# RAPID H. PYLORI ANTIBODY TEST

A rapid qualitative immunochromatographic test for the detection of antibodies against H. Pylori in human whole blood, serum or plasma

Cat.# 1O02C2

***For In Vitro Diagnostic Use Only***

**INTENDED USE**

Rapid H. Pylori Antibody Test is a rapid immune-chromatographic assay for the detection of antibodies to H. pylori in human whole blood, serum or plasma. The assay is to provide an aid in diagnosis of H. pylori infection.

**SUMMARY AND EXPLANATION**

Helicobacter pylori is a corkscrew-shaped, gram-negative rod that lives in the mucous layer of the stomach. H. pylori infection is now accepted as the most common cause of gastritis, and is etiologically involved in gastric ulcer, duodenal ulcer, gastric adenocarcinoma and primary gastric B-cell lymphoma.1,2

The organism is very common, infected at least half of the world's population. H. pylori infection is typically acquired in childhood. Once acquired, infection persists chronically, probably continuing in the stomach throughout life. The damage to gastric structure and function of stomach is constant and direct. Approximately one in six of H. pylori infection develops peptic ulcer disease and a small portion of H. pylori infection leads to gastric cancer.3

The diagnostic tests for H. pylori can be classified into two categories: Invasive and Noninvasive tests. Direct detection by invasive test procedures requires an endoscopy and biopsy specimens from antrum and stomach body.4 The presence of H. pylori is then confirmed by direct culture, histological examination or rapid urease test. The endoscopy and biopsy specimens offer direct detection of active H. pylori infections. Although the procedure is highly specific and high positive predictive value, the cost and discomfort to the patients are very high.

The most widely available noninvasive test is probably the serological based test. The serology test detects H. pylori specific IgG antibody in patient serum with current or prior infection.5,6 Serology test is a simple, convenient test with relative high sensitivity. The main limitation of serology test is the inability to distinguish current and past infections. Antibody may be present in the patient's serum long after eradication of the organism.6 The urease breath test (UBT) with 14C or 13C labeled urea, is a noninvasive test based on the urease activity of the organism. UBT detects active H. pylori infection and is highly sensitive and specific. The UBT requires a high density and active bacteria and should not be performed until 4 weeks after therapy to allow residual bacterial to increase to a sufficient number for detection.7

Rapid H. Pylori Antibody Test is an immune-chromatographic assay that uses double antigen sandwich technology to detect the presence of H. pylori antibody in human blood specimens. The test is simple and easy to perform and the test results can be visually interpreted within 10 minutes

**PRINCIPLE OF THE ASSAY**

Rapid H. Pylori Antibody Test employs chromatographic lateral flow test device in a cassette format. Colloidal gold conjugated H. pylori antigens (Au-Ag) are dry-immobilized at the end of nitrocellulose membrane strip. H. Pylori antigens are bond at the Test Zone (T) When the sample is added, it migrates by capillary diffusion rehydrating the gold conjugate. If anti-H. pylori antibodies present in sample, Antibodies will bind with the gold conjugated antigens forming particles. These particles will continue to migrate along the strip until the Test Zone (T) where they are captured by H. pylori antigens generating a visible red line. If there are no anti-H. Pylori antibodies in sample, no red line is formed in the Test Zone (T). A built-in control line will always appear in the Control Zone (C) when the test has performed properly, regardless of the presence or absence of anti-H. pylori antibodies in the specimen.

**MATERIAL PROVIDED**

Each kit contains:

1. Rapid H. Pylori Test card in foil pouch
2. Product insert

**MATERIALS REQUIREED BUT NOT SUPPLIED**

1.Sepcimen collection container
2.Timer or clock.

**STORAGE AND STABILITY**

The sealed pouches in the test kit may be stored between 4-30°C for the duration of the shelf life as indicated on the pouch.

**WARNINGS AND PRECAUTIONS**

1. This kit is for ***IN VITRO*** diagnostic use only.
2. This kit is for ***PROFESSIONAL*** use only.
3. Read the instructions carefully before performing the test.
4. This product does not contain any human source materials.
5. Do not use kit contents after the expiration date.
6. Handle all specimens as potentially infectious.
7. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective material. When the assay procedure is complete, dispose specimens after autoclaving them at 121° C for at least 20 min. Alternatively, they can be treated with 0.5% Sodium Hypochlorite for 1-2 hours before disposal.
8. Do not pipette reagent by mouth and no smoking or eating while performing assays.
9. Wear gloves during the whole procedure.

**SPECIMEN COLLECTION AND PREPARATION**

1. No prior special preparation of the patient is required before sample collection by approved techniques.
2. Fresh serum / plasma is preferable. Serum / plasma may be stored at 2-8°C up to 3 days in case of delay in testing. For long-term storage, freeze the specimen at -20°C for 3 months or -70°C for longer periods.
3. The test works best on fresh whole blood samples. If testing cannot be done immediately, Blood samples collected with a suitable anticoagulant such as EDTA or Heparin or Oxalate should be stored at 2-8°C up to 3 days. Blood samples should not be frozen.
4. Repeated freezing and thawing of the specimen should be avoided.
5. Do not use haemolysed, clotted, contaminated, lipamic and viscous/turbid specimen.
6. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
7. Do not heat inactivate the sample.
8. Shipment of samples should comply with local regulations for transport of etiologic agents.

**QUALITY CONTROL**

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which is not provided with this test kit may be commercially available.

**PROCEDURE**

For Serum or Plasma

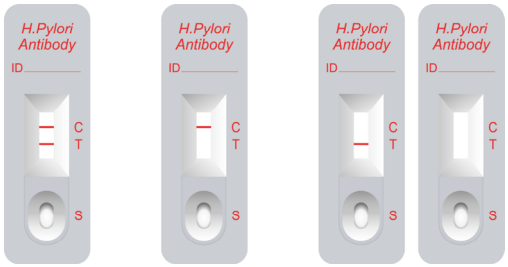
1. Bring the kit components to room temperature before testing.
2. Open the pouch and remove the card. Once opened, the test card must be used immediately.
3. Label the test card with patient's identity.
4. Apply 2-3 drops (80-120 µL) of serum or plasma to the sample well marked as "**S**'.
5. At the end of 10 minutes read the results. A strong positive sample may show result earlier.

For Whole Blood

1. Bring the kit components to room temperature before testing.
2. Open the pouch and remove the card. Once opened, the test card must be used immediately.
3. Label the test card with patient's identity.
4. Apply one drop (approx 40µl) of whole blood to the sample well marked as "**S**'.
5. Add one drop ( approx 40 µl) sample buffer into the sample well marked as "**S**".
6. At the end of 10 minutes read the results. A strong positive sample may show result earlier.

## INTERPRETATION OF RESULTS

1. Negative
   Only control line appears.
2. Positive
   Both control line and the test line appear. It indicates the antibodies to H. pylori have been detected.
3. Invalid
   If after 10 minutes no line is visible within the Control Zone, the result is invalid. The test should be repeated with a new test card.




Positive Negative Invalid

## LIMITATIONS OF THE PROCEDURE

1. The test is for qualitative detection of anti-H. pylori antibodies in human serum, plasma or whole blood sample and does not indicate the quantity of the antibodies.
2. The test is for *in vitro* diagnostic use only.
3. As in case of all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test but should rather be made after all the clinical findings have been evaluated.

## PERFORMANCE CHARACTERISTICS

1. **Accuracy**

A panel of 30 positive and 67 negative patient sera was tested with a reference ELISA test. The results are summarized in the following table. The agreement is 100%.

| | ***ELISA H. Pylori Antibody Test*** | | |
|---|---|---|---|
| ***Rapid H. Pylori Ab Test*** | | Positive | Negative |
| | Positive | 30 | 2 |
| | Negative | 0 | 65 |
| | Agreement | 100% | 97% |

2. **Interference**

No interference was found with bilirubin (10 mg/dL), hemoglobin (20 mg/dL) or triglycerides (600 mg/dL) on the sensitivity and specificity of the test.

## REFERENCES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4. El-Zimaity HM, Al-Assi MT, Genta RM, Graham DY. Confirmation of successful therapy of *Helicobacter pylori* infection: number and site of biopsies or a rapid urease test. *Am J Gastroenterol*. 1995;90:1962-1964.
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