



HpSAg DetectR™ **H. pylori Stool Antigen**

Overview

Helicobacter pylori is an extremely pervasive bacterium that infects 25-50% of individuals in developed countries and up to 70-90% of individuals in developing countries.¹ *H. pylori* infection is the principal cause of peptic ulcer disease and the primary risk factor for gastric carcinoma; ~15% of patients with long-term infection will develop one or the other sequelae.² Some patients (10-20%) with gastritis or peptic ulcers due to *H. pylori* infection will not respond to standard treatment.³

Although a number of tests are available for the diagnosis of infection, they are often invasive, costly and time consuming. Some only indicate exposure to *H. pylori* without directly detecting active infection. For example, antibody assays

have excellent sensitivity for screening, but due to the persistence of antibodies, cannot reliably distinguish between active infection and a resolved episode.

In contrast, the *H. pylori* Stool Antigen (HpSAg) test directly detects antigens present *only* during active *H. pylori* infection. Efficacy of eradication can, therefore, be assessed by testing for active infection before and after treatment.^{3,4} In addition, the HpSAg assay is the only FDA-approved test that can monitor the effectiveness of antibiotic therapy during the 14 days of treatment; the Urea Breath Test is not reliable until 4 weeks after treatment ends³. Positive results after 5-7 days or longer of therapy may indicate “treatment failure” and warrant a closer look at compliance, resistance or lack of efficacy.³

Clinical Utility

?? The only FDA-approved test for all of the following:

- ✍ Detection of active infection
- ✍ Monitoring effectiveness of therapy during treatment
- ✍ Confirmation of antibiotic cure (eradication)

?? Differentiates between active and latent infection; serology only detects exposure⁵

?? Relative sensitivity = 95.6%; Relative specificity = 94.7% (compared to urea breath test)⁴

?? HpSAg is a highly reliable method for initial diagnosis of *H. pylori* infection and confirmation of eradication³

?? HpSAg identifies 95% of persistent infection cases 7 days post-treatment; the Urea Breath Test is not reliable until 4 weeks after treatment ends³

Ordering Information & Specimen Requirements

Test Code	Test Name	Specimen Requirements
2443	HpSAg DetectR™	10 mL fresh stool; FROZEN. Collect in a clean, leak-proof plastic container with no preservatives. Specimens treated with 10% formalin, SAF or PVA are not acceptable. Ship frozen on dry ice within 24 hours of collection.
<p><i>Specify “Send HpSAg DetectR™ to Specialty Laboratories”</i> <i>For immediate attention and sample pick-up, call 800-421-4449.</i></p>		

Methodology

Enzyme Immunoassay (EIA)

Related Tests

7741 *Helicobacter pylori* IgG, IgM, & IgA Antibodies, EIA

References

1. Dunn BE, Cohen H, Blaser MJ. *Helicobacter pylori*. Clin Microbiol Rev 1997;10:720-41.
2. Logan RP, Walker MM. ABC of the upper gastrointestinal tract: epidemiology and diagnosis of *Helicobacter pylori* infection. Br Med J 2001;323:920-2.
3. Vaira D, Vakil N, Menegatti M, et al. The stool antigen test for detection of *Helicobacter pylori* after eradication therapy. Ann Intern Med 2002;136:280-7.
4. Vaira D, Malfertheiner P, Mergraud F, et al. Noninvasive antigen-based assay for assessing *Helicobacter pylori* eradication; a European multicenter study. The European *Helicobacter pylori* HpSA study group. Am J Gastroenterol 2000;95:925-9.
5. Vaira D, Vakil N. Blood, urine, stool, breath, money and *Helicobacter pylori*. Gut 2001;48:287-9.

**For complete information on this and other related tests,
please call Client Services at 800-421-4449 or visit our Web site at
www.specialtylabs.com and sign-up for our e-mail notification program.**