H. Pylori Ag Rapid Test

Catalog No.: BG1001C

INTENDED USE

The H.pylori Stool Antigen Test is an *in vitro* qualitative immunochromatographic assay for the rapid detection of *Helicobacter pylori* antigens in human stool specimen. The test results are intended to aid in the diagnosis of *H. pylori* infection, to monitor the effectiveness of therapeutic treatment and to confirm the eradication of *H. pylori* in peptic ulcer patients.

SUMMARY

Helicobacter pylori is a corkscrew-shaped, gram-negative rod that lives in the mucous layer of the stomach. *H. pylori* infection is now accepted as the most common cause of gastritis, and is etiologically involved in gastric ulcer, duodenal ulcer, gastric adenocarcinoma and primary gastric *B*-cell lymphoma.1,2 The organism is very common, infected at least half of the world's population. *H. pylori* infection is typically acquired in childhood. Once acquired, infection persists chronically, probably continuing in the. stomach throughout life. The damage to gastric structure and function of stomach is constant and direct. Approximately one in six of *H. pylori* infection develops peptic ulcer disease and a small portion of *H. pylori* infection leads to gastric cancer.3 The diagnostic tests for *H. pylori* can be classified into two categories: Invasive and Noninvasive tests. Direct detection by invasive test procedures requires an endoscopy and biopsy specimens from antrum and stomach body.4 The presence of *H. pylori* is then confirmed by direct culture, histological examination or rapid urease test. The endoscopy and biopsy specimens offer direct detection of active *H. pylori* infections. Although the procedure is highly specific and high positive predictive value, the cost and discomfort to the patients are very high. The most widely available noninvasive test is probably the serological based test. The serology test detects *H. pylori* specific IgG antibody in patient serum with current or prior infection.5,6 Serology test is a simple, convenient test with relative high sensitivity. The main limitation of serology test is the inability to distinguish current and past infections. Antibody may be present in the patient's serum long after eradication of the organism.6 The urease breath test (UBT) with 14C or 13C labeled urea, is a noninvasive test based on the urease activity of the organism. UBT detects active *H. pylori* infection and is highly sensitive and specific. The UBT requires a high density and active bacteria and should not be performed until 4 weeks after therapy to allow residual bacterial to increase to a sufficient number for detection.7

H. pylori Antigen Test is an imunochromatographic assay that uses antibody- coated colloidal gold to detect the presence of *H. pylori* antigens in stool specimens. The test detects directly antigens in specimens for an active infection. The test is simple and easy to perform and the test results can be visually interpreted within 15 minutes

PRINCIPLE OF THE ASSAY

H. pylori Stool Antigen Test is a sandwich solid phase immunochromatographic assay. To perform the test, an aliquot of diluted stool sample is added to the sample well of the test cassette. The sample flows through a label pad containing H. pylori antibody coupled to red-colored colloidal gold. If the sample contains H. pylori antigens, the antigen will bind to the antibody coated on the colloidal gold particles to form antigen-antibody-gold complexes. These complexes move on the nitrocellulose membrane by capillary action toward the test line region on which H. pylori specific antibodies are immobilized. As the complexes reach the test line, they will bind to the antibody on the membrane in the form of a line. A second red control line will always appear in the result window to indicate that the test has been correctly performed and the test device functions properly. If H. pylori antigen is not present or lower than the detection limit of the test, only the control line will be visible. If the control line dose not developed, the test is invalid.

MAIN CONSTITUENT

1. Test Cassette: 20 test / box
   Test Strip: 50 tests / box
2. Sample collection tube with diluent 1ml ×20 for cassette
   Sample diluent 30ml×1 for strip
3. Product instruction: 1

PRECAUTION FOR USERS

1. Do not pipet reagent by mouth and no smoking or eating while performing assays.
2. Wear gloves during the whole process and avoid reagents or specimen spilling-out.
3. Wipe up the spills using 5% hypochlorite solution.
4. Decontaminate all liquids or solid wastes before deposing.
5. For in-vitro diagnostic use only.
6. Must not use kit beyond the expiration date.
7. Do not mix components from kits with different lot number.
8. Avoid microbial contamination of reagents.

SPECIMEN COLLECTION

Stool specimens should be collected in containers that do not contain media, preservatives, animal serum or detergents as any of these additives may interfere with the HP Stool Ag Test. Specimens may be stored at 2-8℃ for 3 days without interfering with the assay performance. For long-term storage of specimens, -20℃ or colder is recommended. Repeated freezing and thawing of specimens is not recommended and may cause erroneous results. Do not store specimens in self-defrosting freezers.

STORAGE AND STABILITY

The HP Stool Ag Test can be stored at any temperature between 4-30℃. **Do not freeze**. The stability of the kit under these storage conditions is 24 months. Use up the reagents as soon as possible after the kit is unpacked within 3 months.

ASSAY PROCEDURE

1. Bring Membrane Plate and samples to room temperature (20-30℃) before use (approximately 30 minutes).

2. Remove the test cassette/strip from the sealed foil pouch and place the plate on flat desk.

3. Bring all materials and specimens to room temperature (8～30℃).

4.1 **H. pylori Stool Antigen test Strip**

1) Add 500µl sample diluents into the test tube.
2) Add proper specimens (S:5 mm in diameter, L: 50µl) into the tube to make the concentration of the solution up to 5%～10% and mix thoroughly.
3) Deliver 100µl (2～3drops) of diluted stool sample to the sample pad of the test strip.

4.2 **H. pylori Stool Antigen test Cassette**
1) To take a portion of feces (about 100mg), insert the sterile swab into a stool sample that presents the most secretion under visual inspection.
2) Open the sample collection tube and then insert the swab into the sample collection tube containing assay diluents.
3) Swirl the swab at least 10 times until the samples has been dissolved into the assay diluents and discard the swab while squeezing the swab against the wall of tube, replace the cap.
4) Deliver 100µl (2～3drops) of diluted stool sample to the sample well of the test card.
5. Read the result in 5～10 minutes. A strong positive sample may show result earlier.

Note: Results after 15 minutes may not be accurate.

RESULT

INTERPRETATION OF RESULTS

Negative: One pink line appears in control line, showing the test has been carried out correctly. There will be no line in test region

Positive: In addition to a pink colored control line, a distinct pink colored band will also appear in the test region.

Invalid: A total absence of color in both regions is an indication of procedure error and/or that the test reagent has deteriorated. The test should be repeated using a new strip.

Assay Specificity
Following bacterial and viral strains were used to test the specificity of HP Stool Ag Test. Positive and negative stools were spiked with >1x108 organism/ml and tested by HP Stool Ag Test. *H. pylori* positive stool remained positive with the spiked organisms. Negative stool remained negative with the spiked organisms.

LIMITATION

1. The product is only for testing the HP antigen in feces.
2. The kit cannot be used as a quantitative reagent.
3. The positive results should be further verified by the clinical information.
4. All high sensibility immunological test systems are inevitable to no specificity and biological false positive results.
5. The negative results may be caused by the concentration of antibody is lower than the product analysis sensitivity.

PRECAUTIONS

1. For IVD only.
2. Store at dry place once open to atmosphere, and use up within 9 weeks. Do not mix the different batches.
3. This kit does not produce biological safety problems, but dealing with the used reagent and sample as infectious substances;
4. The thick fecal samples can block the test card. Centrifuge or keep it standing, and test the supernatant.
5. Do not add too much sample; otherwise it will cause erroneous results.

REFERENCE

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