Overview

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

Monitoring response to therapy

Testing Algorithm
See *Helicobacter pylori* Diagnostic Algorithm in Special Instructions

Special Instructions
- *Helicobacter pylori* Diagnostic Algorithm
- Pediatric UHR Calculation Information card

Method Name
Infrared Spectrophotometry (SP)

NY State Available
Yes

Specimen

Specimen Type
Breath

Advisory Information
An alternative test for the diagnosis of active *Helicobacter pylori* infection in patients is the HPSA / *Helicobacter pylori* Antigen, Feces, which requires a different collection.

Necessary Information
For patients between 3 and 17 years old, complete the Pediatric UHR Calculation Information card: See Special Instructions for link to required form.

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, Axic, 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**

1. **For patients between 3 and 17 years old, the Pediatric UHR Calculation Information card is required**, see Special Instructions.
2. 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**

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<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Breath</td>
<td>Ambient</td>
<td>7 days</td>
<td>BREATH TEST BAG</td>
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**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* antigen is 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-Urea Breath Test (Meretek UBT) 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 \textit{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 \textit{H pylori} is only recommended if treatment is planned.

The (13)C-Urea Breath Test (Meretek UBT) is a highly sensitive and specific noninvasive, nonradioactive test for
diagnosing \textit{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 \textit{H pylori} active infection than culture, PCR, 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 \textit{Helicobacter pylori} Diagnostic Algorithm in Special Instructions.

\textbf{Reference Values}

\textbf{Negative}

Reference values apply to all ages.

\textbf{Interpretation}

The \textit{Helicobacter pylori} urea breath test can detect very low levels of \textit{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 \textit{H pylori}, the
(13)C-urea does not produce (13)CO2 in the stomach.

A negative result does not rule out the possibility of \textit{H pylori} infection. If clinical signs are suggestive of \textit{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 \textit{H heilmannii}.

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

\textbf{Cautions}

This test is not appropriate for asymptomatic people.

Testing for \textit{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 patient should have fasted for at least 1 hour before administering the breath test.

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**


**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 NH(4)(+) according to the following equation:

\[
\text{HPU}_{\text{urease}}: (\text{NH}_2)_2 (13)\text{CO} + \text{H}_2\text{O} + 2\text{H} \rightarrow (13)\text{CO}_2 + 2\text{NH}_4(13)\text{C-urea}
\]

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. (Graham DY, Malaty HM, Cole RA, et al: Simplified 13C-urea breath test for detection of *Helicobacter pylori* infection. Gastroenterology 2001;96:1741-1745)

**PDF Report**

No

**Day(s) and Time(s) Test Performed**

Monday through Friday, Sunday; 6:30 a.m.-5 p.m.

**Analytic Time**

Same day/1 day

**Maximum Laboratory Time**

2 days

**Specimen Retention Time**

Discard immediately after testing
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 or approved by the U.S. 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

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