



**In vitro Diagnostic
Catalog Number: R0191C**

INTENDED USE

The H. Pylori Ab Combo Rapid Test 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 H. Pylori Ab Combo Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST

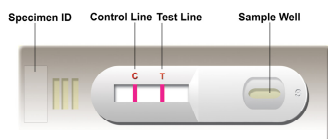
Helicobacter pylori is associated with a variety of gastrointestinal diseases included non-ulcer dyspepsia, duodenal and gastric ulcer and active, chronic gastritis^{1,2}. The prevalence of *H. pylori* infection could exceed 90% in patients with signs and symptoms of gastrointestinal diseases. Recent studies indicate an association of *H. Pylori* infection with stomach cancer³.

H. Pylori colonizing in the gastrointestinal system elicits specific antibody responses^{4,5,6} 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 H. Pylori Combo Ab Rapid Test 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 H. Pylori Ab Combo Rapid Test 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

1. Each kit contains 30 test devices, each sealed in a foil pouch with four items inside:
 - a. One cassette device.
 - b. One pipette dropper.
 - c. One sealed pipette dropper containing sample diluent
 - d. One desiccant.
2. One package insert (instruction for use).

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 sample 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 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 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.

Plasma

1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.
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

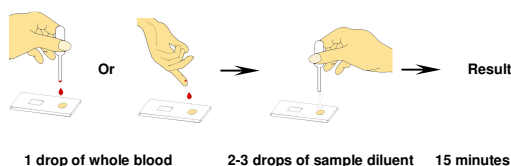
Drops of whole blood can be obtained in a collection tube (containing EDTA, citrate or heparin, respectively) by either finger tip puncture or veinpuncture. Do not use any hemolyzed blood for testing.

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.

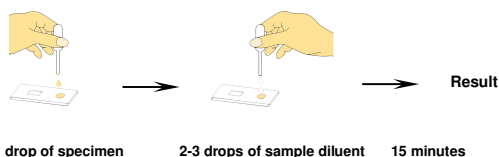
Note: be sure to check for air bubbles close to the dispensing tip of the dropper. Remove any air bubbles at the tip by squeezing a few drops of liquid out. Then immediately squeeze 2-3 drops of sample diluent into the sample well.



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.



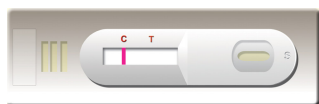
Step 5: Set up clock/watch or timer.

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

- 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.



- 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.

- 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.

H. Pylori Patients	H. Pylori Ab Combo Rapid Test		Total
	Positive	Negative	
Positive	65	10	75
Negative	18	182	200
Total	83	180	275

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

LIMITATIONS OF TEST

- 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.
- 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.
- 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*.
- 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.
- 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.
- Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

- Marshall,B.J.et.al.1985. Med. J. Australia. 149:439-44,
- Soll,A.H. 1990. New England J. Med.322:909-916.
- Parsonnet,J.et.al.1991. New England J. Med. 325:1127-31.
- Ansong,R. et.al.1991. J.Clin.Micro. 29:51-53,
- Pronovost,A.P.et.al. 1994. J.Clin.Microbiol.32:46-50.
- Megraud,F.et.al.1989. 27:1870-3,1989
- Marshall,B.J.et.al. 1988. Lancet. Dec.1437-42

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