



premier®
HpSA® Flex

An enzyme immunoassay
for the detection of *H. pylori*
antigens in human stool

Diagnose. Monitor. Confirm. For all phases of *H. pylori* Patient Management

Premier® HpSA® Flex is a highly sensitive, non-invasive, 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}**

- The CDC estimates 1 out of every 3 patients is infected with *H. pylori*, one of the world's most common bacterial infections.^{3,4}
- AGA and ACG guidelines recommend a test, treat, and retest approach to confirm the eradication of *H. pylori*. Active infection tests such as 13C-urea breath tests or stool antigen tests are recommended rather than serology (antibody).^{5,6}
- Guidelines indicate that about 50% of patients with a positive *H. pylori* serology test do NOT have an active infection.⁴

With education and awareness, *H. pylori* testing will dramatically increase. Is your lab ready?

- Premier® HpSA® Flex is an enzyme immunoassay with high-volume throughput approved for fresh (unpreserved) and preserved stool specimens.
- What impact would the ability to perform multiple tests from one specimen have on your laboratory's efficiency, processing, and workflow?

meridian BIOSCIENCE®
LIFE DISCOVERED. LIFE DIAGNOSED.



Follow Guideline Recommendations

- Premier® HpSA® Flex aligns with the AGA and ACG guidelines for *H. pylori* non-invasive active infection testing.
- Guidelines recommend testing for *H. pylori* prior to prescribing a proton pump inhibitor following the "Test, Treat, Retest and Confirm Eradication" protocol.^{5,6}

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.

Premier® HpSA® Flex Features:

- ELISA technology lends itself to high-volume throughput.
- Detachable microwells maximize determinations per kit utilization.
- Can be read visually or on automated systems.
- Approved for fresh unpreserved stool and preserved stool specimens in Cary-Blair or C&S.
- Flexible options for stool transport vials can improve laboratory efficiencies, preserve sample integrity, and streamline sample processing.

Total Solutions, One Trusted Partner

Seamlessly integrate Para-Pak® stool transport vials for a comprehensive solution to meet all your testing needs.



Para-Pak® Clean Vial
Cat #900312



Para-Pak® C&S
Cat #900612

Product Specifications

An enzyme immunoassay (EIA) in vitro qualitative procedure for the detection of *Helicobacter pylori* antigens in human stool. Test results are intended to aid in the diagnosis of *H. pylori* infection and to monitor response during and post-therapy in patients.

Time to Result

60-90 minutes

Sample Type

Fresh stool (unpreserved)
Preserved stool (Cary-Blair or C&S)

Sample Storage

Fresh stool (unpreserved):

- Store at 2-8C for up to 72 hours
- Store frozen -20C to -80C until tested

Preserved stool (Cary-Blair or C&S):

- Store at 19-27C up to 120 hours
- Store at 2-8C up to 120 hours
- Stored frozen -20C to -80C up to 14 days

Kit Storage

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

Performance

	Diagnosis	Eradication
Unpreserved stool	PPA 100% NPA 100%	Sensitivity 94.7% Specificity 96.1%
Preserved stool (Cary-Blair or C&S)	PPA 100% NPA 98.5%	Sensitivity 94.7% Specificity 96.1%

Catalog Number

Premier® HpSA® Flex - 619096

CPT Code

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. Helicobacter pylori and peptic ulcer disease: the key to cure. Centers for Disease Control and Prevention website. <http://www.cdc.gov/ulcer/keytocure.htm>. Updated September 28, 2006. Accessed March 12, 2019.
4. Chey WD, Wong BCY; Practice Parameters Committee of the American College of Gastroenterology. American College of Gastroenterology guideline on the management of Helicobacter pylori infection. Am J Gastroenterol. 2007;102(8):1808-1825.
5. Chey, W. D., Leontiadis, G. I., Howden, C. W., & Moss, S. F. ACG Clinical Guideline: Treatment of Helicobacter pylori Infection. American Journal of Gastroenterology, 2018; 113(7), p1102. doi: 10.1038/s41395-018-0132-6.
6. Talley, N. J. American Gastroenterological Association Medical Position Statement: Evaluation of Dyspepsia. Gastroenterology, 2005; 129(5):1753-1755. <https://doi.org/10.1053/j.gastro.2005.09.019>

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

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

meridianbioscience.com/contact-us

