H. pylori Test Card Instruction For Use

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GENERAL BIOLOGICALS CORP.

H. pylori IgG Test Card

One Step H. pylori Test Device (Serum/Plasma)

Cat. No.: 4500188 (4RHP3)

Instructions

A rapid, one step test for the qualitative detection of antibodies to Helicobacter pylori (H. pylori) in human serum or plasma.

For professional in vitro diagnostic use only.

INTENDED USE

The One Step H. pylori Test Device (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. 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. Non-invasive techniques include the urea breath test, which requires expensive laboratory 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 One Step H. pylori Test Device (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 One Step H. pylori Test Device (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 device, 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.

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 beyond 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 all procedures 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 assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect test results.

INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

NEGATIVE: One colored line appears in the control line region (C). No apparent red or pink 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 procedural technique and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

EXPECTED VALUES

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

Performance Characteristics

Clinical Sensitivity, Specificity and Accuracy

One Step H. pylori Test Device vs. Biopsy

<table>
<thead>
<tr>
<th>Method</th>
<th>Biopsy</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>H. pylori Test Device</td>
<td>Results</td>
<td>Positive</td>
</tr>
<tr>
<td>Positive</td>
<td>94</td>
<td>27</td>
</tr>
<tr>
<td>Negative</td>
<td>4</td>
<td>85</td>
</tr>
</tbody>
</table>

Total Results: 98

Relative Sensitivity: 95.9% (89.9%-98.9%)*
Relative Specificity: 75.9% (66.9%-83.4%)*
Accuracy: 85.2% (79.7%-89.7%)*
* 95% Confidence Interval

The discrepanst specimens were resolved by ELISA for IgG antibodies to H. pylori.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either 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.

DIRECTIVE FOR USE

- The One Step H. pylori Test Device (Serum/Plasma) can be performed using either serum or plasma.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. 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. 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

- Test devices
- Materials Provided
  - Specimen collection container
  - Centrifuge
  - Package insert
  - Control
- Materials Required But Not Provided
  - Specimen collection container
  - Control
  - Timer

DIRECTIONS FOR USE

1. Place the test, serum or plasma specimen, and/or controls to reach room temperature (15-30°C) prior to testing.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 drops of serum or plasma (approx. 100 μL) to the specimen well (S) of the test device, and start the timer. Avoid trapping air bubbles in the specimen well (S). Please see the illustration below.
3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 20 minutes.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

1. The One Step H. pylori Test Device (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 specimen only. Neither the quantitative value nor the rate of increase in H. pylori antibody concentration can be determined by this qualitative test.
2. The One Step H. pylori Test Device (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 One Step H. pylori Test Device (Serum/Plasma) has been compared with Culture/Histology, demonstrating an overall accuracy of 93.2%.

SELECTED REFERENCES

One Step *H. pylori* Test Device vs. Biopsy/ELISA

<table>
<thead>
<tr>
<th>Method</th>
<th>ELISA</th>
<th>Total Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>H. pylori</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test Device</strong></td>
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</tr>
<tr>
<td>Results</td>
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<tr>
<td>Positive</td>
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<td>107</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>85</td>
</tr>
<tr>
<td><strong>Total Results</strong></td>
<td>94</td>
<td>192</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Relative Sensitivity: &gt;99.0% (96.2%-100%)*</th>
<th>Relative Specificity: 86.7% (78.4%-92.8%)*</th>
<th>Accuracy: 93.2% (88.7%-96.3%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>* 95% Confidence Interval</td>
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</table>

**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 One Step *H. pylori* Test Device (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 One Step *H. pylori* Test Device (Serum/Plasma) has a high degree of specificity for human antibodies to *H. pylori*.

**Interference Studies**

The One Step *H. pylori* Test Device (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.

**BIBLIOGRAPHY**