



TECHNICAL NOTICE

SOUTH BEND MEDICAL FOUNDATION

March 2009

Overview of *Helicobacter pylori* Testing

Use:

- Testing for *Helicobacter pylori* should be only performed if the clinician plans to offer treatment for positive results.
- *H. pylori* testing is indicated in patients with active peptic ulcer disease, a past history of documented peptic ulcer or gastric MALT lymphoma
- The test-and-treat strategy for *H. pylori* is a proven management strategy for patients with uninvestigated dyspepsia who are under the age of 55 years old and have no “alarm” features, such as bleeding, anemia, early satiety, unexplained weight loss, progressive dysphagia, odynophagia, recurrent vomiting, family history of GI cancer or previous esophagogastric malignancy. If one or more of these signs, symptoms or history exist, more extensive or invasive investigation may be indicated.

Clinical Significance:

- Non-Invasive Tests for *H. pylori*

About 30-40% of the U.S. population is infected with *H. pylori*. The *H. pylori* Urease Breath Test and stool antigen test are currently the most accurate non-invasive diagnostic tools for detecting *H. pylori* and are the choice of method for the initial diagnosis and confirmation of eradication.

- *H. pylori* Urease Breath Test (#23063)

Urease breath test (UBT) is a non-invasive test that uses non-radioactive ¹³C to detect active *H. pylori* infection through breath samples. In the presence of urease associated with gastric *H. pylori*, ¹³C-urea is decomposed to ¹³C-CO₂ and ammonia ion. Detection of ¹³C-CO₂ indicates the presence of *H. pylori* infection.

The test is an accurate non-invasive test for detecting *H. pylori* both before and after treatment. Sensitivity and specificity of the test (N=444) when comparing to combined endoscopic methods (CLOtest, histology and culture per DAIDP guidelines) for initial visit are 95.2% and 89.7%, respectively. Sensitivity and specificity of the test (N=275) when comparing to combined endoscopic methods (CLOtest, histology and culture per DAIDP guidelines) for post-treatment visit (four weeks or more after end of treatment) are 95.5% and 96%, respectively.

- *H. pylori* Antigen, EIA, Feces (#21070)

The stool antigen test is also an accurate non-invasive test for *H. pylori* detection both before and after treatment. Sensitivity and specificity of the test (N=200) when comparing to combined endoscopic methods (culture, rapid urease, histology and UBT) for initial visit are 96.1% and 95.7%, respectively. Sensitivity and specificity of the test (N=97) when comparing to combined endoscopic methods (culture, histology and rapid urease methods) for post-treatment visit (four weeks or more after end of treatment) are 94.7% and 96.1%, respectively.

- *H. pylori* Rapid Urease Test, Mucosal Biopsy (#21040)

Gastric tissue, collected by the physician during a biopsy procedure, is placed into Selective Rapid Urea media.

H. pylori, known to produce large amounts of urease, can be rapidly detected by the assessment of urease activity.

This test can complement biopsies sent for morphologic analysis with microorganism staining for *H. pylori*.

- Serological testing for *H. pylori* IgG and IgM antibodies

Detecting the presence of IgG and IgM antibodies in a blood sample is a cost-effective initial approach to testing for *H. pylori* in symptomatic or at-risk asymptomatic patients. However, it is appropriate to confirm a positive serological result with a different method when the pretest probability of infection is low.

- *H. pylori* IgG Antibody (#28075)

- *H. pylori* IgM Antibody (#28076) is a new SBMF test (see additional Technical Notice, February 2009)

Please direct questions or comments regarding this notice to William J. Kaliney, M.D., Deborah H. Sun, Ph.D., or Sherrie White of South Bend Medical Foundation, (574) 234-4176 or (800) 544-0925.

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