

BreathID[®]

BREATH TEST SYSTEM



Advanced Technology
for Accurate Detection
of *H. pylori* Infection

*Non-invasive,
non-radioactive
¹³C Urea Breath Testing*



BreathID[®]

BREATH TEST SYSTEM

For initial diagnosis and post-treatment follow-up of Helicobacter Pylori infection

FAST

- 10 minutes from start to results[±]
- Enables on-the-spot testing (patients presenting with symptoms)
- Test & treat in a single visit

Urea Breath Testing

*"Identifies active infection.
Excellent PPV and NPV.
Useful before and after
H. pylori therapy."*

- ACG 2007 Guidelines¹

ACCURATE

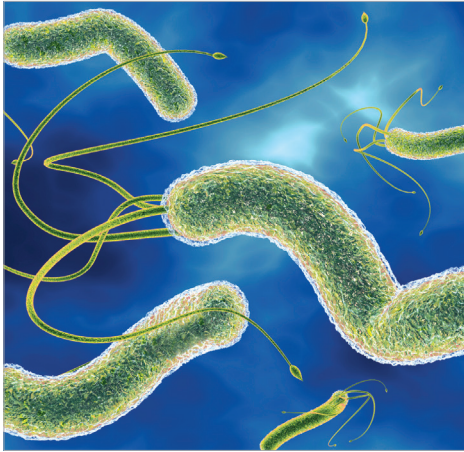
- 100% Sensitivity, 99.2% Specificity²
- ~150 exhalations included in analysis
- Validated in multiple studies published in peer-reviewed journals
- Used in numerous pharmaceutical and academic clinical trials

EASY

- CLIA non-regulated (no CLIA license required)
- Any trained staff member can operate the system
- Simple, 1-button operation
- Easy for patient – patient breathes normally



[±] In a review of 12,783 positive and negative test results, median test duration ranged from 8.02 to 12.98 minutes.



Patients with common symptoms & major conditions may have an *H. pylori* infection³

- Dyspepsia
- Symptoms similar to GERD, IBS and other bowel & digestive conditions
- Gastric inflammation
- Peptic and gastric ulcers

TEST then TREAT

- Definitively rule-in / rule-out infection
- Appropriately prescribe therapy
- Reduce the unnecessary use of antibiotics
- Prevent advanced conditions from occurring (*H. pylori*-related ulcers, cancer)

AAFP and ACG recommend a test-and-treat strategy: Testing patients < age 55, based on symptoms (including undifferentiated dyspepsia).^{1,4}

CONFIRM ERADICATION

- First-line triple therapy is effective in 80% of cases⁵
- 1-in-5 positive patients remain infected following therapy⁵
- ACG's 2007 Guidelines state: UBT is "useful ... after *H. pylori* therapy" and is the most applicable test for confirmation of eradication post treatment:⁷

Blood antibody testing

"Not recommended after *H. pylori* therapy."

Urea breath testing

"the most reliable nonendoscopic test to document eradication."

The Breath Test is the best test for the non-invasive detection of active *H. pylori* infection

Blood Antibody Tests have limited diagnostic value

“A positive (*H. pylori* serology) test is no better than a coin toss in predicting the presence of active infection.” (ACG Guidelines, 2007)¹

“Serology based office tests have no current role in the management of *H. pylori* infection.” (The Maastricht Consensus Report, 2002)⁶

Urea Breath Testing is the only non-invasive test for *H. pylori* that offers enhanced revenue potential for your practice

H. pylori Test	Est. Net Profit per Patient*
Blood Antibody	\$0 to \$10
Stool Antigen	-\$30 to \$10
BreathID Urea Breath	\$45 to \$55

* The information and examples below utilize the national median Medicare rates for the CPT codes listed, as published in the 2011 Clinical Lab Fee Schedule. Estimated net profit per patient ranges are based on those Medicare rates minus estimated cost of supplies, which are believed to be accurate but which may vary. Medicare rates may vary based on the provider's locality. The rates of other 3rd party payers, including commercial insurers, may also vary. As with any procedure, it is the provider's responsibility to determine the reimbursement specifics that pertain to their patients and practice.

1. Chey W, et al. American college of gastroenterology guideline on the management of helicobacter pylori infection. Am J Gastro 2007; 102: 1808-25.
2. Data on file, Exalenz Bioscience, Ltd.
3. Centers for Disease Control (CDC): *H. pylori* fact sheet. www.cdc.gov October 2010.
4. Ables A, et al. Update on Helicobacter pylori treatment. Am Fam Physician 2007; 75, 351-8.
5. Buzas GM. First-line eradication of Helicobacter pylori. World J Gastro 2010; 16(31), 3865-70.
6. Malfertheiner P, et al. Current concepts in the management of Helicobacter pylori infection – the Maastricht 2-2000 consensus report. Ailment Pharmacol Ther 2002; 16:167-180.