OneStep H.Pylori Antigen RapiCard™ InstaTest

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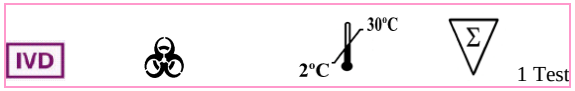

INTENDED USE

Cortez Diagnostics OneStep H. pylori Antigen RapiCard™ InstaTest is a rapid chromatographic immunoassay for the qualitative detection of *H. pylori* antigens in human feces specimens to aid in the diagnosis of *H. pylori* infection.

SUMMARY AND EXPLANATION

H. pylori is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. It is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis. Both invasive and non-invasive methods are used to diagnose *H. pylori* infection in patients with symptoms of gastrointestinal disease. Specimen-dependent and costly invasive diagnostic methods include gastric or duodenal biopsy followed by urese testing (presumptive), culture, and/or histologic staining. A very common approach to the diagnosis of *H. pylori* infection is the serological identification of specific antibodies in infection patients. 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 organisms. HpSA (*H. pylori* stool antigen) testing is gaining popularity for diagnosis of *H. pylori* infection and also for monitoring the efficacy of the treatment of *H. pylori* infection. Studies have found that more than 90% of patients with duodenal ulcer and 80% of patients with gastric ulcer are infected with *H. pylori*.

The OneStep H. Pylori Antigen RapiCard™ is a rapid chromatographic immunoassay for the qualitative detection of *H. pylori* antigens in human feces specimens, providing results in 10 minutes. The test utilizes antibodies specific for *H. pylori* antigens to selectively detect *H. pylori* antigens in human feces specimens.

TEST PRINCIPLE

OneStep H. pylori Antigen RapiCard™ InstaTest is a qualitative, lateral flow immunoassay for the detection of *H. pylori* antigens in human feces specimens. In this test, the membrane is pre-coated with anti-*H. pylori* antibodies on the test line region of the test. During testing, the specimen reacts with the particle coated with anti-*H. pylori* antibodies. The mixture migrates upward on the membrane by capillary action to react with anti-*H. pylori* antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains monoclonal anti-*H. pylori* antibodies coated particles and monoclonal anti-*H. pylori* antibodies coated on the membrane.

SPECIMEN COLLECTION AND PREPARATION

- The feces specimen must be collected in clean, dry, waterproof container containing no detergents, preservatives or transport media.
- Bring the necessary reagents to room temperature before use.
- If specimens are to be shipped, they should be packed in complicance with federal regulations coverin the transportation of etiologic agents.

MATERIALS AND COMPONENTS

Materials provided with the test kits

- Test Cassettes
- Specimen collection tubes with extraction buffer
- Package Insert

Materials required but not provided

- Specimen collection containers
- Centrifuge
- Timer
- Pipette and disposable tips
- Droppers

ASSAY PROCEDURE

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30 ˚C) prior to testing.

1. To collect fecal specimens:
   Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8 ˚C if not tested within 6 hours. For long term storage, specimens should be kept below -20 ˚C.
2. To process fecal specimens:
   a. For solid specimens:
      Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites to collect approximately 50 mg of feces (equivalent to ¼ of a pea). Do not scoop the fecal specimen.
   b. For liquid specimens:
      Hold the dropper vertically, aspirate fecal specimens, and then transfer 2 drops (approximately 80 µL) into the specimen collection tube containing the extraction buffer.
      Tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to m, ix the specimen and the extraction buffer. Leave the tube alone for 2 minutes.
3. Bring the pouch to room temperature before opening it. Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
4. Hold the specimen collection tube upright and open the cap onto the specimen collection tube. Invert the specimen collection tube and transfer 2 full drops of the extracted specimen (approximately 80 µL) to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
5. Read results at 10 minutes after dispensing the specimen. Do not read results after 20 minutes.

Note: If the specimen does not migrate (presence of particles), centrifuge the extracted specimens contained in the extraction buffer vial. Collect 80 µL of supernatant, dispense into the specimen well (S) of a new test cassette and start afresh following the instructions mentioned above.

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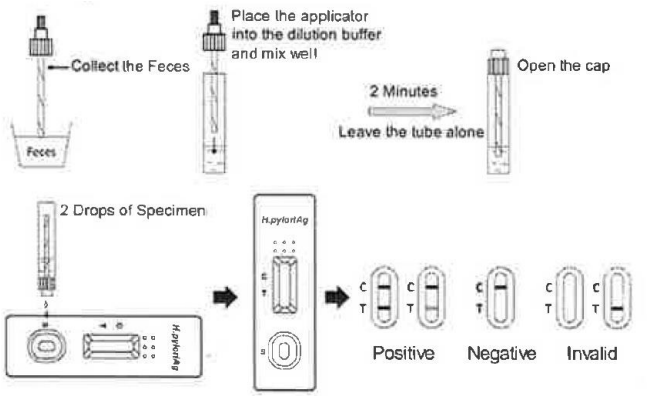

RESULTS

Positive:
Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T). **NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of *H. pylori* antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

Negative:
Only one colored line appears in the control region (C). No line appears in the test line region (T).

Invalid:
Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The OneStep H. pylori Antigen RapiCard™ InstaTest has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. The results show that the sensitivity of the OneStep H. pylori Antigen RapiCard™ InstaTest is >98.8% and the specificity is 98.4% relative to Endoscope-based methods.

Method		Endoscope-based method		Total Result
OneStep H. pylori Antigen RapiCard™ InstaTest	Results	Positive	Negative	
	Positive	168	3	171
	Negative	2	189	191
Total Result		170	192	362

Relative Sensitivity: >98.8% (95% CI*: 95.8.0%-99.9%)
Relative Specificity: 98.4% (95% CI*: 95.5%-99.7%)
Accuracy: 98.6% (95% CI*: 96.8%-99.5%)
*Confidence Interval

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of four specimens: negative, low-titer positive, middle-titer positive, and high-titer positive specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same four specimens: negative, low-titer positive, middle-titer positive, and high-titer positive specimens. Three different lots of the OneStep H. pylori Antigen RapiCard™ InstaTest have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

Cross reactivity with following organisms has been studied at 1.0E+09 organisms/ml. The following organisms were found negative when tested with the OneStep H. pylori Antigen RapiCard™ InstaTest:

Acinetobacter calcoaceticus	Acinetobacter spp.
Candida albicans	Chlamydia trachomatis
E. coli	Enterococcus faecalis
Group A Streptococcus	Group B Streptococcus
Hemophilus influenza	Klebsiella pneumonia
Neisseria meningitides	Proteus mirabilis
Pseudomonas aeruginosa	Rotavirus
Staphylococcus aereus	Adenovirus
Branhamella catarrhalis	Gardnerella vaginalis
Enterococcus faecium	Group C Streptococcus
Neisseria gonorrhea	Proteus vulgaris
Salmonella choleraesius	

Interfering substances

The following potentially interfering Substances were added to HPG negative and positive specimens

- Ascorbic acid:20 mg/dl
- Uric acid:60mg/dl
- Glucose :2000mg/dl
- Oxalic acid:60mg/dl
- Aspirin:20mg/dl
- Caffeine 40 mg/dl
- Bilirubin:100 mg/dl
- Urea :2000mg/dl
- Albumin:2000mg/dl

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal valid procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF PROCEDURE

1. The OneStep H. pylori Antigen RapiCard™ InstaTest is for in-vitro diagnostic use only. The test should be used for the detection of *H. pylori* antigens in feces specimens only. Neither the quantitative value nor the rate of increase in *H. pylori* antigens concentration can be determined by this qualitative test.
2. The OneStep H. pylori Antigen RapiCard™ InstaTest will only indicate the presence of *H. pylori* in the specimen and should not be used as the sole criteria for *H. pylori* to be etiological agent for peptic or duodenal ulcer.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *H. pylori* infection.
5. Following certain antibiotic treatments, the concentration of *H. pylori* antigens may decrease to the concentration below the minimum detection level of the test. Therefore, diagnosis should be made with caution using antibiotic treatment.

EXPECTED VALUES

The OneStep H. pylori Antigen RapiCard™ InstaTest has been compared with Endoscope-based methods, demonstrating an overall accuracy of 98.6%.

PRECAUTIONS

1. For professional in vitro diagnostic use only. Do not use after expiration date.
2. The test should remain in the sealed pouch until use.
3. Do not eat, drink or smoke in the area where the spcimens or kits are handled.
4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. The used test should be discarded according to local regulations.
7. Humidity and temperature can adversely affect results.

STORAGE

The test kit can be stored at temperatures 2 °C to 30 °C (36°F-86°F) in the sealed pouch to the date of expiration. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

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ISO 13485
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