A rapid test for the qualitative detection of antibodies to *Helicobacter pylori* in whole blood, serum or plasma

For professional in-vitro diagnostic use only

**INTENDED USE**

The *H. pylori* test is a rapid chromatographic immunoassay for the qualitative detection of antibodies to *Helicobacter pylori* in whole blood, 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. Both invasive and non-invasive methods are used to diagnose *H. pylori* infection in patients with symptoms of gastrointestinal disease. Specifically, the non-invasive diagnostic methods include gastric or duodenal biopsy followed by urease testing (presumptive), culture, and/or histologic staining. Non-invasive techniques include the rapid breath test, which requires expensive equipment and moderate radiation exposure, and serological methods. Individuals infected with *H. pylori* develop antibodies which correlate strongly with histologically confirmed *H. pylori* infection.

The *H. pylori* test is a simple test that utilizes a combination of *H. pylori* antigens to qualitatively and selectively detect *H. pylori* antibodies in whole blood, serum, or plasma.

**PRINCIPLE**

The *H. pylori* test is a qualitative membrane-based immunoassay for the detection of *H. pylori* antibodies in whole blood, 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 device, it reacts with *H. pylori* antigen-coated particles in the test line region indicating a positive result. The specimen contains *H. pylori* antibodies, a coloured line will appear in the test line region indicating a positive result. If the specimen does not contain *H. pylori* antibodies, a colourless line will appear in the test line region indicating a negative result. To serve as a procedural control, a colourless 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 *H. pylori* 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.**
- **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 in the sealed pouch 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.

**SPECIMEN COLLECTION AND PREPARATION**

The *H. pylori* test can be performed using whole blood (from venipuncture or fingerstick), serum, or plasma.

To collect Venipuncture Whole Blood specimens:

- Collect anti-coagulated blood specimen (sodium or lithium heparin, potassium or sodium EDTA, sodium oxalate, sodium citrate) following standard laboratory procedures.

To collect Fingerstick Whole Blood specimens:

- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to form a rounded drop of blood over the puncture site.

Add the Fingerstick Whole Blood specimen to the test by using a capillary tube:

- Touch the end of the capillary tube to the blood until filled to approximately 50 µl. Avoid air bubbles.
- Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well (S) of the test device.

Add the Fingerstick Whole Blood specimen to the test by using hanging drops:

- Position the patient's finger so that the drop of blood is just above the specimen well of the test device.
- Allow 2 hanging drops of fingerstick whole blood to fall into the specimen well of the test device, or move the patient's finger so that the hanging drop touches the specimen well. Avoid touching the finger directly to the specimen well.

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, specimens should be kept below -20 °C and use uncoagulated serum or plasma before the expiry date of the test device.

**MATERIAL PROVIDED**

- *H. pylori* test, separately packed
- Disposable dropper
- Timer

**MATERIAL REQUIRED BUT NOT PROVIDED**

- Specimen collection container
- Lancets (for fingerstick whole blood only)
- Centrifuge
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)
- Buffer

**TEST PROCEDURE**

1. Allow the *H. pylori* test device, specimen, buffer, and/or controls to reach room temperature (15-30 °C) prior to testing. Do not open pouches until ready to perform the assay.

2. Remove the *H. pylori* test device from its protective pouch and use it as soon as possible (bring the device to room temperature before opening the pouch to avoid condensation of moisture on the membrane). Place the test device on a clean and level surface. Label the device with patient or control identification.

3. Serum or Plasma specimens

   Hold the dropper vertically and transfer 4 drops of serum or plasma (approximately 100 µl) to the specimen well of the test device.

4. Venipuncture Whole Blood specimens

   Hold the dropper vertically and transfer 2 drops of whole blood (approximately 50 µl) to the specimen well of the test device.

5. Fingerstick Whole Blood specimens

   To use a capillary tube: Fill the capillary tube and transfer approximately 50 µl of fingerstick whole blood to the specimen well (S) of the test device.

   To use hanging drops: Allow 2 hanging drops of fingerstick whole blood (approximately 50 µl) to fall into the center of the specimen well on the test device.

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QUALITY CONTROL
An internal procedural control is included in the test. A coloured line appearing in the control line region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking 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 test is for in-vitro diagnostic use only. The test should be used for the detection of H. pylori antibodies in whole blood, 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 test 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 test has been compared with Culture/Histology, demonstrating an overall accuracy of 90.7 %.

PERFORMANCE CHARACTERISTICS
Clinical Sensitivity, Specificity and Accuracy
The H. pylori test has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals who presented for endoscopic examination. Biopsy (Culture) served as the reference method for the H. pylori test. Histology and a Rapid Urease Test (RUT) were performed on all negative culture specimens. The specimen was considered positive if Culture was positive. The specimen was also considered positive if the Culture was negative, but both Histology and RUT were positive. The specimen was considered positive if Culture was positive. The specimen was also considered positive if the Culture was negative, but both Histology and RUT were positive. 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.

H. pylori test vs. Biopsy/Histology/RUT

<table>
<thead>
<tr>
<th>Method</th>
<th>Total</th>
<th>Biopsy/ Histology/RUT</th>
<th>Positive</th>
<th>Negative</th>
<th>Positive</th>
<th>Negative</th>
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<tr>
<td>Test card</td>
<td>119</td>
<td>105</td>
<td>20</td>
<td>19</td>
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<tr>
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<td>128</td>
<td>20</td>
<td>19</td>
<td>54</td>
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</tr>
</tbody>
</table>

Relative Sensitivity: 93.0 % (87.1 % - 96.7 %)"  
Relative Specificity: 92.9 % (83.8 % - 93.3 %)"  
Accuracy: 90.7 % (87.0 % - 93.7 %)"  
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. The negative, low positive, medium positive and high positive values were correctly identified >99 % of the time.

Cross-Reactivity
Sera containing known amounts of antibodies to H. pylori have been tested with C. jejuni, C. fetus, C. coli, P. aeruginosa, E. coli, Hepatitis A, B, C, E, HIV and Syphilis. No cross-reactivity was observed, indicating that the H. pylori test has a high degree of specificity for antibodies to H. pylori.

Interference Studies
The H. pylori test has been tested for possible interference from visibly hemolyzed and lipemic specimens, as well as serum 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.

LITERATURE