

Helicobacter pylori Breath Test

A NONINVASIVE TEST FOR DETECTION OF ACTIVE HELICOBACTER PYLORI INFECTION

Clinical Background

- Helicobacter pylori infection causes gastritis and 90 percent of gastric ulcers. It has been implicated as a risk factor for development of gastric adenocarcinoma and gastric B-cell lymphoma.
- Prevalence of the infection in the United States is approximately 30–35 percent.^{1,2}
- *H. pylori* can be detected through biopsy, determination of *H. pylori* antibody in blood or antigen in stool, and with a urea breath test.
- Treatment of the infection consists of multi-drug therapy over a two-week period.
- The Breath Tek™ UBiT® test offered by ARUP is a noninvasive breath test using a stable nonradioactive isotope of carbon.

Clinical Utility

- A positive result indicates the presence of urease associated with *H. pylori*. The *H. pylori* breath test detects active infections that require treatment. The use of a test method that detects active infections results in more appropriate use of antibiotics and reductions in unnecessary treatment.³ The performance of the test in children under the age of 18 has not been established. There has been no correlation established between the number of *H. pylori* organisms and the calculated difference in ¹³CO₂ to ¹²CO₂ ratios.
- Overall, the sensitivity and specificity of the test is >95 percent.⁴
- The test is the most reliable nonendoscopic test to document eradication of *H. pylori* infection.⁴
- Routine post-treatment testing is recommended in patients with *H. pylori*-associated ulcer or persistent dyspepsia.

Indications for Ordering

- The Breath Tek™ UBiT® test is intended for use in the qualitative detection of urease associated with *H. pylori* in the human stomach and as an aid in the initial diagnosis and post-treatment monitoring of *H. pylori* infection in adult patients.

Limitations

- The test should not be administered if the patient has taken proton pump inhibitors, bismuth preparations, or antibiotics within the previous two weeks. H₂ receptor antagonists in usual dosages do not interfere with the test.⁵
- To ensure accuracy for monitoring treatment, the *H. pylori* breath test should be administered at least four weeks following completion of eradication therapy.
- A negative result does not rule out the possibility of *H. pylori* infection. False-negative results do occur with this procedure. If clinical signs are suggestive of *H. pylori* infection, retest with a new sample or an alternate method. Known causes of false-negative results include: use of antimicrobials; proton pump inhibitors and bismuth preparations within the two weeks preceding the test; administration of the breath test less than four weeks after completion of therapy to eradicate *H. pylori*; and premature or late collection of the post-dose sample.
- Known causes of false-positive results include: achlorhydria; rinsing the PranaActin®-Citric in the mouth allowing contact with urease-positive bacteria; and the presence of other gastric spiral organisms, such as *Helicobacter heilmannii*.

Methodology

- The Breath Tek™ UBiT® test for *H. pylori* is administered by first collecting a baseline breath sample. The patient then drinks a solution of PranaActin®-Citric included in the collection kit.
- The PranaActin®-Citric consists of ¹³C labeled urea (a nonradioactive form of carbon), citric acid, and aspartame. When *H. pylori* is present in the stomach, the bacterial enzyme urease breaks down the labeled urea into ¹³CO₂ and NH₃. The ¹³CO₂ is absorbed by the blood and then exhaled in the breath.
- The patient fills a second breath bag at 15 minutes post dose.
- The breath samples are analyzed by the UBiT®-IR300 infrared spectrophotometer, which measures the ratio of ¹³CO₂ to ¹²CO₂ in the pre and post samples.
- Results are reported as positive or negative.
- In patients found to be positive for *H. pylori* infection, the ¹³CO₂ to ¹²CO₂ ratio of the post-dose sample is significantly higher than the baseline sample.
- In the absence of gastric *H. pylori*, the ¹³C labeled urea is not broken down and the ratio observed in the pre- and post-breath samples remains unchanged.

References

1. Graham K, Graham D. 2002. *Contemporary diagnosis and management of H pylori-associated gastrointestinal diseases*. Pennsylvania: Handbooks in Health Care Co.
2. Uemura N, et al. Helicobacter pylori infection and the development of gastric cancer. *NEJM* 2001;345:784–9.
3. Chey W, Fendrick M. Noninvasive Helicobacter pylori testing for the “test and treat” strategy. *Arch Intern Med* 2001;162:2129–32.
4. Chey WD, Wong BCY. American College of Gastroenterology guideline on the management of Helicobacter pylori infection. *Am J Gastroenterol* 2007;102:1808–25.
5. Chey, W. Diagnosis of Helicobacter pylori. *Pract Gastroenterol* 2001;April:28–41.
6. Vaira D, Vakil N. Blood, urine, stool, breath, money, and H pylori. *Gut* 2001; 48:287–9

Test Information

0020646 Helicobacter pylori Breath Test

For specific collection, transport, and testing information, refer to the ARUP Web site at www.aruplab.com.

For information on test selection, ordering, and interpretation, refer to ARUP Consult® at www.arupconsult.com.