**INTENDED USE**

The H. Pylori Ab Combo Rapid Test is a sandwich lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The test cassette consists of: 1) a burgundy colored conjugate pad containing H. Pylori antigens including CagA conjugated with colloidal gold (H. Pylori conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated H. Pylori antigens, and the C band is pre-coated with goat anti-rabbit IgG.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. The antibodies: either the IgG, the IgM, or the IgA, to H. Pylori present in the specimen will bind to the H. Pylori conjugates. The immunocomplex is then captured on the membrane by the pre-coated H. Pylori antigens, forming a burgundy colored T band, indicating a H. Pylori Ab positive test result.

Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-rabbit IgG/antiabbit IgG-gold conjugates regardless the presence of any antibodies to H. Pylori. Otherwise, the test result is invalid and the specimen must be retested with another device.

**MATERIALS REQUIRED AND AVAILABLE FOR PURCHASE**

1. Positive Control (1 vial, red cap, 1 mL)
2. Negative Control (1 vial, green cap, 1 mL)

**MATERIALS REQUIRED BUT NOT PROVIDED**

1. Clock/watch or Timer
2. Lancing device or finger tip puncture device for taking blood specimen
3. Clean scissors for cutting tip of the dropper containing diluent

**WARNINGS AND PRECAUTIONS**

For In Vitro Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15°C-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolyzed blood specimen for testing.
7. Wear protective clothing and disposable gloves while handling the reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as biohazardous waste.
11. Handle the Negative and Positive Control in the same manner as patient specimens.
12. The testing results should be read within 15 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 15 minutes may give erroneous results.
13. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air-conditioning.

**REAGENT PREPARATION AND STORAGE INSTRUCTIONS**

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. The positive and negative controls should be kept at 2°C-8°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

**SPECIMEN COLLECTION AND HANDLING**

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

**Plasmas**

1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by venipuncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into new pre-labeled tube.

**Seraums**

1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately.

Store specimens at 2°C-8°C up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

**Blood**

Drops of whole blood can be obtained in a collection tube (containing EDTA, citrate or heparin, respectively) by either finger tip puncture or venipuncture. Do not use any hemolized blood for testing.

Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.

**ASSAY PROCEDURE**

**Step 1:** Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.

**Step 2:** When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

**Step 3:** Be sure to label the device with specimen’s ID number.

**Step 4:** For whole blood test

Apply 1 drop of whole blood into the sample well. Then immediately cut the tip of the dropper containing sample diluent with scissors and add 2-3 drops of sample diluent into the sample well.
Note: be sure to check for air bubbles close to the dispensing tip of the dropper.
Remove any air bubbles at the tip by squeezing a few drops of liquid out. Then immediately squeeze 2-3 drops of sample diluent into the sample well.

For serum or plasma test
Fill the dropper with the specimen. Holding the dropper vertically, dispense 1 drop of specimen into the sample well making sure that there are no air bubbles. Then immediately cut the tip of the dropper containing sample diluent with scissors and add 2-3 drops of sample diluent into the sample well.

Note: be sure to check for air bubbles close to the dispensing tip of the dropper.
Remove any air bubbles at the tip by squeezing a few drops of liquid out. Then immediately squeeze 2-3 drops of sample diluent into the sample well.

Step 5: Set up clock/watch or timer.
Step 6: Results can be read in 15 minutes. Positive results can be visible in as short as 1 minute.

Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF ASSAY RESULT

1. NEGATIVE RESULT: If only the C band is developed, the test indicates that no detectable antibodies to H. Pylori are present in the specimen. The result is negative.

2. POSITIVE RESULT: If both C and T bands are developed, the test indicates for the presence of antibodies to H. Pylori in the specimen. The result is positive.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

3. INVALID: If no C band is developed, the assay is invalid regardless of color development on the T band as indicated below. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

Clinical Performance
A total of 200 specimens from the non- H. Pylori patients and 75 specimens from the patients under anti H. Pylori treatment were tested by the H. Pylori Ab Combo Rapid Test. Comparison for all subjects is showed in the following table.

<table>
<thead>
<tr>
<th>H. Pylori Patients</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>65</td>
<td>10</td>
<td>75</td>
</tr>
<tr>
<td>Negative</td>
<td>18</td>
<td>182</td>
<td>200</td>
</tr>
<tr>
<td>Total</td>
<td>83</td>
<td>190</td>
<td>275</td>
</tr>
</tbody>
</table>

Relative Sensitivity: 86.7%, Relative Specificity: 91%, Overall Agreement: 89.9%

LIMITATIONS OF TEST

1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of antibodies to H. Pylori in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The H. Pylori Ab Combo Rapid Test is limited to the qualitative detection of IgG, IgM, and IgA anti-H. Pylori in human serum, plasma or whole blood. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable antibodies to H. Pylori. However, a negative test result does not preclude the possibility of exposure to or infection with H. Pylori.
4. A negative result can occur if the quantity of the antibodies to H. Pylori present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. If the symptom persists, while the result from H. Pylori Ab Combo Rapid Test is negative, it is recommended to re-test the specimen with an alternative test device.
6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES


PI-R0191C Rev. C, Effective date: 12-24-2009

Distributed by Labstix Diagnostics Pty Ltd
P O Box 904520, Faerie Glen, 0043
Tel: +27 13 947 8049 / Fax: +27 86 669 7760
info@labstix.co.za / www.labstix.co.za