Test It
Treat It
Test It Again

HpSA®
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PhysLab®

Dear Providers,

Effective immediately, *Helicobacter pylori* Stool Antigen (HpSA®) Test will be made orderable from our laboratory. The reason for this change is to (1) achieve increased sensitivity and specificity for the detection of the *H. pylori* organism and (2) provide a more accurate diagnosis by detecting active infection rather than previous exposure.

The HpSA® test is cleared to be used in patients of all ages for diagnosis, therapy monitoring and to confirm eradication after treatment.

In order to provide the most current, clinical, best practice we encourage the adoption of the American Gastroenterological Association (AGA) and American College of Gastroenterology (ACG) guidelines. The latest AGA and ACG guidelines do not recommend the use of serological tests as they have a low positive predictive value and result in false positive tests, which can lead to unnecessary testing, antibiotic use, and repeat patient visits. The guidelines emphasize the need to test for **diagnosis, treat and retest to confirm eradication using a non-invasive active infection test for *H. pylori* infection**. It is a proven management strategy for patients with uninvestigated dyspepsia who are under the age of 55 yr and have no alarm symptoms.[1]

Order Information

Test Name	Test Number	CPT	Sample
H. pylori Stool Antigen	2095	87338	3-5mg Unpreserved Stool

Helicobacter pylori is recognized as a major cause of peptic ulcer disease, dyspepsia and atrophic gastritis in adults and children, and if left untreated there is an increased risk of developing gastric cancer and mucosal-associated-lymphoid-type (MALT) lymphoma. Approximately 30% - 40% of the United States population is infected with *H. pylori*. The prevalence of infection varies with age and socioeconomic status worldwide. African Americans, Hispanics, Eastern Europeans, Asians and Native Americans from Alaska have an increased prevalence of *H. pylori* infection.

Sincerely,

Robert Bowen, MD
President, Lab Director
Physicians Laboratory

References:
1. Chey WD, Wong BCY, et. al., American College of Gastroenterology Guideline on the Management of *Helicobacter pylori* Infection, Am J Gastroenterol, Aug 2007;102, page 1808.

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Test Code: Meridian Bioscience *H. pylori* stool antigen test

CPT Code: 87338

Specimen Requirements:

- 0.5 mL liquid or 20-25 mm of semi-solid stool
- Store at 2-8 C for up to 72 hours or freeze immediately

Collect liquid/semi-solid stool and transfer to a properly labeled, sterile, leak-proof container. Do not place stool in preservative, transport media, or swab. Watery, diarrheal stool is not acceptable. Turnaround time: 1 day after received in Lab.

Clinical Use:

- Aid in diagnosis of patients with *H. pylori* infection
- Therapy monitoring for early predictor of therapy failure
- Confirmation of cure and eradication

Serology testing is no longer recommended by AGA because:

- It does not test for active infection and does not confirm eradication
- 50% of serology positive tests are false positives. "A positive serology test is no better than a coin toss in predicting the presence of active infection"[2]
- A false positive result can lead to:
  - » Unnecessary treatment, increased antibiotic resistance, possible side effects and increased patient anxiety

Three methods can be used to diagnose active *H. pylori* infection

1. Stool Antigen Detection: This method detects *H. pylori* antigen in stool specimens and can be used for diagnosis, therapeutic monitoring, and proof of cure post treatment
2. Upper GI tract biopsy, followed by histologic exam, rapid urease testing, and culture
3. Urea breath test employing C13 radiolabeled Urea (Requires outside referral)

Order a Meridian HpSA® test for active *H. pylori* infection:

- Meridian's HpSA® stool antigen test is the only FDA-cleared test for use in diagnosis, therapeutic monitoring and eradication confirmation
- Offers superior performance over serology tests
- Can be used for patients of all ages and does not require fasting prior to testing
- Non-invasive with no risks for side effects
- Does not require specialized training for physician office staff or special set up
- Complies with ASGE guidelines for Bariatric surgery pre-operative testing

References:
1. AGA Board, American Gastroenterological Association Medical Position Statement: Evaluation of Dyspepsia, Nov 2005, page 1754.
2. Chey WD, Wong BCY, et. al., American College of Gastroenterology Guideline on the Management of *Helicobacter pylori* Infection, Am J Gastroenterol, Aug 2007;102, page 1816.
3. ASGE Guidelines, Gastrointestinal Endoscopy, Volume 68, No. 1 : 2008.

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