A rapid test for the qualitative detection of antibodies to Helicobacter pylori (H. pylori) in whole blood, serum, or plasma. For professional in vitro diagnostic use only.

INTENDED USE
The H. pylori Rapid Test Device (Whole Blood, Serum, or Plasma) is a rapid Chromatographic immunoassay for the qualitative detection of antibodies to H. 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. Specimen-dependent and costly invasive diagnostic methods include gastric or duodenal biopsy followed by laboratory equipment and moderate radiation exposure, and serological methods. Individuals infected with H. pylori develop serum antibodies in whole blood, serum, or plasma.

SPECIMEN COLLECTION AND PREPARATION
• Add the Fingerstick Whole Blood specimen to the test device by using a disposable specimen dropper. Avoid air bubbles.
• Fingerstick Whole Blood specimen: Hold the dropper vertically and transfer 4 drops of serum or plasma (approximately 40 µl) and start the timer. See illustration below.
• Whole blood collected by fingerstick should be tested immediately.
• For Fingerstick Whole Blood specimen: Fill the capillary tube and transfer 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 device by using hanging drop:
  • Position the patient’s finger so that the drop of blood is just above the specimen well (S) of the test device.
  • Allow 2 hanging drops of fingerstick whole blood to fall into the specimen well (S) of the test device, or move the patient’s finger so that the hanging drop touches the specimen well (S). Avoid touching the finger directly to the specimen well (S).
  • 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. Whole blood collected by venipuncture should be stored at 2–8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
  • 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 federal regulations covering the transportation of etiologic agents.

MATERIALS
Materials Provided
• Test devices
• Disposable specimen droppers
• Buffer (for whole blood only)
• Package insert

Materials Required But Not Provided
• Specimen collection containers
• Lancets (for fingerstick whole blood only)
• Disposable heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)
• Centrifuge (for plasma only)
• Timer

DIRECTIONS FOR USE
Allow the test device, specimen, buffer, and/or controls to equilibrate to room temperature (15–30°C) prior to testing.
1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface. For Serum or Plasma specimen: Hold the dropper vertically and transfer 4 drops of serum or plasma (approximately 100 µl) to the specimen well (S) of the test device, then Start the timer. See illustration below.
   For Venipuncture Whole Blood specimen: Hold the dropper vertically and transfer 2 drops of whole blood (approximately 50 µl) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µl) and Start the timer. See illustration below.
   For Fingerstick Whole Blood specimen: Fill the capillary tube and transfer approximately 50 µl of fingerstick whole blood specimen to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µl) and start the timer. See illustration below.
3. Wait for the red line(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 above)

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

**NOTE:** The intensity of the red 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 red in the test region (T) should be considered positive.

NEGATIVE: One red line appears in the control region (C). No apparent 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 device. 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 the qualitative value nor the rate of increase in H. pylori antibody concentration can be determined by this qualitative test.

LIMITATIONS
1. The H. pylori Rapid Test Device (Whole Blood/Serum/Plasma) 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 Rapid Test Device (Whole Blood/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.

PERFORMANCE CHARACTERISTICS

Sensitivity
The H. pylori Rapid Test Device (Whole Blood/Serum/Plasma) 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 Rapid Test Device (Whole Blood/Serum/Plasma). 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 result shows that the sensitivity H. pylori Rapid Test Device (Whole Blood/Serum/Plasma) is 93.0% relative to Biopsy/Histology/RUT.

Specificity
The H. pylori Rapid Test Device (Whole Blood/Serum/Plasma) uses an antigen that is highly specific for H. pylori antibodies in whole blood/serum/plasma. The results show that the Specificity of the H. pylori Rapid Test Device (Whole Blood/Serum/Plasma) is 89.2% relative to Biopsy/Histology/RUT.

The H. pylori Rapid Test Device vs. Biopsy/Histology/RUT

<table>
<thead>
<tr>
<th>Method</th>
<th>Biopsy/Histology/RUT</th>
<th>Total Results</th>
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</thead>
<tbody>
<tr>
<td>H. pylori Test Device</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>119</td>
<td>20</td>
</tr>
<tr>
<td>Negative</td>
<td>9</td>
<td>166</td>
</tr>
<tr>
<td>Total Results</td>
<td>128</td>
<td>185</td>
</tr>
</tbody>
</table>

Relative sensitivity: 93.0%
Relative Specificity: 89.2%
Accuracy: 90.7%

Precision

Intra-Assay
Within-run precision has been determined by using 15 replicates of three specimens: a negative, a low positive and a high positive. The negative, low positive and high positive values were correctly identified >99% of the time.

Inter-Assay
Between-run precision has been determined by 15 independent assays on the same three specimens: a negative, a low positive and a high positive. Three different lots of the H. pylori Rapid Test Device (Whole Blood/Serum/Plasma) have been tested using negative, low 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 C. jejuni, C. fetus, C. coli and E. Coli. No cross-reactivity was observed, indicating that the H. pylori Rapid Test Device (Whole Blood/Serum/Plasma) has a high degree of Specificity for antibodies to H. pylori.

Interference Studies
The H. pylori Rapid Test Device (Whole Blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and icteric specimens, as well as serum specimens containing high bilirubin levels. In addition, no interference was observed in specimens containing up to 1000 mg/dL hemoglobin; up to 1000 mg/dL bilirubin; and up to 2000 mg/dL human serum albumin.

BIBLIOGRAPHY


Explanation of Symbols

IVD Directive 98/79/EC

Use only once

Diprotest L45270

98/97/EC

IVD-Directive 98/79/EC

01-12-2003

595122infoE1

Richtl ass. to

ISO-Directive 98/74/EC

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