# H.PYLORI ANTIBODY

# IMMUNOPAK

Whole Blood/Serum/Plasma

Last update 10-2020

Ref. RDT-HPY.116M, 25 Test

## INTENDED USE

The H.pylori Antibody Rapid Test Card is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies to H.pylori in human Whole Blood/Serum/Plasma. It provides an aid in the diagnosis of infection with H.pylori.

## INTRODUCTION

H.pylori is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis. H.pylori infection is found in more than 90% of duodenal ulcer patients and in around 75% of all peptic ulcer sufferers. H.pylori infection is also more common in gastric cancer patients. The risk of gastric cancer has been estimated to be six-fold higher in H.pylori infected populations than in uninfected populations. H.pylori infections occur in human populations throughout the world. In developed countries, about 50% of the population may have H.pylori infection by the age of 60 years, while only 10-20% of adults in the third decade of life have it. Transmission is most probably by the fecal-oral or oral-oral route.

Both invasive and non-invasive methods are used to diagnose H.pylori infection in patients with symptoms of gastrointestinal disease. Invasive methods include culture of gastric biopsy samples, histologic examination of stained biopsy specimens, or direct detection of the urease activity in the biopsy (CLO test). These methods need to obtain a biopsy sample by endoscopy, which is expensive, and usually results discomfort and risk to the patient. Noninvasive techniques include urea breath tests and serological methods. Urea breath test requires expensive laboratory equipment and moderate radiation exposure. Serologic tests are employed to detect antibodies as human immune response to H.pylori, for example the ELISA and the Western immunoblot.

The H.pylori Antibody Rapid Test Card detect antibodies to H.pylori infection in human Whole Blood/Serum/Plasma. It is a noninvasive method and does not use radioactive isotopes. The test is easy to perform and requires no specialized equipment. Visual interpretation provides an accurate qualitative result. It is a useful on-site aid in the diagnosis of H.pylori infection. Diagnosis of H.pylori infection by antibody immunoassay can reduce the number of patients requiring endoscopy.

## PRINCIPLE

The H.pylori Antibody Rapid Test Card is an immunoassay based on the principle of the double antigen-sandwich technique. During testing, a Whole Blood/Serum/Plasma specimen migrates upward by capillary action. The antibodies to H.pylori if present in the specimen will bind to the H.pylori conjugates. The immune complex is then captured on the membrane by the pre-coated H.pylori antigens, and a visible pink-purple line will show up in the test line region indicating a positive result. If antibodies to H.pylori are not present or are present below the detectable level, a pink-purple line will not form in the test line region indicating a negative result.

To serve as a procedural control, a pink-purple line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

## PRESENTATION

| | 25 Tests |
|---|---|
| H.pylori Antibody Cards | 25 Cards |
| Assay buffer | 1 Vial |

## PRECAUTION

- For in vitro diagnostic use only.
- For healthcare professionals and professionals at point of care sites.
- Do not use after the expiration date. Interpret the result after 20 minutes.
- Please read all the information in this leaflet before performing the test.
- The test card should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test card should be discarded according to federal, state and local regulations.

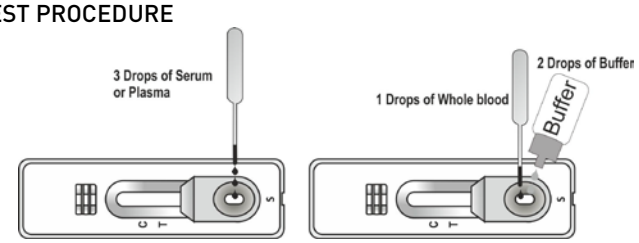
## STORAGE AND STABILITY

- Store as packaged in the sealed pouch at 2°C-40°C. The kit is stable within the expiration date printed on the label.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.

## SPECIMEN COLLECTION AND STORAGE

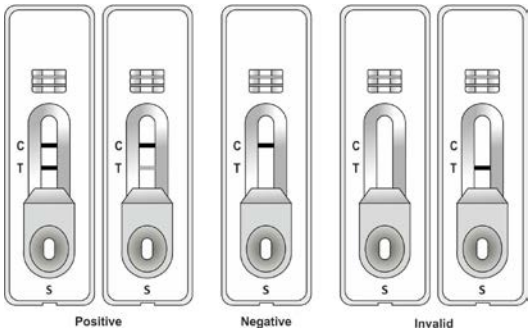
- The test can be used to test Whole Blood/Serum/Plasma specimens.
- Collect blood specimen (containing EDTA, citrate or heparin) by vein puncture following standard laboratory procedures.
- Separate the serum or plasma as soon as possible by centrifugation after collecting.
- Store specimens at 2°C-8°C (36-46°F) if not tested immediately. Store specimens at 2°C-8°C up to 7 days. The specimens should be frozen at -20°C (-4°F) 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.

## TEST PROCEDURE




1. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the test cassette on a clean and level surface.
3. For serum or plasma specimen: Hold the dropper vertically and transfer 3 drops of serum or plasma to the specimen well (S) of the test cassette, then start the timer. See illustration below.

4. For whole blood specimens: Hold the dropper vertically and transfer 1 drop of whole blood (approximately 25µl) to the specimen well(S) of the test cassette, then add 2 drops of buffer (approximately 70µl) and start the timer.
5. Read results at 15 minutes. Do not interpret the result after 20 minutes.




## INTERPRETATION OF RESULTS

1. **Positive:** One pink-purple line should be in the control region (C), and another apparent pink-purple line adjacent should be in the test region (T). This positive result indicates the presence of antibodies to H.pylori.
2. **Negative:** One pink-purple line appears in the control region (C). No line appears in the test region (T). This negative result indicates the absence of antibodies to H.pylori.
3. **Invalid:** A total absence of pink-purple line in both regions or no pink-purple line appears in the control (C) region is an indication of procedure error and/or test reagent deterioration. Repeat the test with a new cassette.

## LIMITATIONS

- The H.pylori Antibody Rapid Test Card is limited to provide a qualitative detection. The intensity of the test line does not necessarily correlate to the concentration of the antibody in the blood.
- The results obtained from this test are intended to be an aid in diagnosis only. Each physician must interpret the results in conjunction with the patient's history, physical findings, and other diagnostic procedures.
- A negative test result indicates that antibodies to H.pylori are either not present or at levels undetectable by the test.

## REFERENCES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4. Kist M., Immunology of Helicobacter pylori. In Helicobacter pylori in peptic ulceration and gastritis, edited by Marshall BJ., McCallum RW., and Guerrant RL., 1991, Chapter 8, 92-110.



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