



***Helicobacter pylori* Stool Antigen**

Questions & Answers

Q. What antigen does HpSAg detect?

A. The *Helicobacter pylori* Stool Antigen (HpSAg) test detects antigens to *H. pylori* from an affinity-purified whole cell lysate mixture.

Q. Why is a direct antigen test superior to a serology-based test?

A. A direct antigen test can differentiate between active and latent infection; whereas, serology only detects exposure.

Q. In what clinical conditions would the HpSAg test be useful?

A. The HpSAg is FDA-approved for the following:

- ? Diagnosis of active infection in symptomatic patients
- ? Monitoring effectiveness of antibiotic therapy during the 14 days of treatment
- ? Confirmation of antibiotic cure

Q. How does the HpSAg compare to the urea breath test?

A. HpSAg has been shown to have over 95% correlation with the reference methods for diagnosing *H. pylori* infection. UBT has exhibited similar performance data. However, unlike HpSAg, UBT is not FDA-approved for monitoring during the course of treatment.

Q. How good is the HpSAg test? How does it compare to Endoscopy?

A. ? HpSAg has >95% sensitivity, >94% specificity, and correlation to endoscopy of 95.5%.
 ? HpSAg is also non-invasive and costs a fraction of what is usually charged for endoscopy.

Q. How does The HpSAg test compare to other tests?

Critical Features	Serology	<i>H. pylori</i> Urea Blood Test	Urea Breath Test	Biopsy	Specialty's HpSAg
Rapid	Yes	No	No	No	YES
Relative Invasiveness	Low	Low	Low	Severe	Low
Sample	Whole blood/ serum	Whole blood	Special breath collection bag	Tissue	Unpreserved STOOL
Easy-to-use	Yes	Moderately	No	No	YES
Detects Active Infection	No	Yes	Yes	Yes	YES
Confounding Factors	False positives	Pending FDA approval, need to collect blood samples	Method of collection, mouth bacteria, drug interference	Quality of sample, additional procedure necessary	
Sensitivity	80-95%	N/A	90-98%	77-95%	>95%
Specificity	80-95%	N/A	90-98%	90-100%	>95%
Technical Skill Level	Phlebotomist Med Tech	Phlebotomist Med. Tech	Nurse Med Tech	GI Endoscopist	
FDA-approved test for Cure	No	No	Yes	Yes*	
FDA-approved test for monitoring therapy during treatment	No	No	No	No	

*CLO test FDA approved

Q. What does the patient have to do to prepare for the HpSAG test?

A. The patient simply collects a stool sample (using Specialty Laboratories' sample collection protocol for unpreserved stool specimens) in a clean, dry, leak-proof container and delivers it to his/her physician's office within 24 hours. Patients DO NOT have to fast, have blood samples drawn or ingest anything before the stool sample is collected. It is a very convenient protocol compared to procedures the patient may have to follow for other tests.

Q. Can HpSAG be used at any point after initiating treatment?

A. Yes. A positive HpSAG test at 5-7 or more days after initiating therapy indicates a "treatment failure". This failure can be due to lack of compliance, resistance, or lack of efficacy of a treatment regimen. A negative result would indicate that the therapy has eliminated or reduced infection below level of detection, although eradication cannot be confirmed (at this point).

Q. Can the HpSAG test be used to prove eradication prior to 4 weeks post-treatment?

A. No. Currently established standards require a minimum of 4 weeks after completion of treatment in order to ascertain successful eradication.

Q. Do any of the symptom-relieving compounds, such as bismuth, H2 blockers or PPI's interfere with the HpSAG test?

A. None of these compounds interferes with the test itself. Bismuth and PPI's are known to suppress *H. pylori*. A negative result for a patient within 2 weeks of ingesting these compounds may be indicative of suppression and therefore, give a false-negative result. The test should be repeated on a specimen obtained 2 weeks after discontinuing treatment. As mentioned above, a positive result should be considered accurate.

Q. Have studies been performed on the effectiveness of HpSAG on children?

A. HpSAG data has been studied in the age ranges of 17 and over. The HpSAG test lends itself well to testing children because of the specimen type used and its noninvasiveness. However, the FDA guidelines on this patient population have not been established; therefore, a claim with regard to children cannot be made for any diagnostic test for *H. pylori* infection.

Q. Why should I choose Specialty as the lab of choice for HpSAG?

- A. ? Specialty has the largest gastroenterology offering of esoteric tests in the industry, and is a leader in test innovation.
- ? Specialty was the first comprehensive reference laboratory to offer a complete line of *H. pylori* tests providing extensive experience and knowledge for this disease.
- ? Specialty was the first commercial laboratory to offer the HpSAG test, and has been performing it for over 5 years.
- ? Specialty is the only lab to provide the "Use and Interpretation of Laboratory Tests in Gastroenterology."

Ordering Information & Specimen Requirements

Test Code	Test Name	Specimen Requirements
2443	<i>Helicobacter pylori</i> Stool Antigen	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.

Related Tests - 7741 *Helicobacter pylori* IgG, IgM, & IgA Antibodies, EIA

References

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