HELMOCOBACTER PYLORI (SERUM TEST)

Cat. No: DT50150S-25/50 25/50 Tests

INTENDED USE
D-Tek's H. pylori Rapid Test is a lateral flow immunochromatographic assay for qualitative determination of IgG antibodies specific to Helicobacter pylori (H. pylori) in human serum. The test is intended for professional use as an aid in the diagnosis of H. Pylori infections.

Do not use plasma or specimens containing anticoagulants that may interfere with the sensitivity and specificity of the test.

SUMMARY AND EXPLANATION
Helicobacter pylori (also known as Campylobacter pylori) are gram negative bacteria infecting gastric mucosa. H. Pylori infection has been shown to be associated with the causative agent of type B active chronic gastritis, gastric lesions and some cases of duodenal ulcers. Current tests for diagnosing H. pylori infection involve histological staining and/or culture of antral biopsy methods. However, these techniques are invasive and alternative, non-invasive methods such as the urea breath test and serological test are available. Various serological methods have been employed, including the complement fixation rest, the bacterial agglutination test, the passive hemagglutination test, the hemagglutination assay, immunoblotting techniques, and enzyme-linked immunosassays. All of these techniques have demonstrated a correlation between the level of reactivities and the presence of H. Pylori in the gastric antrum.

D-Tek ' One-Step H. pylori test is a rapid immunochromatographic assay for qualitative determination of anti-H. Pylori antibodies. It is a presumptive test intended for use as an aid in the diagnosis of H. Pylori infections.

TEST PRINCIPLE
The immunochromatographic device contains dye-conjugated and immobilized H. Pylori antigens which, in the presence of the antibody, combine to produce an antigen-antibody-dye conjugate sandwich, that appears as a distinct visual pattern in the test zone of the devise. The antibody in the test specimen is detected in approximately ten minutes.

In the test procedure, serum specimen is allowed to migrate through the absorbent area of the devise. If the antibody against H. Pylori is present, labeled antigen-dye conjugate binds to it, forming an antigen-antibody-dye complex. The presence of the antibody is visually determined as a pink-rose color band when immobilized antigen in the Test Zone ("T") captures the complex forming an antigen-antibody-antigen-dye sandwich. Proper test performance is verified in the Control Zone ("C") by the appearance of a pink-rose band, produced by a parallel immunochemical reaction as immobilized reagent captures dye conjugate regardless of the test sample.

REAGENTS AND MATERIALS PROVIDED
Test Device with a Dropper and desiccant sealed in a pouch

MATERIALS REQUIRED BUT NOT PROVIDED
Specimen collection container, Watch or timer, Positive and Negative control.

KIT STORAGE
Store the test kit at room temperature 59-86°C (15-30°C) Refer to the expiration date for stability of the sealed device.

PRECAUTIONS
1. When handling serum, preclude any pipetting by mouth.
2. Do not allow smoking or eating where the specimens are being handled.
3. Wear disposable gloves while handling kit reagents or specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Wipe up spills thoroughly using an appropriate intermediate-to-high-level disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials as if they were infections in a biohazard container.
7. Do not use the kit or reagents after the expiration date.
8. For in vitro diagnostic use only.

SPECIMEN COLLECTION AND STORAGE
The One-Step H.pylori test may be performed using human serum.

Collect blood aseptically by venipuncture into a clean tube without anticoagulants. Permit blood to clot for twenty to thirty minutes at room temperature. Centrifuge to obtain clear serum and transfer serum into a clean plastic or glass tube. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior for assaying. If serum specimens are not tested immediately they should be refrigerated at 2-8°C. For storage periods greater than three days, freezing is recommended. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

ASSAY PROCEDURE
Note: Read all procedural instructions before running patient samples or controls.

PROCEDURE NOTES
1. Bring all samples and controls to room temperature (15-28°C) prior to testing.

2. Do not remove the Test Device from its foil pouch until ready to perform the test.

TEST PROCEDURE
1. Remove the test device from its sealed foil pouch by tearing along the "notch". Place the test device on a level surface.
2. Add 4 drops of serum specimen (160-200 µl) with the dropper provided directly into the sample port (marked "S") of the test device. Note: If migration is not observed in 30 seconds in the results window, add one or two extra drops of serum specimen.
3. Strong positive results may be observed in 2-3 minutes. Weak positive results may take longer time up to 10 minutes.

To avoid an incorrect reading or invalid result, do not interpret test results after more than 10 minutes.

INTERPRETATION OF RESULTS

1. **Positive**: Two pink-rose bands appear—one in the Control Zone ("C") and one in the Test Zone ("T"). The sample should be considered positive for the presence of antibodies to H. Pylori.

A faint line in the region indicates a borderline specimen which should be re-tested using an alternative method for confirmation.

2. **Negative**: One pink-rose band appears in the Control Zone ("C") with no apparent band in the Test Zone ("T"). The sample should be considered negative for anti-bodies to H. Pylori.

3. **Invalid**: If no pink-rose band appears in the Control Zone, or if a band appears in the Test Zone, but not in the Control Zone, then the test is invalid. It is recommended that the specimen be retested using a new device.

QUALITY CONTROL
1. **Internal Controls**: The OneStep H. Pylori Test contains built-in quality control features. The development of the pink-rose line in the Control Zone ("C") indicates that the sample has been absorbed into the device, that capillary flow has occurred, and that antibody reactivity is still at a high level. If the C line does not develop within 5 minutes, review the whole procedure and repeat test with a new device.
2. **External Controls:** Good laboratory practice is recommended with the use of control material to ensure proper kit performance. The expected results should be obtained when using controls.

**LIMITATIONS OF THE TEST**

1. The test is a qualitative test for detection of IgG antibody specific to H. Pylori. A positive result does not distinguish active infection and colonization of H. Pylori.

2. The test is in vitro diagnostic use only.

3. This product is designed for testing human serum only.

4. Samples with bacterial contamination should not be used. They may interfere with the test and give false positive results.

5. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

6. The test allows to detect anti-H. Pylori antibody as a general indication of H. Pylori infection. It does not allow to differentiate between types of the infection (current, ongoing, etc.).

**PERFORMANCE CHARACTERISTICS**

**SENSITIVITY AND SPECIFICITY**

100 clinical confirmed human serum specimens were tested with the D-Tek HP test. Among the 100 specimens, 50 were confirmed negative and 50 were positive. The results obtained from D-Tek Test were 49 negative and 51 positive.

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>H. Pylori Positive</td>
<td>49</td>
<td>1</td>
<td>50</td>
</tr>
<tr>
<td>Negative</td>
<td>2</td>
<td>48</td>
<td>50</td>
</tr>
<tr>
<td>Total</td>
<td>51</td>
<td>49</td>
<td>100</td>
</tr>
</tbody>
</table>

The positive results agreed 98% (50/51). The negative results agreed 98% (49/50).

**CROSS-REACTIVITY**

The cross-reactivity experiments of the D-Tek H. Pylori Immunochromatographic Assay was performed with other bacteria using 10µg of their extract spiked into normal human serum pool. The organisms tested included:

- Campylobacter jejuni
- Campylobacter fetus
- Campylobacter coli
- Escherichia coli

No cross reactivity was observed.

**REPRODUCIBILITY**

The precision was determined by replicate assays of 100 serum specimens, 50 positive and 50 negative with three different production lots. The results indicate 100% precision for the replicate within each lot and no appreciable inter-lot variation across the three different lots of devices.

**INTERFERING SUBSTANCES**

To determine the interference of structurally unrelated analytes, the following analytes were spiked into known H.Pylori free human serum pools, as well as the H. Pylori positive human serum pools and were tested with the ADI H.Pylori Test. No significant interference with either negative or positive results was observed at the concentrations listed below:

<table>
<thead>
<tr>
<th>Chemical Analyses</th>
<th>Concentrations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetocetic Acid</td>
<td>2000 mg/dl</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>20 mg/dl</td>
</tr>
<tr>
<td>Acetylalanyllic Acid</td>
<td>20 mg/dl</td>
</tr>
<tr>
<td>Ascorbic Acid</td>
<td>20 mg/dl</td>
</tr>
<tr>
<td>Benzoylcegonine</td>
<td>10 mg/dl</td>
</tr>
<tr>
<td>Caffein</td>
<td>20 mg/dl</td>
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<tr>
<td>Cannabinol</td>
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<tr>
<td>DMSO</td>
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<tr>
<td>EDTA</td>
<td>80 mg/dl</td>
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<tr>
<td>Ephedrine</td>
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<tr>
<td>Ethanol</td>
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<tr>
<td>Gentisic Acid</td>
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</tr>
<tr>
<td>Methadone</td>
<td>10 mg/dl</td>
</tr>
<tr>
<td>Methanol</td>
<td>10%</td>
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<tr>
<td>Phenothiazine</td>
<td>20 mg/dl</td>
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<tr>
<td>Salicyclic Acid</td>
<td>20 mg/dl</td>
</tr>
<tr>
<td>8-Hydroxybutarate</td>
<td>2000 mg/dl</td>
</tr>
<tr>
<td>Uric Acid</td>
<td>20 mg/dl</td>
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</tbody>
</table>

**REFERENCES**


