



immunocard
STAT!®

HpSA®

CLIA-waived rapid test to detect
H. pylori stool antigen and confirm
eradication of disease.

DIAGNOSE. MONITOR. CONFIRM. FOR ALL PHASES OF *H. PYLORI* PATIENT MANAGEMENT

ImmunoCard STAT!® HpSA® is a CLIA-waived, easy-to-use, active infection test for *H. pylori*.

***H. pylori* causes 9 out of 10 ulcers and is one of six common infections that can lead to cancer, which may be prevented with early detection.^{1,2}**

- Guidelines indicate that about 50% of patients with a positive *H. pylori* serology do NOT have active infection.³
- 28% of patients on chronic PPI therapy are *H. pylori* positive and can therefore be treated appropriately.⁴

Is your lab currently testing for *H. pylori* with a fast, accurate test?

- What impact would a 5-minute turnaround time and 3-step workflow have on your lab's testing efficiency?
- Is your lab testing for active infection for *H. pylori* according to the AGA and ACG guidelines, which state serology tests are no longer recommended?

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Follow Guideline Recommendations

- Guidelines recommend testing for *H. pylori* with a non-invasive active infection test prior to prescribing a proton pump inhibitor following the “Test, Treat, Retest, and Confirm Eradication” protocol⁵.

Follow National Health Plan Standards

- Both CMS and private health plans nationwide have adopted the AGA and ACG guidelines for active *H. pylori* infection testing and are no longer reimbursing for serology.

Patients Prefer Testing for Active Infections

- ImmunoCard STAT![®] HpSA[®] is less invasive and highly accurate with a sensitivity greater than 90% compared to endoscopy⁶.

Rapid Solution for *H. pylori* Testing

- Less than 1-minute hands-on-time
- Simplified QC
- Simple workflow with convenient benchtop incubation



Product Specifications

A rapid in vitro qualitative procedure for the detection of *Helicobacter pylori* antigens in human stool. The stool antigen detection is intended to aid in the diagnosis of *H. pylori* infection and to demonstrate loss of *H. pylori* stool antigen following treatment.

Turnaround Time

5 minutes

Sample Type

Fresh stool (unpreserved) — minimum 100µL

Sample Storage

Store at 2 - 8C for up to 72 hours

Stored frozen (≤ -20C) until tested, with up to 2 freeze/thaw cycles

Kit Storage

Kit and all reagents should be stored at 2 - 8C

Performance

Diagnosis	Eradication
90.6% Sensitivity	95.4% Sensitivity
91.5% Specificity	100% Specificity

Catalog Number

ImmunoCard STAT![®] HpSA — 750220

CPT Codes

87338

References

1. Peterson, W.L. “*Helicobacter Pylori* and Peptic Ulcer Disease: NEJM.” *New England Journal of Medicine*, 11 Apr. 1991, www.nejm.org/doi/pdf/10.1056/NEJM199109053251015.
2. Lancet, The. “Chronic Disease Management in Ageing Populations.” *The Lancet*, vol. 379, no. 9829, 2012. Pg. 1851., doi:10.1016/s0140-6736(12)60790-9.
3. Chey WD, Wong BCY, et al. American College of Gastroenterology Guidelines on the Management of *Helicobacter pylori* Infection. *Am J Gastroenterol*, Aug 2007:102, p 1816.
4. Heidelbaugh JJ, et. Al. Overutilization of proton-pump inhibitors: what the clinician needs to know. *Therap Adv Gastroenterol*. 2012 Jul; 5(4): 219-232.
5. American Gastroenterological Association medical position statement: evaluation of dyspepsia: *Gastroenterology*. 2005;1129:1756-1780.
6. Meridian ImmunoCard STAT HpSA Package Insert, 12/2016.

**Ready to get a handle on testing for *H. pylori*?
Let's talk.**

Contact a specialist at 1-888-763-6769.

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