H. pylori Ab Rapid Test Cassette (Whole Blood/Serum/Plasma)

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INTENDED USE

The H. pylori Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM, and IgA) anti- *Helicobacter pylori* (*H.pylori*) in human whole blood, serum or plasma. 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 Rapid Test Cassette (Whole Blood/Serum/Plasma) 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 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 cancer[3].

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 evidence[7].

The H. pylori Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is a latest generation of chromatographic immunoassay which utilizes recombinant antigens to detect the antibodies to H.pylori in human whole blood, serum or plasma. The test is user friendly, highly sensitive and specific.

PRINCIPLE

The H. pylori Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) 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 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 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.pyloriantigens, 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.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use beyond expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against micro-biological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Humidity and temperature can adversely affect test results.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

1. The H. pylori Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
2. To collect Fingerstick Whole Blood specimens:
◦ Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
◦ Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
◦ Puncture the skin with a new sterile lancet for each person. Wipe away the first sign of blood.
◦ Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
◦ Add the Fingerstick Whole Blood specimen to the test device by using a capillary tube:
· Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.
· Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood into the specimen well (S) of the test device.
◦ Add the Fingerstick Whole Blood specimen to the test device by using hanging drops:
· Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test device.
· Allow 2 hanging drops of fingerstick whole blood to fall into the center of specimen well (S) on the test device, or move the patient's finger so that the hanging drop touches the center of the specimen well (S). Avoid touching the finger directly to the specimen well (S).
3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
4. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
5. 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.
6. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS PROVIDED

25 Sealed pouches each containing a test cassette, a dropper and a desiccant
1 Buffer, 4.0 mL
1 Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

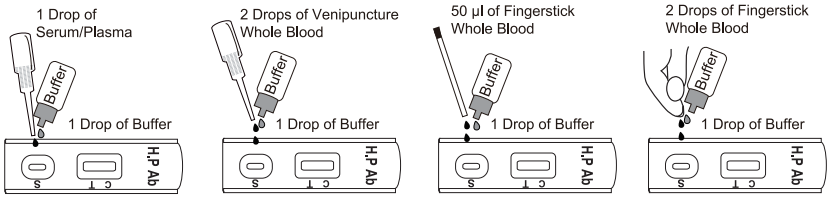
1. Specimen collection containers
2. Lancets (for fingerstick whole blood only)
3. Centrifuge (for plasma only)
4. Timer
5. Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

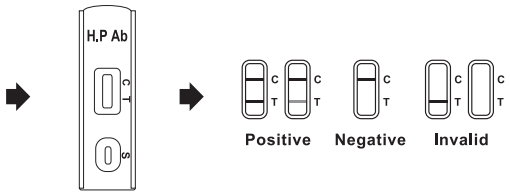
DIRECTIONS FOR USE

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

1.Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface.
For Serum or Plasma Specimens: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 30 µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
For Venipuncture Whole Blood Specimens: Hold the dropper vertically and transfer 2 drops of venipuncture whole blood (approximately 50 µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
For Fingerstick Whole Blood Specimens: Allow 2 hanging drops of fingerstick whole blood (approximately 50 µL) to fall into the center of the specimen well (S) on the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
3. Wait for the red line(s) to appear. The result should be read in 15 minutes.
Note: Low levels of H.plori antibodies might result in a faint line appearing in the test region(T) after an extended period of time; therefore ,do not interpret the result after 15 minutes.

H. pylori Ab Rapid Test Cassette (Whole Blood/Serum/Plasma)





INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

***NOTE:** *The intensity of the red color in the test line region (T) will vary depending on the concentration of H.p antibodies in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.*

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

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. H. pylori Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of H.pylori antibodies in whole blood, serum or plasma specimen only.
2. H. pylori Ab Rapid Test Cassette (Whole Blood/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.

PERFORMANCE CHARACTERISTICS

Clinical Performance

A study was performed with 175 patient specimen including both symptomatic gastrointestinal disorders and samples from non-symptomatic patients and 100 normal specimen. Comparison for all subjects with the H. pylori Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) and reference ELISA kit is showed in the following table:

Method		H.pylori Ab Rapid Test		Total Results
ELISA	Results	Positive	Negative	
	Positive	170	5	175
	Negative	1	99	100
Total Results		171	104	275

Relative Sensitivity: 97.1%
Relative Specificity: 99.0%
Accuracy: 97.8%

REFERENCE

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4. Ansong,R. et.al.1991. J.Clin.Micro. 29:51-53,
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7. Marshall,B.J.et.al. 1988. Lancet. Dec.1437-42

INDEX OF SYMBOLS

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

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