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DETECTION OF *HELICOBACTER PYLORI* ANTIGEN IN STOOL BY ENZYME IMMUNOASSAY

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SUMMARY

Detection of *Helicobacter pylori* antigens in stool specimens in patients with signs and symptoms of chronic gastritis and/or peptic disease is an accurate and non-invasive approach for the diagnosis of *H. pylori* infection. The stool antigen assay has been accepted as a diagnostic test for primary infection with accuracy equivalent to that of the urea breath test (UBT). Importantly, administration of proton pump inhibitors (PPIs), antimicrobials and/or bismuth preparations must be stopped for a minimum of two weeks prior to testing to avoid false-negative results. The assay may also be used to assess treatment effectiveness (eradication) but testing must be delayed at least four weeks following completion of therapy when used as a test-of-cure. Effective immediately, an *H. pylori* stool antigen enzyme immunoassay will be performed on Tuesdays and Fridays by Marshfield Labs with results available the same day, pending arrival time in the laboratory. This qualitative monoclonal assay is cleared by the FDA for detection of *H. pylori* antigens in human stool.

BACKGROUND

Since its discovery by Marshall and Warren in 1984, *H. pylori* has been recognized as one of the most common and medically important pathogens worldwide. *H. pylori* has been firmly established as an etiologic agent in chronic gastritis and peptic ulcer disease, and has been associated with gastric mucosa-associated lymphoid tissue (MALT) lymphoma and gastric adenocarcinoma.

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The ecological niche in humans appears to be restricted to the stomach and the duodenum. Individuals who harbor the organism are divided into two groups. The first shows no signs or symptoms of gastrointestinal disease and is considered "colonized". The second group shows gastrointestinal signs and symptoms and is considered "infected". The process by which an individual becomes colonized or infected is unknown. Many possible routes of transmission of *H. pylori* to humans have been postulated and include animals, contaminated water and oral reservoirs.

DIAGNOSTIC ASSAYS

Diagnostic tests for *H. pylori* can be categorized as non-invasive (stool antigen test, urea breath test and serology) or invasive (endoscopy, biopsy).

The stool antigen test has been evaluated extensively and has been accepted as an accurate non-invasive test that permits assessment of infection before and following therapy with accuracy equivalent to that of the UBT. Utilizing monoclonal antibodies directed against *H. pylori* antigens, assay sensitivity, specificity and predictive values have been found to be greater than 90% both before and after treatment, regardless of organism prevalence. The test is simple to administer and perform, and is a recognized option in both the American College of Gastroenterology 2007 *H. pylori* Management Guideline and the 2012 Maastricht IV Florence Consensus Report.

The urea breath test (UBT) is a type of noninvasive test that detects the highly active urease of *H. pylori*. Although UBT is highly sensitive and specific, it is time consuming, requires specialized detection equipment and involves the ingestion of isotopically labeled urea by the patient. Serological tests, also noninvasive, are based on the detection of IgG antibodies against *H. pylori* and are useful for primary screening of patients that present with uncomplicated infections, yet do not distinguish between past exposure and active infection. Antibody tests are of little benefit in documenting eradication.

During invasive testing, a biopsy is taken from the upper gastrointestinal tract and examined microscopically and in selected cases, immunohistochemically. This strategy offers the advantages of detecting an active infection and has a high specificity and high positive predictive value. The disadvantages of invasive testing include risk and discomfort to the patient, and patchy colonization that might be missed by biopsy. Culture of biopsy material is time consuming, can yield false negative results due to inherent technical difficulties and is not widely available.

REPORTING AND LIMITATIONS

The *H. pylori* stool antigen assay is qualitative (positive or negative) only. Test results should be viewed in light of clinical evaluation and other diagnostic procedures. Administration of PPIs, antimicrobials and bismuth preparations may lead to decreases in bacterial load, causing false negative results for the fecal antigen test (also for the UBT and biopsy-based tests). To avoid false negative

TEST INFORMATION

Test Name:
Helicobacter pylori Antigen, Stool

Test Code:
HPYAG

Specimen Requirements:
Collect fresh stool specimens in a clean, airtight container with no preservative. Transport to laboratory promptly and refrigerate at 2-8°C.

Minimum Volume:
5 grams of stool.

Rejection Criteria:
Grossly bloody (i.e., containing no visible stool), watery, diarrheal, or very mucoid stool is not acceptable. Stool in transport media, preservative, or swab is not acceptable.

Available:
Test is performed Tuesday and Friday. Results available same day.

Reference Value:
Negative

CPT Code:
87338

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tests, administration of these agents must be stopped for a minimum of two weeks prior to testing. The assay should not be used to test asymptomatic patients, given variable rates of colonization in otherwise healthy individuals.

RESPONSE TO TREATMENT

Recurrence of *H. pylori* infection following standard treatment can result from lack of patient compliance with the drug regimen, ineffective drugs, resistant strains of *H. pylori*, improper dosage, etc., and generally occurs by four weeks following termination of therapy. This observation supports accepted medical practice that determination of eradication utilizing any diagnostic method should be performed at least four weeks following completion of therapy.

QUESTIONS

Please contact Dr. Thomas Fritsche, Dr. Jeffrey Resnick or Dr. Thomas Novicki with clinical and interpretive questions regarding this test at extension 1-6700, 715-221-6700, or 800-222-5835.

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