Spectrum For Diagnostic Industries

H. pylori Ab Rapid Test Cassette

(Serum, Plasma and Whole Blood)

REF: 524 30 030 30 test

INTENDED USE

The Spectrum H. pylori Ab Test Device is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM, and IgA) anti- Helicobacter pylori (H. pylori) in human serum, plasma, whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with H. pylori. Any reactive specimen with the Spectrum H. pylori Ab Test Device must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY

Helicobacter pylori is associated with a variety of gastrointestinal diseases included non-ulcer dyspepsia, duodenal and gastric ulcer and active, chronic gastritis1,2. The prevalence of H. pylori infection could exceed 90% in patients with signs and symptoms of gastrointestinal diseases. Recent studies indicate an association of H. pylori infection with stomach cancer3.
H. pylori colonizing in the gastrointestinal system elicits specific antibody responses4,5,6 which aids in the diagnosis of H. pylori infection and in monitoring the prognosis of the treatment of H. pylori related diseases. Antibiotics in combination with bismuth compounds have been shown to be effective in treating active H. pylori infection. Successful eradication of H. pylori is associated with clinical improvement in patients with gastrointestinal diseases providing a further evidence7.
The Spectrum H. pylori Ab Test Device is a latest generation of chromatographic immunoassay which utilizes recombinant antigens to detect the antibodies to H. pylori in human serum or plasma. The test is user friendly, highly sensitive and specific.

TEST PRINCIPLE

The Spectrum H. pylori Ab Test Device is a 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 Cag-A conjugated with colloid 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 if 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/rabbit IgG-gold conjugate regardless the presence of any antibodies to H. pylori. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

The test contains H. pylori antigen coated particles and anti-human IgG coated on the membrane.

1. Test Cassettes
2. Buffer
3. Droppers
4. Package inserts.

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer
- Centrifuge
- Lancets(for finger stick whole blood only)

WARNINGS AND PRECAUTIONS

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 hemolized blood specimen for testing.
7. Wear protective clothing and disposable gloves while handling the kit 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, ie. Electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTION

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°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 PREPARATION

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

Plasma

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.

Serum

1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
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 by either finger tip puncture or veinpuncture. 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.

TEST PROCEDURE

Allow the test cassette, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

To collect fecal specimens:

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.

   For Serum or Plasma specimen:

   . Hold the dropper vertically and transfer 3 drops of serum or plasma (approximately 75 μL) to the specimen well of test Cassette and start the timer. See illustration below.

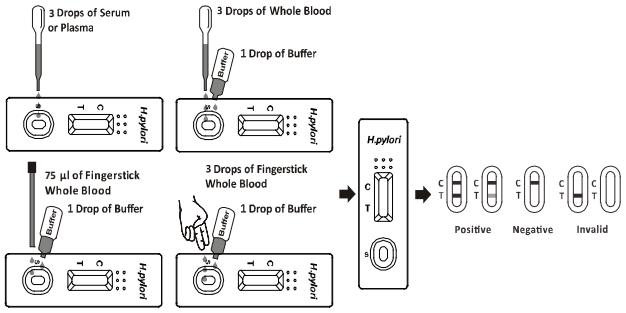
   For Venipuncture Whole Blood specimen:

   . Hold the dropper vertically and transfer 3 drops of whole blood (approximately 75 μL) to the specimen well, then add 1 drop of buffer (approximately 40 μL), and start the timer. See illustration below.

   For Fingerstick Whole Blood specimen:

   . To use a capillary tube: Fill the capillary tube and transfer approximately 75μL of fingerstick whole blood specimen to the specimen area of test cassette, then add 1 drop of buffer (approximately 40 μL) and start the timer. See illustration below.

   . To use hanging drops: Allow 3 hanging drops of fingerstick whole blood specimen (approximately 75 μL) to fall into the specimen area of test cassette, then add 1 drop of buffer (approximately 40 μL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 20 minutes.



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).

***NOTE:** The intensity of the color in the test line region (T) may vary depending on the concentration of H.pylori antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

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

QUALITY CONTROL

1. Internal Control: This test contains a built-in control feature, the C band. The C line develops after adding specimen and sample diluent. Otherwise, review the whole procedure and repeat test with a new device.
2. External Control: Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:

a. New operator uses the kit, prior to performing testing of specimens.
b. A new lot of test kit is used.
c. A new shipment of kits is used.
d. d. The temperature used during storage of the kit falls outside of 2-30oC.
e. The temperature of the test area falls outside of 15 - 30oC.
f. To verify a higher than expected frequency of positive or negative results.
g. To investigate the cause of repeated invalid results.

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 Spectrum H. pylori Ab Test Device 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. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

Expected Values

The H. pylori Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with Culture/Histology, demonstrating an overall accuracy of 94.6%.

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 Spectrum H. pylori Ab Test Device. Comparison for all subjects is shown in the following table.

Spectrum H. pylori Ab Test Device			
H. pylori Patients	Positive	Negative	Total
Positive	65	10	75
Negative	18	182	200
Total	83	180	275

Relative Sensitivity: 86.7%
Relative Specificity: 91%
Overall Agreement: 89.8%

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