H. pylori Antibody Rapid Test Device (Serum/Plasma)
For professional in vitro diagnostic use only

INTENDED USE
The H. pylori Antibody Rapid Test Device (Serum/Plasma) is a rapid visual immunoassay for the qualitative detection of specific IgM and IgG antibodies to Helicobacter pylori in human serum, or plasma specimens. This kit is intended for use as an aid in the diagnosis of H. pylori infection.

INTRODUCTION
Gastritis and peptic ulcers are among the most common human diseases. Since the discovery of *H. pylori*, many reports have suggested that this organism is one of the major causes of ulcer diseases. Although the exact role of *H. pylori* is not yet fully understood, eradication of *H. pylori* has been associated with the elimination of ulcer diseases. The human serological responses to infection with *H. pylori* have been demonstrated. The detection of IgG antibodies specific to *H. pylori* has been shown to be an accurate method for detecting *H. pylori* infection in symptomatic patients. *H. pylori* may colonize some asymptomatic people. A serological test may be used either as an adjunct to endoscopy or as an alternative measure in symptomatic patients.

PRINCIPLE
The H. pylori Antibody Rapid Test Device (Serum/Plasma) detects IgM and IgG antibodies specific to *Helicobacter pylori* through visual interpretation of color development on the internal Device. *H. pylori* antigens are immobilized on the test region of the membrane. During testing, the specimen reacts with *H. pylori* antigen conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there are sufficient antibodies to *Helicobacter pylori* in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS
MATERIALS PROVIDED
- Test Devices.
- Disposable Droppers.
- Package insert.

MATERIALS REQUIRED BUT NOT PROVIDED
- Specimen collection containers.
- Timer.
- Centrifuge.

PRECAUTIONS
- For professional in vitro diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

STORAGE AND STABILITY
- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE
- The H. pylori Antibody Rapid Test Device (Serum/Plasma) is intended for use with human serum, or plasma specimens.
- Only clear, non-hemolized specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave 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.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.

PROCEDURE
Bring tests, specimens, Buffer and/or controls to room temperature (15-30°C) before use.
1. Remove the test from its sealed pouch, and place it on a clean, level surface. For best results, the assay should be performed within one hour.
2. Using a disposable pipette, transfer 2 drop of specimen (approximately 75 µL) to the sample pad of the Device and start the timer.
3. Avoid trapping air bubbles on the sample pad, and do not add any solution to the result area.
4. As the test begins to work, color will migrate across the membrane.
5. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.
INTERPRETATION OF RESULTS

Please refer to the illustration below.

**POSITIVE RESULTS**
Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

**NEGATIVE RESULTS**
Only one colored band appears, in the control region (C). No colored band appears in the test region (T).

**INVALID RESULTS**
Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

**NOTE:**
1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operation procedure or expired tests are the most likely reasons for control band failure.

**QUALITY CONTROL**
- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. 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 THE TEST**
- The *H. pylori* Antibody Rapid Test Device (Serum/Plasma) is for professional *in vitro* diagnostic use, and should only be used for the qualitative detection of *H. pylori* antibodies. No meaning should be inferred from the color intensity or width of any apparent bands.
- This test should be used for symptomatic individuals with gastrointestinal disorders. Diagnosis of gastritis and/or peptic ulcers should be based on test results in conjunction with other clinical and laboratory findings.
- A positive result suggests only the presence of antibodies specific to *H. pylori*, and does not distinguish between active and past infections. A positive result is not necessarily indicative of gastrointestinal disease.
- 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 rule out the possibility *H. pylori* infection, as antibodies to *H. pylori* may be present below the minimum detection level of the test.
- Specimens from patients infected with *C. jejuni* may exhibit a low level of cross-reactivity in this test.

**PERFORMANCE CHARACTERISTICS**

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<thead>
<tr>
<th>Table: <em>H. pylori</em> Antibody Rapid Test vs. Biopsy/Histology/RUT</th>
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<tbody>
<tr>
<td>H. pylori Antibody Rapid Test</td>
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**REFERENCES**


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