MAYO CLINIC LABORATORIES

Test Definition: UBT

Helicobacter pylori 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

Method Name

Qualitative 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.

Specimen Required

Patient Preparation:

1. Patient should be fasting for 1 hour.
2. Patients should not have taken bismuth/Tritec, antimicrobials, proton-pump inhibitors (eg, Prilosec, Prevacid, Aciphex, Protonix, and Nexium) or bismuth preparations (eg, Pepto-Bismol) for 2 weeks prior to testing. If these instructions are not followed, test results may be inaccurate. **Do not administer this test.**
3. Histamine 2-receptor antagonists (H2RA) 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. **Do not administer this test.**
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 - Meridian Breath ID (T906: fees apply)

Collection Instructions:

1. **Do not** collect if patient is younger than 3 years of age.
2. Follow instructions included with kit.
3. Mixing the (13)C-Urea Tablet

a. Dissolve the Citrica and the (13)C-enriched urea tablet in 150 to 200 mL (5.1 to 6.8 oz.) 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 urea tablet are completely dissolved.

Note: Tiny particles may remain visible after thorough 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.

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)

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 (preferred)	14 days	BREATH TEST BAG

Clinical & Interpretive

Clinical Information

Helicobacter pylori is 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 noninvasive. The most common invasive test method requires an endoscopic gastric biopsy. The tissue collected from the biopsy is then examined in a laboratory by microbiologic culture of the organism, direct detection of urease activity in the tissue, by molecular testing, or by histological examination of stained tissue. Biopsy-based methods present an element of patient risk and discomfort and may provide false-negative results due to sampling errors.

The (13)C-urea breath tests provides a non-invasive and non-hazardous analysis of the exhaled breath. The BreathID test measures the (12)CO2 and (13)CO2 components of the exhaled breath before and after the oral ingestion of (13)C-enriched urea. This establishes the baseline ratio of (13)CO2/(12)CO2 and the post ingestion ratio of (13)CO2/(12)CO2 in order to determine the delta over baseline (change in the (13)CO2/(12)CO2 ratio).

The BreathID Hp Lab System, using molecular correlation spectroscopy (MCS), is intended for use to noninvasively

measure changes in the (13)CO2/(12)CO2 ratio of exhaled breath, which may be indicative of increased urease production associated with active *H pylori* infection in the stomach. MCS uses infrared light to precisely match the CO2 molecule wavelength allowing for a smaller sample and minimal cross-sensitivity and low power consumption.

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 Citrica powder/(13)C-urea solution contains phenylalanine (84 mg/dose; for reference, 12 ounces of a typical diet cola contains approximately 80 mg).

The patient should not have taken antimicrobials, proton pump inhibitors (PPI), or bismuth preparations for 2 weeks prior to the test. If PPI are used within 2 weeks of 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 Citrica powder/(13)C-urea solution after five minutes of 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.

Data is insufficient for recommending the use of this test on patients with total or partial gastrectomy.

Data is insufficient to recommend the use of this test on pregnant and lactating women.

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, 75 mg (13)C-urea tablet and 4.3 g Citrica powder are dissolved in water, and the resulting solution is ingested by the patient. The presence of the Citrica creates an acidic environment in the stomach and delays the transfer of the ingested solution to the duodenum. These two characteristics facilitate the decomposition of the urea by *H pylori*, if present. Thus, in the presence of urease associated with gastric *H pylori*, (13)C-urea is decomposed to (13)CO2 and ammonia.

The (13)CO2 is absorbed into the blood and then exhaled in the breath. Absorption and distribution of (13)CO2 is fast. Therefore, the cleavage of urea by the *H pylori* urease that produces the (13)CO2 occurs immediately after the solution is ingested and enables immediate detection of increased (13)CO2 in the exhaled breath of *H pylori*-positive patients. In the case of *H pylori*-negative patients, the (13)C-urea does not produce (13)CO2 in the stomach because there are no human enzymes that can decompose the urea in the stomach.(Package insert: IDkit Hp Two for Exalenz BreathID Hp Lab System, Exalenz Bioscience Ltd; Revision 03, 03/2018)

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 & 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