

The BreathID® System – A Point-of-Care Tool for Detecting H. pylori Infection: An Overview

H.elicobacter pylori or H. pylori is a bacterium that infects the human gastrointestinal tract. In the United States, the infection rate is about 20 to 30 percent. Most people who are carriers of the bacteria experience no signs or symptoms of infection. However, H. pylori infection causes inflammation of the stomach lining and is the most common cause of stomach ulcers. H. pylori infection may also contribute to stomach cancer and other digestive system disorders.

Non-invasive Testing for H. pylori

Blood Antibody Tests – A small amount of blood is drawn to determine if the body has created antibodies to H. pylori. A positive test result indicates that the patient is currently infected or has been so in the past. In general, guidelines do not recommend conducting blood tests for diagnosis in populations where H. pylori prevalence is low-medium, such as in the U.S.

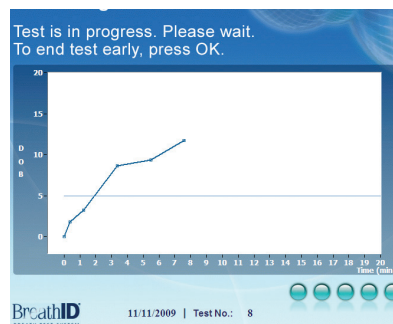
Stool Antigen Tests – This test detects foreign proteins (antigens), including those associated with H. pylori infection, in a stool sample. Stool sampling generally takes place at a laboratory, not in the physician's office. Results are not given immediately, thus patients may need to visit their physician more than once.

¹⁴C-Urea Breath Test - Ingested ¹⁴C-labeled urea is metabolized by the presence of H. pylori to produce CO₂. ¹⁴C breath tests involve exposure to a radioactive material. In addition, it requires a long fasting period of six hours which may be inconvenient to the patient.

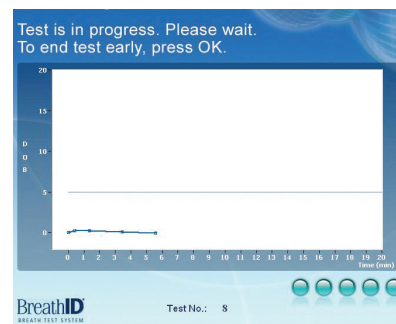
¹³C-Urea Breath Test – As with ¹⁴C-urea breath testing, ingested ¹³C-labeled urea is metabolized by the presence of H. pylori to produce CO₂. The BreathID® System samples the subject's breath through a nasal breathing cannula.

BreathID® System – Sample Screen Shots¹

H. pylori Positive



H. pylori Negative



BreathID® System - Clinical Evidence

The following are five extracts from over fifteen studies performed using the BreathID® System.

Studies with BreathID Demonstrate a >97% Correlation to Histology and CLOtest®

In a pivotal US study², 315 patients were evaluated pre-therapy and 77 patients post-therapy; the test compared the sensitivity and specificity of the BreathID® test in detecting the presence of *H. pylori* bacteria pre treatment with histology and the CLOtest® test. Sensitivity and specificity were above 99%. In another study³, 97 patients were analyzed for *H. pylori* using the BreathID® System and then compared to the rapid urease test and histology. Complete agreement was observed between the “gold standard” and the BreathID® test in 96.9% (94 out of 97) of the patients. The sensitivity and specificity of BreathID® were 97.8% and 96.1%, respectively.

Study Shows BreathID®'s Ability for Completing Most Tests within 10 Minutes⁴

In this study, 186 subjects were tested simultaneously by the BreathID® System and by the traditional isotope ratio mass spectrometry (IRMS). The IRMS showed 101 subjects were positive and 85 were negative for *H. pylori*. The correlation for the BreathID® System was 100% for positive cases and 98% for negative cases. Results were obtained more rapidly with the BreathID® method. After 6 minutes, a conclusive test result could be established for 64% of the subjects, and after 10 minutes, results were achieved for 92% of the subjects.

Studies with Patients Testing Under Proton Pump Inhibitors (PPI)

Two studies evaluated patients taking PPIs using the BreathID® method. In one study⁵, 52 patients who were positive for *H. pylori* received either Omeprazole 20 mg/day or Pantoprazole 40 mg/day for 14 days. A repeat breath test was performed on day 14 while patients received their last pill. A total of 43 patients completed the study. False negative detection of *H. pylori* was only 2.6% using the BreathID® method. In a second study⁶, patients who had tested positive for *H. pylori* by urea breath test were randomized to receive either omeprazole 20 mg/day, pantoprazole 40 mg/day, lansoprazole 30 mg/day or esomeprazole 40 mg/day for 14 days. A repeat breath test was performed on day 14 of treatment. One hundred and seventy-nine patients completed the study. Treatment with omeprazole or pantoprazole prior to the urea breath test was associated with low false negative results, while lansoprazole and esomeprazole caused clinically unacceptable high false negative rates (pantoprazole 2.2%; omeprazole 4.1% vs. lansoprazole 16.6% : esomeprazole 13.6%).

Disclaimer: The BreathID® System is intended for use in the qualitative detection of H. pylori. It has an approved 510(K) and an approved NDA for the 13C-urea Tablet and Citrica Powder.

1 BreathID® System Operating in PATIENT MODE (Hp FasTest)

2 http://www.accessdata.fda.gov/cdrh_docs/pdf/K011668.pdf

3 Shirin H. et al. Evaluation of a Novel Continuous Real Time 13C Urea Breath Analyzer for Helicobacter Pylori, *Aliment Pharmacol Ther* 2001; 15: 389-394

4 Israeli E. et al. A Novel 13C-Urea Breath Test Device for the Diagnosis of Helicobacter pylori Infection, *J Clin Gastroenterol* 2003;37(2):139-141

5 Shirin H. et al. Effect of Proton Pump Inhibitors on the Continuous Real Time 13C -Urea Breath Test. *The American Journal of Gastroenterology* Vol. 98, No. 1, 2003 46-50

6 Levine, A. et al. Masking of 13C urea breath test by proton pump inhibitors is dependent on type of medication: comparison between omeprazole, pantoprazole, lansoprazole and esomeprazole. *Aliment Pharmacol Ther* 2004; 20: 117-122

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