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

REF L031-10611	English

A rapid test for the qualitative detection of antibodies 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 antibodies to *H. pylori* in serum, or plasma to aid in the diagnosis of *H. pylori* infection.

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 histologically 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 contains *H. pylori* antigen coated particles and anti-human IgG coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged
- Handle all 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.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- 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.
- DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

- The *H. pylori* Antibody Rapid Test Cassette (Serum/Plasma) can be performed using serum, or plasma.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- 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, Serum and plasma specimens should be kept below -20°C.
- 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.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS

Materials Provided

- Test Cassettes
- Package insert
- Disposable specimen droppers

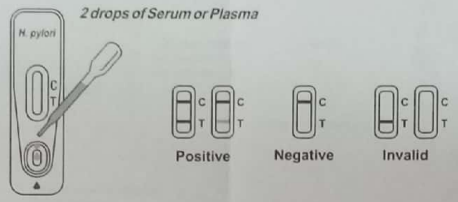
Materials Required But Not Provided

- Specimen collection containers
- Centrifuge (for plasma only)
- Timer

DIRECTIONS FOR USE

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

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible.
2. Place the test cassette on a flat surface. Hold the dropper vertically and **transfer 2 drops of serum or plasma** (approximately 80 µL) into the Specimen Well of the test cassette, then start the timer. Avoid air bubbles. See illustration below.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes**. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)
POSITIVE:* Two distinct colored 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* antibodies present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.
NEGATIVE: One colored line appears in the control line 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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct sample application to the specified specimen well.
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. The test should be used for the detection of *H. pylori* antibodies in serum or plasma specimens only. 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 ELISA method, demonstrating an overall accuracy of 95.9%.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The *H. pylori* Antibody Rapid Test Cassette (Serum/Plasma) has been compared to a leading commercial EIA *H. pylori* test using clinical specimens. The results show that the relative sensitivity of the *H. pylori* Antibody Rapid Test Cassette (Serum/Plasma) is 95.3%, and the relative specificity is 96.4%.

Method		EIA		Total Results
H. pylori Antibody Rapid Test Cassette	Results	Positive	Negative	
	Positive	122	5	127
	Negative	6	133	139
Total Results		128	138	266

Relative Sensitivity: 95.3% (90.15%-97.83%)*
Relative Specificity: 96.4% (91.80%-98.44%)*
Accuracy: 95.9% (92.75%-97.68%)*
*95% Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of four 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 four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of the *H. pylori* Antibody Rapid 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.

BIBLIOGRAPHY

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Index of Symbols

	Manufacturer	Σ	Tests per kit	30°C / 2°C	Store between 2-30°C
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
	Consult instructions for use	LOT	Lot Number	REF	Catalog #
EC REP	Authorized Representative				

ACON Laboratories, Inc.
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MDSS GmbH
Schiffgraben 41
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Number: 1150958001
Effective date: 2017-11-17