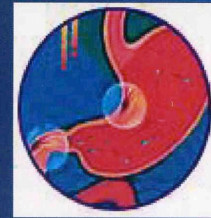


Rapid Diagnosis of *Helicobacter pylori* infections

Direct Noninvasive Qualitative Detection of
H.pylori Antigen in Human Fecal Specimens



Easy procedure for storing and transporting the stools,
avoiding the need for freezing

Ideal for pediatric population

- * One Step 5 min immunochromatographic test
- * Rapid, Convenient, Easy-to-use
- * Accurate & Reliable
- * Highly sensitive
- * Safe
- * No instrumentation
- * No special training
- * Minimizes risk of contamination



Rapid Diagnosis of H.pylori Infections

Helicobacter pylori are gram-negative bacteria that infect gastric mucosa. H.pylori infection is common, even in pediatric patients. H.pylori is now recognized as related to gastritis and peptic ulcer disease. Furthermore, H.pylori infection is involved in the pathogenesis of gastric adenocarcinoma and lymphoma in adulthood. The gold-standard diagnostic test remains endoscopy with biopsy analyses (histologic analysis and urease rapid test or culture of gastric biopsy specimens).

Invasive tests are not always suitable for the pediatric population; there is an increased interest in noninvasive tests for children. Among the noninvasive tests, the urea breath test (¹³C urea breath test) is certainly the best, but it is more expensive, not always available (poor feasibility limit) and difficult to apply to the noncompliant child. In addition, its cut-off value in pediatric patients remains unsettled. H.pylori detection from stool with polymerase chain reaction is limited by the presence of inhibitors of H.pylori DNA amplification in feces. H.pylori is difficult to culture from stool. The direct detection of H.pylori antigen in feces is considered useful for diagnosis and to confirm eradication. The method is simple, rapid, and inexpensive; in fact, only one stool specimen is required. The method does not need a technician or expensive equipment, and easy procedures are used for storing and transporting the stools, avoiding the need for freezing the stool sample. H.pylori fecal antigen is a highly reliable diagnostic method for H.pylori infection. Before extending its use in the general healthy population, many studies have compared the accuracy of this test with that of an invasive test in symptomatic patients. It could be used in epidemiological studies to determine the prevalence of H. pylori infections in asymptomatic subjects.

Principle of the Procedure

One Step H. pylori Fecal Antigen Test is a rapid, visual immunochromatographic assay for the qualitative detection of *Helicobacter pylori* antigen in fecal samples. This test is intended as an aid in the diagnosis of H. pylori infection, and is recommended for professional use.

The One-Step H. pylori Test has been designed to detect H. pylori antigen in human fecal samples through visual interpretation of color development in the test device. The test device contains a membrane strip, which is pre-coated with anti-H pylori antibody at the Test Line region (T) and goat anti-mouse antibody at the Control Line region (C). An anti-H.pylori antibody color particle conjugate pad is located at the end of the membrane. When H. pylori antigen is present in the patient's fecal sample and dissolved in buffered saline, the mixture of colloidal gold conjugate and extracted sample moves along the membrane chromatographically by capillary action. This mixture migrates to the Test region (T) and forms a visible line as the antibodies complex with the H. pylori antigen. If H. pylori are not present in the extracted sample, no visible color band will form at the Test region (T). A colored band will always appear at the Control region (C) to serve as a procedural indicator for the proper performance of the test and the device