H.PYLORI ANTIBODY DEVICE

(2-30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADHPB1	25 Tests

Intended Use:
The *H. pylori* Antibody Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of specific IgG antibodies to *Helicobacter pylori* in human serum, or plasma specimens. This kit is intended for use as an aid in the diagnosis of *H. pylori* infection.

Summary:
H. pylori is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. It is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis. Both invasive and non-invasive methods are used to diagnose H. pylori infection in patients with symptoms of gastrointestinal disease. Specimen dependent and costly invasive diagnostic methods include gastric or duodenal biopsy followed by urease testing (presumptive), culture, and/or histologic staining. Non-invasive techniques include the urea breath test, which requires expensive laboratory equipment and moderate radiation exposure, and serological methods. Individuals infected with H. pylori develop antibodies which correlate strongly with histologically confirmed H. pylori infection. The H. pylori Antibody Rapid Test Device (Whole Blood/Serum/Plasma) is a simple test that utilizes a combination of H. Pylori antigen coated particles and anti-human IgG to qualitatively and selectively detect H. pylori antibodies in whole blood, serum, or plasma.

Test Principle:
The *H. pylori* Antibody Rapid Test Device (Whole Blood/Serum/Plasma) is a qualitative membrane based immunoassay for the detection of H. pylori antibodies in whole blood, serum, or plasma. In this test procedure, anti-human IgG is immobilized in the test line region of the test. After specimen is added to the specimen well of the device, it reacts with H. pylori antigen coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized anti-human IgG. If the specimen contains H. pylori antibodies, a coloured line will appear in the test line region indicating a positive result. If the specimen does not contain H. pylori antibodies, a coloured line will not appear in this region indicating a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

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

Materials Provided
Individually pouched test devices
Disposable pipettes
Buffer
Package Insert

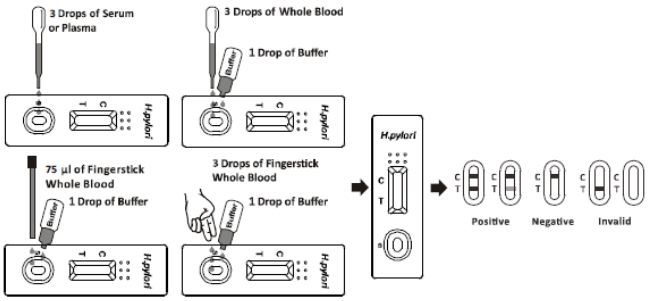
Materials not provided: Timer, Specimen collection container, Centrifuge, Lancets (for fingerstick whole blood only), Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

Precautions:
- For professional in vitro diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

Reagent Preparation and Stability:
Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

Specimen Collection and Storage:
- The H.pylori Antibody Rapid Test Cassette can be performed using whole blood (from venepuncture or fingerstick) serum or plasma.
- 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 sterile lancet. 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 by using a capillary tube:
  - Touch the end of the capillary tube to the blood until filled to approximately 75 µL. Avoid air bubbles.
  - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
- Add the Fingerstick Whole Blood specimen to the test by using hanging drops:
  - Position the patient's finger so that the drop of blood is just above the specimen area of the test cassette.
  - Allow 3 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. 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 venepuncture 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.
- 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.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

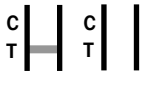
Assay Procedure:
Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.
1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results the assay should be performed within one hour.
2. Transfer 3 drops of serum or plasma (approximately 75 µL) to the specimen well (S) of the device with the provided disposable pipette and start the timer.
3. For Venepuncture Whole blood: Hold the dropper vertically and add 3 drops of Whole blood (~75 µL) and then add 1 drop of buffer (~40 µL) and start the timer.
4. For Fingerstick Whole Blood – Capillary method: Fill the capillary tube with 75 µL of whole blood specimen and add the Specimen area of the test Device.
5. For Fingerstick Whole blood – To use a capillary tube: fill the capillary tube and transfer approximately 75 µL of fingerstick whole blood specimen to the specimen area of the device, then add 1 drop of buffer (approximately 40 µL) and start the timer.
   Hanging drops: Allow 3 hanging drops of fingerstick whole blood (~75 µL) to fall into the specimen area of the test device and then add 1 drop of the buffer (~40 µL) and start the timer.
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
   As the test begins to work, colour will migrate across the result area in the center of the device.
6. Wait for the coloured band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.



Interpretation of Results:

POSITIVE: Two coloured bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one coloured band appears, in the control region (C). No apparent coloured band appears in the test region (T).



INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

Prestige Diagnostics U.K. Ltd 40 Ballymena Business Centre, Galgorm, Co. Antrim, BT42 1FL, United Kingdom. Tel: +44 (0) 28 2564 2100
www.prestigediagnostics.co.uk info@prestigediagnostics.co.uk

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Quality Controls:
A procedural control is included in the test. A coloured 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 of the Test:
1. The H. pylori Antibody Rapid Test Device (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 specimens only. Neither the quantitative value nor the rate of increase in H. pylori antibody concentration can be determined by this qualitative test.
2. The H. pylori Antibody Rapid Test Device (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.

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

Performance Characteristics:

Clinical Sensitivity, Specificity and Accuracy

The H. pylori Antibody Rapid Test Device (Whole Blood/Serum/Plasma) has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals who presented for endoscopic examination. Biopsy (Culture) served as the reference method for the H. pylori Antibody Rapid Test Device (Whole Blood/Serum/Plasma). Histology and a Rapid Urease Test (RUT) were performed on all negative culture specimens. The specimen was considered positive if Culture was positive. The specimen was also considered positive if the Culture was negative, but both Histology and RUT were positive. The result shows that the sensitivity of the H. pylori Antibody Rapid Test Device (Whole Blood/Serum/Plasma) is 96.8% and the specificity is 93.0% relative to Biopsy/Histology/RUT.

H.pylori Antibody Rapid Test Device vs. Biopsy/Histology/RUT

Method		Biopsy/Histology/RUT		Total Results
H.pylori Rapid Test Device	Results	Positive	Negative	
	Positive	150	15	165
	Negative	5	200	205
Total Results		155	215	370

Relative Sensitivity: 96.8% (95% CI*:92.6%-98.9%)
Relative Specificity: 93.0% (95% CI*:88.8% - 96.0%)
Accuracy: 94.6% (95% CI*:91.8%-96.7%)

Precision:

Intra-Assay

Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of the H. pylori Antibody Rapid Test Device (Whole Blood/Serum/Plasma) have been tested using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

Sera containing known amounts of antibodies to H. pylori have been tested with Hepatitis A, B, C, E, HIV and Syphilis. No cross-reactivity was observed, indicating that the H. pylori Antibody Rapid Test Device (Whole Blood/Serum/Plasma) has a high degree of specificity for antibodies to H. pylori.

Interfering Substances

The H. pylori Antibody Rapid Test Device (Whole Blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens, as well as serum specimens containing high bilirubin levels. In addition, no interference was observed in specimens containing up to 1,000 mg/dL hemoglobin; up to 1,000 mg/dL bilirubin; and up to 2,000 mg/dL human serum albumin.

References:

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GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse

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Prestige Diagnostics U.K. Ltd 40 Ballymena Business Centre, Galgorm, Co. Antrim, BT42 1FL, United Kingdom. Tel: +44 (0) 28 2564 2100
www.prestigediagnostics.co.uk info@prestigediagnostics.co.uk

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