

# HISTORY MUSEUM

Diagnosing *H. pylori* Using Serology-based Tests Is History!



**What are you doing to test, treat, and confirm eradication of the world's most common bacterial infection?**

# BreathID<sup>®</sup> Hp Urea Breath Test

## The Shifting Evolution in *H. pylori* Diagnostic Testing

### Leading Experts Agree: Blood Antibody Testing “Has No Current Role In The Management of *H. pylori*.”<sup>3</sup>

When it comes to testing patients for *H. pylori*, are you making the choice the experts are clearly recommending? In the past, the most often chosen test method for *H. pylori* was the blood antibody test. Fast. Cheap. Easy. That doesn't mean most effective. Today, clinical data is clearly driving best practices to evolve. Consider the positions of just a few of the experts setting today's guidelines and reimbursement policies:

#### > Leading Clinical Positions

Organization	Blood Antibody Test	Urea Breath Test (UBT)
American College of Gastroenterology <sup>1</sup>	“A positive blood antibody test is <b>no better than a coin toss</b> for predicting active <i>H. pylori</i> infection.”	“UBT is the <b>most reliable</b> non-endoscopic test to document eradication of <i>H. pylori</i> infection.”
Mayo Clinic Laboratories <sup>2</sup>	Serologic testing for <i>H. pylori</i> “ <b>results should be considered with significant caution.</b> ”	“A <b>distinct advantage</b> of [UBT] is that it can also be used to determine treatment efficacy.”
European Helicobacter Study Group <sup>3</sup>	“The blood antibody test has <b>no current role</b> in the management of <i>H. pylori</i> infection.”	“The diagnostic accuracy of the UBT is >95% in studies. The UBT is an <b>accurate, practical, and readily available</b> test.”
Quest Diagnostics Laboratories <sup>4</sup>	“Serology-based methods cannot distinguish between active and resolved infection. These tests are not recommended for initial diagnosis of <i>H. pylori</i> infection or for confirming eradication. <b>Thus, serology-based tests are not offered by Quest Diagnostics.</b> ”	“These assays (UBT and stool-antigen) have been recommended by the American College of Gastroenterologists (ACG) as the <b>most accurate noninvasive tests for diagnosis of <i>H. pylori</i> infection and for confirmation of eradication after therapy.</b> ”

#### > Leading Reimbursement Positions

Organization	Blood Antibody Test	Urea Breath Test (UBT)
Cigna <sup>5</sup>	“Serology blood testing <b>will not be covered</b> to test for <i>H. pylori</i> ...”	“The overall body of literature suggests that non-invasive testing with UBT is <b>as clinically useful as endoscopy</b> in managing select patients with uncomplicated upper gastrointestinal symptoms.”
Aetna <sup>6</sup>	“Blood antibody testing for <i>H. pylori</i> is experimental and investigational because of <b>insufficient evidence of its effectiveness.</b> ”	“Stenstrom et al (2008) stated that <b>urea breath tests are the best way to diagnose current <i>H. pylori</i> infection.</b> ”
Anthem Blue Cross and Blue Shield <sup>7</sup>	“Serologic (in <i>H. pylori</i> testing) use is no longer recommended because it has <b>poor predictive value, leads to increased antibiotic resistance.</b> ”	“UBT ( <b>CPT codes 83013, 83014</b> ) is FDA-cleared for the initial diagnosis and to confirm eradication.”
Geisinger Health Plan <sup>8</sup>	“Eliminate the use of serology testing. Serology testing <b>will not be reimbursed.</b> ”	“UBT ( <b>CPT codes 83013, 83014</b> ) is FDA-cleared for the initial diagnosis and to confirm eradication.”



The **BreathID<sup>®</sup> Hp** urea breath test system is a quick in-office *H. pylori* test giving you immediate, highly accurate diagnostic results.

**Smart Care. Smart Revenue. Smart Choice.**



1) American College of Gastroenterology Guideline on the Management of *Helicobacter pylori* Infection, *Am J Gastroenterol*, 2007;102:1808–1825. 2) *Helicobacter pylori* Infection: Test Utilization Strategies for Diagnosis, Mayo Foundation for Medical Education and Research, Nov 2013, Communique (<http://www.mayomedicallaboratories.com/articles/communique/2013/11-hpylori-infection/index.html>). 3) *Current concepts in the management of Helicobacter pylori infection: the Maastricht III Consensus Report*, *Gut* 2007;56:772-781. 4) *Helicobacter pylori* Infection: Laboratory Support of Diagnosis and Management, Quest Diagnostics Laboratories, 9/2015, [http://www.questdiagnostics.com/testcenter/testguide.action?dc=CF\\_Hpylori](http://www.questdiagnostics.com/testcenter/testguide.action?dc=CF_Hpylori) 5) *Helicobacter pylori* Serology Testing, Cigna, Cigna Medical Coverage Policy, Aug 2014 ([https://cignaforhcp.cigna.com/public/content/pdf/coveragePolicies/medical/mm\\_0308\\_coveragepositioncriteria\\_urea\\_breath\\_test\\_for\\_heliobacter\\_pylori.pdf](https://cignaforhcp.cigna.com/public/content/pdf/coveragePolicies/medical/mm_0308_coveragepositioncriteria_urea_breath_test_for_heliobacter_pylori.pdf)). 6) *Clinical Policy Bulletin: Helicobacter Pylori Infection Testing*, Aetna, April 2014, ([http://www.aetna.com/cpb/medical/data/100\\_199/0177.html](http://www.aetna.com/cpb/medical/data/100_199/0177.html)). 7) *Anthem Adopts AGA and ACG Recommendations for Helicobacter Pylori Testing*, Anthem Blue Cross and Blue Shield, Jan 2011, Network Rapid Update ([http://www.anthem.com/provider/noapplication/f1/s0/t0/pw\\_b156793.pdf?refer=ahprovider](http://www.anthem.com/provider/noapplication/f1/s0/t0/pw_b156793.pdf?refer=ahprovider)). 8) *Operations Bulletin: Helicobacter pylori (H. pylori)*, Geisinger Health Plan, Jun 2011, ([http://www.thehealthplan.com/providers\\_us/opsbulletins/Ops%2006\\_11%20Hpylori.pdf](http://www.thehealthplan.com/providers_us/opsbulletins/Ops%2006_11%20Hpylori.pdf)).

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