

H. pylori Antigen, Stool

Test Code 11939

Clinical Use

- Differential diagnosis of patients with peptic ulcer disease and chronic active gastritis
- Therapeutic monitoring in patients with *Helicobacter pylori* infection
- Consistent with the AGA Test and Treat Guidelines

Clinical Background

Helicobacter pylori (*H. pylori*) is associated very strongly with peptic ulcer disease (duodenal and gastric) and chronic active gastritis. *H. pylori* is also an independent risk factor for gastric cancer and primary malignant lymphoma of the stomach. The infection can be treated successfully with a combination of three drugs for 10 to 14 days.

Four methods can be used to diagnose *H. pylori*

- upper GI tract biopsy, microscopic exam, rapid urease testing, culture
- urea breath test employing C or C-urea
- antibody detection
- antigen detection

This method detects *H. pylori* antigen in stool specimens and can be used for diagnosis or therapeutic monitoring.

Individuals Suitable For Testing

- Adults and pediatric patients

Specimen Requirements

1 g random stool specimen in sterile screw-cap container. Collect minimum 0.5 mL of liquid/semi-solid stool or 20 mm diameter solid stool and transfer to properly labeled sterile leak proof container. Do not place

stool in preservative transport media or swab. Watery, diarrheal stool is not acceptable.

CPT Code*

87338

Method

This enzyme immunoassay employs a polyclonal anti-*H. pylori* capture antibody adsorbed in microwells and a peroxidase-conjugated polyclonal detection antibody. Based on the intensity of color developed, results are reported as *H. pylori* antigen not detected, equivocal, or detected.

Reference Range

H. pylori Antigen: Not Detected

Interpretive Information

A positive result (antigen detected) is indicative of *H. pylori* presence (96% sensitivity); however some individuals may have *H. pylori* antigen but no disease. A negative result (antigen not detected) indicates absence of *H. pylori* or an antigenic level below the assay limit of detection (184 ng *H. pylori* protein/ml of stool) (96% specificity). False negative results may be obtained on specimens from patients who have ingested selected compounds (antimicrobials, proton pump inhibitors, Bismuth preparations) within the two weeks prior to specimen collection. In populations with disease prevalence ranging from 34% to 69% (average 52%), the positive and negative predictive values were 96%.

A positive result >7 days post therapy is indicative of treatment failure. A negative result >4 weeks post therapy indicates eradication of the infection.

*The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.

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