H.pylori Antibody Rapid Test (Cassette) (Serum/Plasma)

INTRODUCTION

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. 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 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. 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, IgM & IgA antibody in patient serum with current or prior infection. 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.

PRINCIPLE

The ***H.pylori* - One Step Rapid Test** is a lateral flow chromatographic immunoassay based on the principle of the double antigen-sandwich technique which detects **IgG,IgM & IgA antibodies** in human serum or plasma.When the sample is added, The sample flows through a label pad containing *H.pylori* antigen coupled to red-colored colloidal gold. If the sample contains *H.pylori* antibodies, the antibody will bind to the antigen coated on the colloidal gold particles to form antigen-antibody-gold complexes. These complexes move on the nitrocellulose membrane by capillary action toward the test line region on which *H.pylori* specific antigens are immobilized. As the complexes reach the test line, they will bind to the antigen on the membrane in the form of a line. A second red control line will always appear in the result window to indicate that the test has been correctly performed.

SPECIMEN COLLECTION & PREPARATION:

For Serum, collect blood into a container without anticoagulant. Allow the blood to clot and separate the serum from the colt.For Plasma blood should be collected with anticoagulant like EDTA, Heparin. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8^{0}C for up to 3 days. For long term storage, specimens should be kept below -20^{0}C.

PRESENTATION:

1.Test device 2 Pipette dropper 3.Desiccant 4.Buffer 5.Package Insert

The Shelf life or expiry of the card is printed on the pouch.

PRECAUTION:

1) For in vitro diagnostic use only.
2) Do not use test kit beyond expiry date.
3) The test device should not be reused.
4) Keep out of the reach of children.
5) Do not freeze the Kits.
6) Specimen with extremely high concentrations of red blood cells, fibrin should be recentrifuged before use.

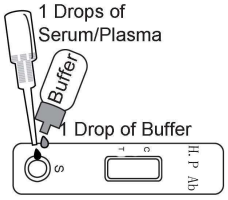
STORAGE AND STABILITY:

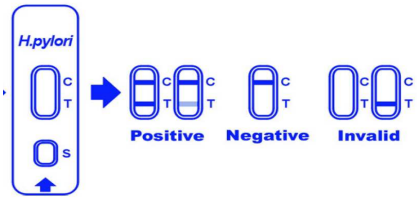
The test kit can be stored at temperatures between 4 - 30°C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

TEST PROCEDURE:

Allow the test, specimen, and/or controls to reach room temperature (15-30^{0}C) prior to testing.

1. Remove the test from the foil pouch and use it as soon as possible.
2. Place the test on a clean and level surface. Hold the dropper vertically and transfer 1 full drop of serum or plasma (approx. 30-45 µl), Then add one drop of buffer (approx.30-45 µl), immediately and start the timer. Avoid air bubbles.
3. Wait for the colored line (s) to appear. Read results in 15 minutes. Do not interpret the result after 15 minutes.





INTERPRETATION OF RESULTS:

• **Negative:** Only one colored band appears on the control (C) region. No apparent band on the test (T) region.

• **Positive:** In addition to a pink colored control (C) band, a distinct pink colored band will also appear in the test (T) region.

• **Invalid:** A total absence of color in both regions and no colored line appears on the control (C) region is an indication of procedure error and / or the test reagent deterioration. Repeat the test with a new kit.

PERFORMANCE EVALUATION:

Relative sensitivity: 97.1%, Relative specificity: 100%

Overall agreement: 98.2%

LIMITATIONS:

1. The test is for in vitro diagnostic use only.
2. The test result should be used only to evaluate the patient with signs and symptoms of gastrointestinal disease. A definitive clinical diagnosis should only be made by the physician after all clinical and Laboratory finding have been evaluated

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