One-Step Helicobacter Pylori (HP) Antigen Test

Cat：HP442

1. Intended use

One-Step *Helicobacter pylori* (*H. pylori*) Antigen Test is a rapid and convenient immuno-chromatographic assay for qualitative detection of *Helicobacter pylori (H.Pylori)* antigen in human fecal samples or biopsy of mucosa samples from the stomach lining. It is intended for professional use as an aid in the diagnosis of *H. pylori* infection in patients with gastrointestinal symptoms. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

2. Summary and principle of the assay

Helicobacter pylori (H. pylori) is a helical shaped gram-negative, microaerophilic bacterium that infects various areas of the stomach and duodenum. It is a major etiological agent for peptic ulcers, gastritis, duodenitis and classified as a class I carcinogen by World Health Organization (WHO) for gastric cancer and MALT-lymphoma. The bacterium is found all over the world and can easily exist in a person without showing any symptoms.

H. pylori is isolated in culture medium and examined by microscopy after staining or is detected by urease tests. Both these techniques are lengthy to implement and their sensitivity and specificity have yet to be demonstrated. The immunochromatographic techniques (rapid) for the detection of *H. pylori* antigen has substantially resolved these problems, ensuring a serological monitoring in a very short span of time using simple, highly specific technology without recourse to invasive techniques. The fecal test for *H. pylori* antigen can be utilized as a rapid screening process for large populations of patients and highly indicative in the early diagnosis of *H. pylori* infection as the immune response can often precede clinical manifestations of disease. From a diagnostic point of view, a high level of *H. pylori* antigen is an indication of type B asymptomatic gastritis.

One-Step HP Antigen test is an antigen-capture immunochromatographic assay, detecting presence of *H. pylori* antigen in fecal samples. Monoclonal antibodies specifically against *H. pylori* antigen are 1) conjugated with colloidal gold and deposited on the conjugate pad, and 2) immobilized on the test region of the nitrocellulose membrane. When fecal sample is added, the gold-antibody conjugate is rehydrated and the *H. pylori* antigen, if present in the sample, interacts with the gold conjugated antibodies. The antigen-antibody-gold complex will migrate towards the test window until the test region (T) where they are captured by the immobilized antibodies, forming a visible red line (test band) indicating a positive results. If *Helicobacter pylori* antigens are absent in the sample, no red line will appear in the test region (T).

To serve as an internal control, a control line should always appear in the control region (C) after the test is completed. Absence of a colored control line in the control region is an indication of an invalid result.

3. Package contents

H. pylori test kit contains following items to perform the assay;

1) H. pylori test device.
2) Specimen collection tube with sample buffer (2 mL/tube)
3) Instructions for use

4. Warnings and precautions

1) For Professional *in vitro* diagnostic use only.
2) Do not reuse.
3) Do not use if the pouch seal or its packaging is compromised.
4) Do not use after the expiration date shown on the pouch.
5) Do not mix and interchange different specimens.
6) Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.
7) Wash hands thoroughly after finishing the tests.
8) Do not eat, drink or smoke in the area where the specimens or kits are being handled.
9) Clean up spills thoroughly with appropriate disinfectants.
10) Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
11) Dispose of all specimens and used kits in a proper biohazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
12) Keep out of reach of children.

5. Specimen collection and storage

1) Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 72 hours.
2) Bring specimens to room temperature prior to testing.
3) If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

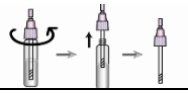
6. Procedure of the test

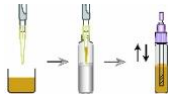
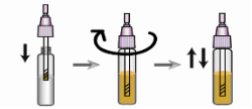
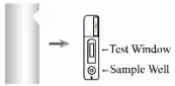
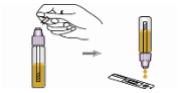
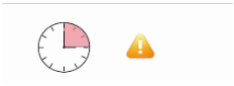
1) For biopsy samples:

a) Collect biopsy of mucosa samples from the stomach lining;
b) Unscrew the cap of the specimen collection tube and take out the specimen collection stick;
c) Put the biopsy sample into the specimen collection tube;
d) Insert the specimen collection stick into the tube and tighten the cap. Shake the tube vigorously to ensure thorough mixture of the specimen and the assay diluent reagent.
e) Follow steps in table below.

2) For fecal samples:

Follow the procedures described below:

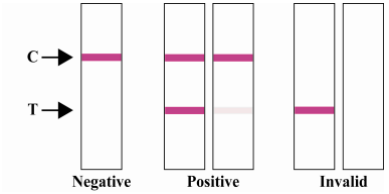
Use clean, dry containers for specimen collection. Best results will be obtained if the assay is performed within 6 hours after collection.	
Unscrew the cap of the specimen collection tube and take out the specimen collection stick.	

For solid specimen: Stab the specimen collection stick into the fecal specimen in at least 3 different sites of the specimen to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.	
For liquid specimens: Using a pipette, hold upright and aspirate fecal specimens, and then transfer 6 drops (approximately 300 µl) into the specimen collection tube containing the extraction buffer.	
Insert the specimen collection stick into the tube and tighten the cap. Shake the tube vigorously to ensure thorough mixture of the specimen and the assay diluents reagent.	
Remove the test cassette from the sealed pouch and use it as soon as possible. Caution: Do not touch the test window and the membrane inside.	
For Biopsy and Fecal samples prepared above: Hold the specimen collection tube upright and break off the tip with hands. Invert the vial and add four full drops (150 µl) of specimen without air bubbles into the sample well of the cassette.	
Read the result within 15 minutes. Note: Strong positive specimens may produce positive results in as little time as 1 minute. Confirm negatives in 15-30 minutes. DO NOT INTERPRET RESULTS AFTER 30 MINUTES	

Note: *Best results will be obtained if the assay is performed right after collecting fecal samples.*

Specimens prepared in the specimen collection tube may be stored for 6 months at -20°C if not tested within 1 hour after preparation.

7. Interpretation of the test



Negative

A red colored band appears only in the control region (C), indicating a negative result for HP Ag

Positive

A clear red control band (C) and a detectable test band (T) appear, indicating a positive result for H.P Ag

Invalid

No visible band in the control region (C). Repeat with a new test device. If test still fails, please contact the distributor with the lot number.

8. Quality Control

Although the testing device contains an internal quality control (red colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance.

Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

9. Storage and stability

1) Test device in the sealed pouches should be stored at 2-30ºC. Do not freeze the test device.
2) The fecal specimen collection device containing the buffer should be stored at 2-30ºC.
3) The test device should be kept away from direct sunlight, moisture and heat.

10. Limitations

1) This product is an in vitro diagnostic test designed for professional use only.
2) Humidity and temperature can adversely affect results.
3) The instructions for use of the test should be followed during testing procedures.
4) There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
5) Although the test demonstrates superior accuracy in detecting Helicobacter pylori antigen in fecal extract, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

11. Literature references

1. Marshall, B. J. Unidentified curved bacilli in the stomach of patients with gastric and peptic ulceration. Lancer I:1984: 1311-1314.

2. de Korwin JD. Epidemiology of Helicobacter pylori infection and gastric cancer. 2014 Feb;64(2):189-93.

3. Howden C. W. Clinical expressions of Helicobacter pylori infection. AM J Med; 1996;100:27S-33S.

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