H. Pylori Ab Rapid Test Device
Package Insert

Cat: IHP-402 **Specimens:** Whole Blood/Serum/Plasma
Version: 02 **Effective Date:** 2015-02

For professional *in vitro* diagnostic use only.

INTENDED USE

The H.Pylori Ab Rapid Test (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies to H.Pylori in whole blood, serum or plasma to aid in the diagnosis of H.Pylori infection.

INTRODUCTION

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. [1,2] 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.[3] Non-invasive techniques include the urea breath test, which requires expensive laboratory equipment and moderate radiation exposure, and serological methods.[4,5] Individuals infected with H.Pylori develop serum antibodies which correlate strongly with histologically confirmed H.Pylori infection.[6,7,8]

The H.Pylori Ab 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 serum or plasma in just minutes.

PRINCIPLE

The H.Pylori Ab Rapid Test Device (Whole Blood/Serum/Plasma) is a qualitative membrane device based immunoassay for the detection of H.Pylori antibodies in whole blood, serum or plasma. In this test, specimen or specimen followed by buffer is added to the specimen well of the test device. The specimen migrates chromatographically along the length of the test strip contained within the device and interacts with the reagents on the strip. If the specimen contains H.Pylori antibodies, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain H.Pylori antibodies, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

KIT COMPONENTS

Individually packed test devices	Each device contains a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions
Disposable pipettes	For adding specimens use
Buffer	Phosphate buffered saline and preservative
Package insert	For operation instruction

MATERIALS REQUIRED BUT NOT PROVIDED

Specimen collection container	For specimens collection use
Timer	For timing use
Centrifuge	For preparation of clear specimens

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- 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.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The One Step H.pylori Test can be performed used on Whole Blood /Serum / Plasma.
- To collect whole blood, serum or plasma specimens following regular clinical laboratory procedures.
- 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 specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8℃ for up to 3 days. For long term storage, specimens should be kept below -20℃. Whole blood should be stored at 2-8℃ if the test is to be run within 2 days of collection. Do not freeze whole blood specimens.
- 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.

PROCEDURE

Allow the 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.
3. Hold the dropper vertically and transfer **2 drops of serum or plasma or 3 drops of whole blood** to the specimen well (S) of the test device, then add 1 drop of buffer and start the timer.
4. Wait for the red line(s) to appear. The result should be read **at 10 minutes.** Do not interpret the result **after 20 minutes.**

INTERPRETATION OF RESULTS

POSITIVE RESULT:

* A colored band appears in the control band region (C) and another colored band appears in the T band region.

NEGATIVE RESULT:

One colored band appears in the control band region (C). No band appears in the test band region (T).

INVALID RESULT:

Control band fails to appear. Results from any test which has not produced a control band at the specified reading 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.

NOTE:

1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level can not be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. 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 Ab 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 Ab 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.

PERFORMANCE CHARACTERISTICS

Table: H. pylori Rapid Test vs. Biopsy/Histology/RUT

		H.Pylori Rapid Test		
		+	-	Total
Biopsy/ Histology/ RUT	+	131	7	138
	-	10	225	235
		141	232	373

Relative Sensitivity: >95.0% (90.0%-97.9%)*
Relative Specificity: >95.7% (92.3%-97.9%)*
Overall Agreement: >95.4% (92.8%-97.3%)*
***95% Confidence Interval**

LITERATURE REFERENCES

1. Marshall, BJ, McGechie, DB, Rogers, PAR and Glancy, RG. Pyloric Campylobacter infection and gastroduodenal disease. Med. J. Australia. (1985), 149: 439-44..
2. Soll, AH. Pathogenesis of peptic ulcer and implications for therapy. New England J. Med. (1990), 322: 909-16.
3. Hazell, SL, et al. Campylobacter pyloridis and gastritis I: Detection of urease as a marker of bacterial colonization and gastritis. Amer. J. Gastroenterology. (1987), 82(4): 292-96.
4. Loffeld, RJLF, et al. Usefulness of several commercial enzyme-linked immunoassays for detection of Helicobacter pylori infection in clinical medicine. Euro. J. Gastroen. Hepa. (1993) 5:333-37.
5. Cutler, AF, et al. Accuracy of invasive and non-invasive tests to diagnose Helicobacter pylori infection. Gastroenterology.(1995), 109: 136-141.
6. Ansorg, R, Von Recklinghausen, G, Pomarius, R and Schmid, EN. Evaluation of techniques for isolation, subcultivation and preservation of Helicobacter pylori. J. Clin. Micro. (1991), 29:51-53.
7. Pronovost, AP, Rose, SL, Pawlak, J, Robin, H and Schneider, R. Evaluation of a new immunodiagnostic assay for Helicobacter pylori antibody detection: Correlation with histopathological and microbiological results. J. Clin. Micro. (1994), 32: 46-50.
8. Megraud, F, Bassens-Rabbe, MP, Denis, F, Belbouri, A and Hoa, DQ. Seroepidemiology of Campylobacter pylori infection in various populations. J. Clin. Micro. (1989), 27: 1870-3.