



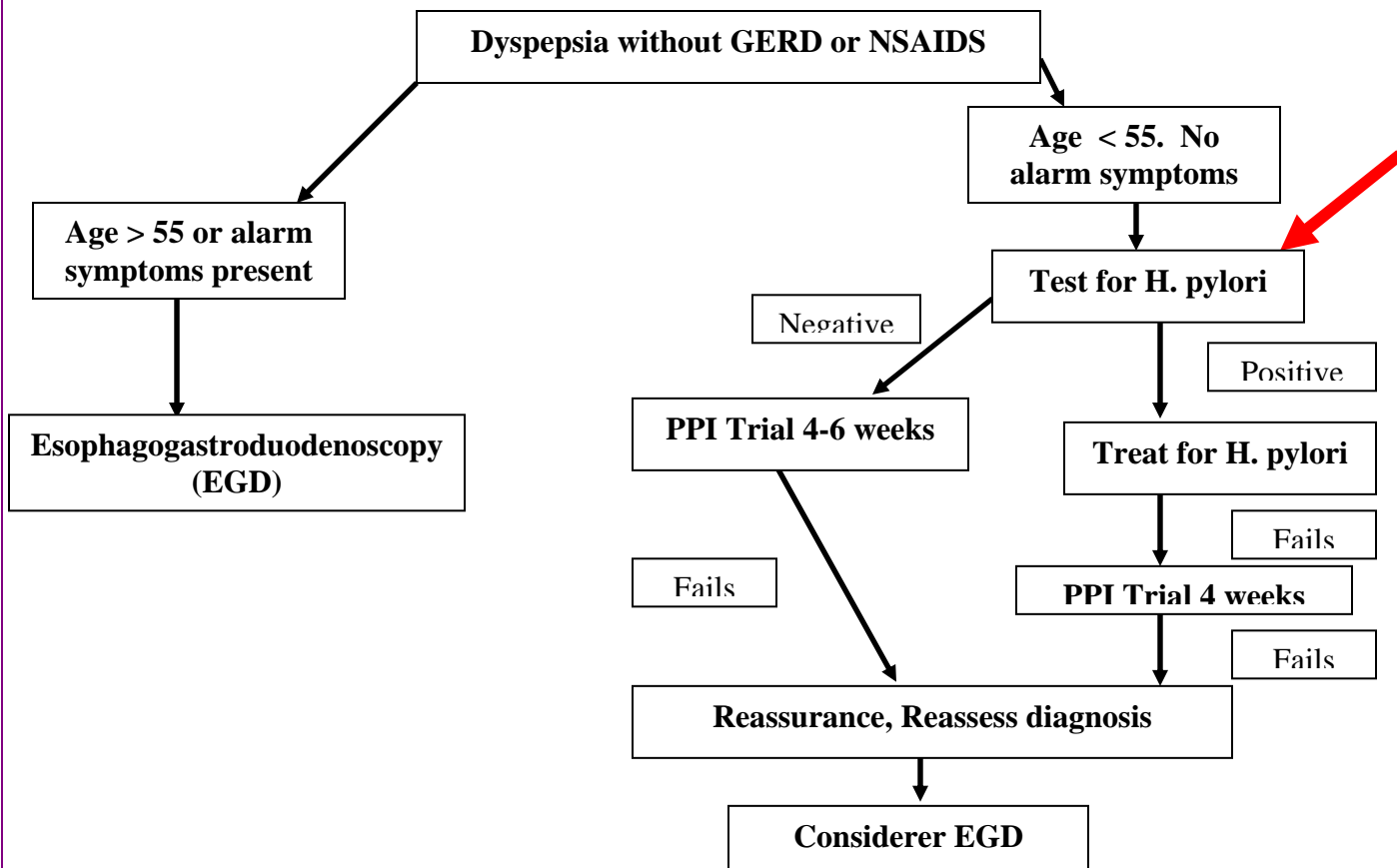
### Non-Invasive, Direct Test for *Helicobacter pylori* Antigen Available at Doctors Laboratory

*Helicobacter pylori* infections remain one of the most common worldwide human infections. It is estimated that a significant number (30-40%) of U. S. population is infected with *H. pylori*.

The bacterium, *Helicobacter pylori*, causes most gastric and duodenal ulcers (PUD). The other significant cause of PUD, which can usually be identified through careful history-taking, is the use of nonsteroidal anti-inflammatory drugs (NSAIDs). In addition, a series of studies support an association between *H. pylori* infection and gastric cancer, mucosa-associated lymphoid tissue (MALT) lymphoma, uninvestigated dyspepsia, iron-deficiency anemia, and idiopathic thrombocytopenic purpura.

Because patients with dyspepsia and other signs and symptoms of PUD typically present to their primary care physicians, *H. pylori* infection and PUD are now considered primary care diseases, rather than diseases that require care by subspecialists such as gastroenterologists. In addition, since inexpensive, reliable diagnostic tests for *H. pylori* infection have been developed, definitive testing for *H. pylori* infection can now be performed by primary care physicians. The infection can be cured by means of a combination regimen that includes selected antibiotics and proton pump inhibitors; an uncomplicated case of PUD does not usually require referral to a gastroenterologist. However, *H. pylori* is not the exclusive cause of PUD; some patients are now known to have recurrent PUD even after effective anti-*H. pylori* therapy.

Most *H. pylori* bacteria are acquired during childhood and persist throughout life, if left untreated. *H. pylori* transmission is more likely to happen within families and can possibly occur when the bacterium passes through vomit or stool. Some other risk factors include smoking and age of 50 years or greater. Therefore "Test-and-treat" is considered a proven management strategy for patients with uninvestigated dyspepsia who are under age 55 with no "alarm features", which include dysphagia, GI bleeding, unexplained anemia or weight loss, and severe vomiting. The following flowchart, published by American College of Gastroenterology, provides guideline to manage dyspepsia when GERD or NSAIDs have been ruled out.



As indicated in above diagram, non-invasive “Test and Treat” strategy is recommended for many cases, with Endoscopy being secondary option.

### **NEW ACG Guidelines for the Management of *H. pylori* Infection:**

#### **1. NO MORE SEROLOGY•**

The American College of Gastroenterology (ACG) now recommends that serology testing no longer be performed to test for *H. pylori* because it only tests for the antibody and does not test for active *H. pylori* infection.

#### **2. STOOL ANTIGEN IS THE RECOMMENDED TEST •**

The new ACG guidelines recommend using a non-invasive Stool Antigen or Urea Breath Test, which test for active *H. pylori* infection.

#### **3. TEST WITH STOOL ANTIGEN BEFORE PRESCRIBING PPIs •**

ACG now recommends that all patients presenting with Dyspepsia, who do not have alarm symptoms, have not been using NSAIDS, and who are not > 55, should be tested for *H. pylori* prior to being prescribed PPIs.

### **Non-Invasive Testing for Active *H. pylori* Infection:**

- **Antigen Test** – Fecal antigen testing by enzyme immunoassay or immunochromatography is one of the simplest and least expensive methods available. It is as simple and noninvasive as serology, can be used regardless of prior testing or treatment, and detects active infection as effectively as urea breath testing with less potential for false negative results while taking acid suppression or bismuth medications. The sensitivity and specificity of fecal antigen testing exceed 90%.

Results of the fecal antigen test aid in the definitive diagnosis of active *H. pylori* infection, can be used to monitor response during and post treatment, and can confirm eradication of *H. pylori*. Confirmation of eradication should be performed 1 month after eradication therapy has been completed and testing for *H. pylori* should not be performed until 2 weeks after stopping proton pump inhibitor therapy.

- **Urea Breath Test** – Breath testing requires that the patient ingest a standard sample of labeled C<sup>13</sup> or C<sup>14</sup> and, at a predetermined time, produce a breath sample. After collection, the breath sample is analyzed by means of a mass spectrometer or scintillation counter.

One limitation of this method is the possibility of false negative results when antibiotics used to eradicate *H. pylori* or proton pump inhibitors used to heal ulcer disease are taken in the period before testing. Breath testing is more expensive than fecal antigen testing but less expensive than invasive (Endoscopy) testing.

### **Accuracy of noninvasive tests for *H. pylori* infection**

Test	Sensitivity	Specificity	Advantages	Disadvantages
Urea breath test	95.2%	89.7%	Excellent Positive and Negative predictive values. Used before and after therapy	Reimbursement and availability inconsistent. Involves ingestion of radioisotopically labeled urea by the patient
Stool antigen test	96.1%	95.7%	Excellent Positive and Negative predictive values. Used before and after therapy	Unpleasantness associated with collection of stool specimen

Doctors Laboratory now offers non-invasive, inexpensive, rapid, yet accurate test for the detection of *H. pylori* antigen, which may be ordered as follows:

Test to Order	Specimen to submit	CPT Code	Unacceptable
9560 – <i>H. pylori</i> Antigen Test	Stool specimen in sterile, screw-capped container. Refrigerated or frozen.	87338	Non-standard containers, e.g. pill bottle, food jar or yogurt cup, diaper

For additional information on this test please contact Microbiology laboratory at ext. 2252.