

H. Pylori IgG/IgM Rapid Test

For detection of *H. Pylori* antibodies in Human Serum, Plasma or Whole Blood.

IVD In-vitro diagnostic use only



Introduction

H. Pylori is associated with a variety of gastrointestinal diseases including gastritis, duodenal and gastric ulcer, non-ulcer dyspepsia, gastric adenocarcinoma and lymphoma. *H. pylori* plays the exact role in gastrointestinal disease still needs to be precisely defined and is the subject of ongoing research. However, the prevalence rates for *H. pylori* infection as demonstrated by histological and bacteriological methods can approach 90% in patients who present clinical symptoms of the gastrointestinal diseases listed above. No evidence shows that *H. pylori* can invade the blood stream since no isolates yet have been detected using commercial blood culture methods. Human populations are infected by *H. pylori* 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.

The *H. pylori* Ab Rapid Test detects IgG antibodies specific to *H. pylori* infection in patient's blood or serum. It is a non-invasive method and does not use radioactive isotopes; the assay procedures are easy and do not require professional training; it provides a rapid result. It is a useful on-site aid in the diagnosis of *H. pylori* infection.

Intended Use

The *H. pylori* Ab Rapid Test is a lateral flow, qualitative immunoassay. It is intended for use at point of care facilities to detect the presence of IgG antibodies specific to *Helicobacter pylori* (*H. pylori*) in human blood or serum. It provides an aid in the diagnosis of infection by *H. pylori*. This test has been evaluated for use with serum specimens of adults, 19 years and older.

Principle

This assay is a double antigen chromatographic lateral flow immunoassay. The test strip in the device includes: 1) a burgundy-colored conjugate pad containing colloidal gold coupled with *H. pylori* antigens, and 2) nitrocellulose membrane containing a test line (T line) and a control line (C line). The T line is coated with *H. pylori* antigens, and the C line is coated with goat anti-*H. pylori* antibody. The antigens used in this device are from *H. pylori* cell lysate. When IgG antibodies specific to *H. pylori* are present in the specimen, the T line will become a burgundy-colored band. If antibodies to *H. pylori* are not present or are present below the detectable level, no T line will develop. The C line should always appear as a burgundy-colored band regardless of the presence of antibodies to *H. pylori*. The C line serves as an internal qualitative control of the test system to indicate that an adequate volume of specimen has been applied and the flow occurred.

Materials Included and Active Ingredients

- 1) H. Pylori Ab kit contains the following items to perform the assay.
 - H. Pylori Ab test device foil pouched with a desiccant
 - Disposable dropper capable of delivering 30 µL sample volume (may not provided)
 - 1 bottle of wash buffer-7 ml PBS diluent with 0.02% sodium azide as a preservative
 - Instruction for use
- 2) Active ingredients of main components of one H. Pylori Ab test strips
 - Gold Conjugates (as main component): *Helicobacter pylori* antigen – gold colloid (1 ± 0.2 µg),
 - Test Line (as main component): *Helicobacter pylori* antigen (4 ± 0.8 µg),
 - Control Line (as main component) Goat anti- *Helicobacter pylori* (2 ± 0.4 µg)

Kit Precautions and Storage Instructions

- 1) For best results, adhere to instructions provided
- 2) All specimens should be handled as potentially infectious
- 3) The test device should be stored at room temperature
- 4) The test device is sensitive to humidity as well as heat
- 5) Do not use beyond expiration date
- 6) Do not use test kit if pouch is damaged or seal is broken
- 7) Use test device immediately after removing from the pouch
- 8) The components (test device and assay diluents) in this kit have been quality control tested as a standard batch unit. Do not mix components from different lot numbers.
- 9) Store kit at room temperature (2 -30 °C). Do not expose the kit to temperature over 30 °C; Freezing to -70 °C will not cause damage to the device.

Warnings

- 1) For in vitro diagnostic use only. DO NOT RE-USE test device
- 2) The instructions must be followed to obtain accurate results. Anyone performing an assay with this product must be trained in its use and laboratory procedures.
- 3) Do not eat or smoke while handling specimens
- 4) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- 5) Avoid splashing or aerosol formation
- 6) Clean up spills thoroughly using an appropriate disinfectant
- 7) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
- 8) Do not mix with other specimens.

Specimen Collection, Storage and Precautions

- 1) Serum (S): Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant .
- 2) Plasma (P): Collect the whole blood into a collection tube (containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.
- 3) Whole Blood (WB): Collect the whole blood by lancing devices. WB can be delivered by pipette directly to the test card.
- 4) If serum or plasma specimens are not tested immediately, they should be refrigerated at 2-8°C. For storage periods longer than 2 weeks, freezing is recommended. They should be brought to room temperature (1-30°C) prior to use.
- 5) Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
- 6) Anticoagulants such as heparin, EDTA and sodium citrate do not affect the test results.
- 7) Use separately disposable capillary pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous results.
- 8) As known relevant interference, hemolytic samples, rheumatoid factors-contained samples and lipaemic, icteric samples can lead to impair the test results.

Test Procedure (Refer to Figure)

- 1) Allow all test components and specimen to come to room temperature prior to testing
- 2) Remove the test device from the foil pouch, and place it on a flat, dry surface
- 3) With a micropipette (not provided) or a disposable dropper, add about 10 µL of serum/ plasma or 20 µL whole blood specimen into the sample well marked "S"; **Allow about 30 seconds for the specimen to be absorbed totally.**

- 4) Add 3 drop of diluents buffer to the sample well.
- 5) As the test begins to work, you will see red color move across the result window in the center of the test device.
- 6) Interpret test results at 15-20 minutes. Caution: Do not read test results after 20 minutes. Reading too late can give false results.

Interpretation of Test Results (Refer to Figure)

1) Negative

The control line is the only visible line on the test device. No IgG or IgM antibodies were detected.

2) IgM Positive

The control line (C) and the IgM line (M) are visible on the test device. This is positive for IgM antibodies. This is an indication of a primary infection

3) IgG Positive

The control line (C) and IgG line (G) are visible on the test device. This is positive for IgG antibodies to virus. This is indicative of secondary or previous infection.

4) IgG and IgM Positive

The control line (C), IgG (G) and IgM (M) lines are all visible on the test device. This is positive for both IgG and IgM antibodies. This is indicative of late primary or early secondary infection.

5) Invalid

The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the likeliest reasons for control line failure. Repeat the test using a new test device.

H.Pylori IgG/IgM Test Procedure

Using micropipette, add 10 µl of serum, plasma or whole blood specimen in the sample well "S"



Put 2 or 3 drops (~80 µl) of assay diluents into the sample well marked as "S"



Interpret test results in 15-20 minutes.



Do not read the results after 20 minutes
Reading too late can give false results.

Interpretation

Negative

One pink line "C" in result window



Positive

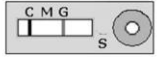
1. IgM positive

Two pink lines "C" and "M" in result window. It is positive even if "M" line is weak.



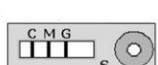
2. IgG positive

Two pink lines "C" and "G" in result window. It is positive even if "G" line is weak.



3. IgG and IgM positive

Three pink lines "C", "M", "G" in result window. It is positive even if "G" line is weak.



Invalid

-No control (C) line in result window.
-It is recommended that the specimen be re-tested.



Limitations of the Test

This test is a qualitative assay for *professional in vitro* diagnostic use only. A positive result does not distinguish active infection from colonization of *H. pylori*. Therefore, positive results should always be evaluated with other confirmatory methods available to the physician. This assay has not been established for patients less than 19 years of age.

Literature references have suggested cross reactivity of IgG antibody with other closely related organisms such as *Borrelia burgdorferi* and *Pseudomonas* species. However, performance of this assay has not been evaluated with these organisms. Therefore, the specificity of this device is not known if this organism is encountered.

Internal Quality Control

There is a "Test line" and a "Control line" on the surface of H. PYLORI antibodies rapid test cassette. Both the Test Line and Control Line in the result window are not visible before applying any samples. The Control Line is used for procedural control. The Control line should always appear if the test procedure is performed properly and the test reagents of the control line are working.

Expected value

H. pylori infections occur in human populations throughout the world, but the prevalence of infection in the population varies with age, standards of hygiene, geographical regions, and probably socioeconomic status. 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. People in developing countries tend to have higher prevalence.

Suggested Reading List

1. O'Connor, JH., Helicobacter pylori and gastric cancer: a review and hypothesis. Eur. J. Gastro. Hepa. 1992; 6: 103-109.
2. Mcguigan JE., Peptic ulcer and gastritis. In Harrison's Principles of Internal Medicine, 12th Edition, 1988, Chapter 238, 1229-1248.
3. Cover TL. and Blaser MJ., Helicobacter pylori: A Bacterial Cause of Gastritis, Peptic Ulcer Disease, and Gastric Cancer, ASM News, 1995; 61: 21-26.
4. Podolsky I, Lee E, Cohen R, Peterson WL. Prevalence of C. pylori in healthy subjects and patients with peptic diseases. Gastroenterology 1989; 96: Suppl: A394. abstract.
5. Kist M., Immunology of Helicobacter pylori. In Helicobacter pylori in peptic ulceration and gastritis, edited by Marshall BJ., McCallum RW., and Guerrant RL., 1991, Chapter8, 92-110.

REF RT-HGM1101-C-1

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