time

Not retained

Performing Laboratory Location

Rochester

Fees and Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

83013

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
UBT	H. pylori C Urea Breath Test	29891-9

Result ID	Test Result Name	Result LOINC Value
81590	H. pylori C Urea Breath Test	29891-9