REF: 20206

H. pylori Antibody Rapid Test Cassette
(Serum /Plasma)
Package Insert

A rapid test for the qualitative detection of antibody to Helicobacter pylori (H.pylori) in serum or plasma.

For professional in vitro diagnostic use only.

【INTENDED USE】

The *H.pylori* Antibody Rapid Test Cassette (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of Antibody to *H. pylori* in serum or plasma.

【SUMMARY】

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.[1,2] 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 urease testing (presumptive), culture, and/or histologic staining.[3] Non-invasive techniques include the urea breath test, which requires expensive laboratory equipment and moderate radiation exposure, and serological methods.[4,5] Individuals infected with *H.pylori*develop antibodies which correlate strongly with histological confirmed *H.pylori*infection.[6,7,8]

The *H.pylori*Antibody Rapid Test Cassette (Serum/Plasma) is a simple test that utilizes a combination of *H.pylori*antigen coated particles and anti-human IgG to qualitatively and selectively detect*H.pylori*antibodies in serum or plasma.

【PRINCIPLE】

The *H.pylori*Antibody Rapid Test Cassette (Serum/Plasma) is a qualitative membrane based immunoassay for the detection of *H.pylori*antibodies in serum or plasma. In this test procedure, anti-human IgG is immobilized in the test line region of the test. After specimen is added to the specimen well of the cassette, it reacts with *H.pylori*antigen coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized anti-human IgG. If the specimen contains *H.pylori*antibodies, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain *H. pylori* antibodies, a colored line will not appear in this region indicating 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 cassette contains *H. pylori* antigen coated particles and anti-human IgG coated on the membrane.

【PRECAUTIONS】

Please read all the information in this package insert before performing the test.

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimen or kits are handled.
3. Handle all the specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

1. The *H.pylori* Antibody Rapid Test Cassette (Serum/Plasma) can be performed using serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
3. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

【MATERIALS】

Materials provided

• Test Cassettes • Droppers • Package Insert

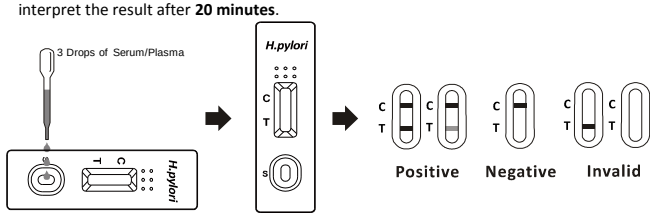
Materials required but not provided

• Specimen collection containers • Centrifuge • Timer

【DIRECTIONS FOR USE】

Allow test cassette, serum or plasma specimen, and/or controls to equilibrate to room temperature (15-30℃) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Hold the dropper vertically and transfer **3 drops of serum or plasma (approximately 75 μL)** to the specimen well of test cassette and start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
3. Wait for the colored line is appeared. The result should be read **at 10minutes.** Do not interpret the result after **20 minutes**.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).

***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of *H.pylori* antibody present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test 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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive 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】

1. The *H.pylori* Antibody Rapid Test Cassette (Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of *H.pylori*antibody in serum or plasma specimen. Neither the quantitative value nor the rate of increase in *H.pylori* antibody concentration can be determined by this qualitative test.
2. The *H.pylori* Antibody Rapid Test Cassette (Serum/Plasma) will only indicate the presence of *H.pylori* antibodies in the specimen and should not be used as the sole criteria for the diagnosis of *H.pylori* infection.
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.

【EXPECTED VALUES】

The *H.pylori* Antibody Rapid Test Cassette (Serum/Plasma) has been compared with a leading commercial *H.pylori* antibody EIA test. The correlation between these two systems is 93.7%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The *H.pylori* Antibody Rapid Test Cassette (Serum/Plasma) has been evaluated with serum and plasma specimens obtained from a population of symptomatic and asymptomatic individuals who presented for endoscopic examination.

Method		ELISA		Total Results
H.pylori Antibody Rapid Test Cassette(Serum/Plasma)	Results	Positive	Negative	
	Positive	211	14	225
	Negative	10	146	156
Total Results		221	160	381

Relative Sensitivity: 95.5% (95%CI*: 91.8%-97.8%) *Confidence Interval

Relative Specificity: 91.3% (95%CI*: 85.7%-95.1%)

Overall Accuracy: 93.7% (95%CI*: 90.8%-95.9%)

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of 4 specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same 4 specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of the *H. pylori* Test Cassette (Serum/Plasma) have been tested using negative, low positive medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

Sera containing known amounts of antibodies to *H.pylori* have been tested with Hepatitis A, B, C, E, HIV and Syphilis. No cross-reactivity was observed, indicating that the *H.pylori*Test Cassette (Serum/Plasma) has a high degree of specificity for human antibodies to *H.pylori*.

Interfering Substances

The *H.pylori*Antibody Rapid Test Cassette (Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens, as well as specimens containing high bilirubin levels. In addition, no interference was observed in specimens containing up to 1,000 mg/dL hemoglobin, up to 1,000 mg/dL bilirubin, and up to 2,000 mg/dL human serum albumin.

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