Helicobacter Pylori (*H.Pylori*) Antigen Test

CE IVD

Cat. No.: HP442

1. Intended use

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 causing 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.

Helicobacter Pylori (*H.Pylori*) Antigen test is an antigen-capture immunochromatographic assay, which detects the 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. If the *H. pylori* antigen is present in sample, it will interact with the gold conjugated antibodies. The antigen-antibody-gold complex will migrate towards the test window until the test region (T) where they will be 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 cassette, Desiccant.
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.

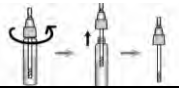
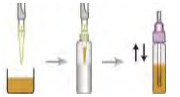
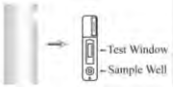
6. Procedure of the test

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:

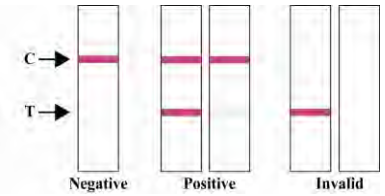
Follow the procedures described below:

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.
Positive
A clear red control band (C) and a detectable test band (T) appear, indicating a positive result.
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. Performance Characteristics

Sensitivity:
Helicobacter Pylori (*H.Pylori*) Antigen Test can detect H. pylori at level of 10^4 cfu/ml.
Specificity:
Helicobacter Pylori (*H.Pylori*) Antigen Test is specific to H. pylori antigen and does not cross-react with the

Acinetobacter baumannii	Proteus mirabilis
Campylobacter jejuni	Providencia rettgeri
Citrobacter kosei	Pseudomonas aeruginosa
Enterobacter aerogenes	Salmonella enteritidis
Enterobacter cloacae	Serratia marcescens
Enterococcus faecalis	Shigella sonnei
Enterococcus faecium	Staphylococcus aureus (MRSA)
Enterococcus gallinarum	Staphylococcus epidermidis
Escherichia coli	Staphylococcus haemolyticus
Klebsiella pneumoniae	Vibrio cholerae
Klebsiella oxytoca	Vibrio parahaemolyticus
Morganella morganii	

Performance Characteristics

The performance of Helicobacter Pylori (*H.Pylori*) Antigen Test was evaluated by 1) Respiratory test and CLO test (rapid urease test), and 2) a comparison study with a leading commercial Helicobacter pylori Antigen Test device and was conducted at external clinical sites. 395 clinic samples were studied. The detail results were tabulated below:

Table 1 Comparison with Respiratory test and CLO test:

		Results of Helicobacter Pylori (*H.Pylori*) Antigen Test		Subtotal
		Positive	Negative	
Respiratory and CLO test	Positive	240	15	255
	Negative	0	140	140
Subtotal		240	155	395

Diagnostic sensitivity: 240/255 = 94.1%
Diagnostic specificity: 140/140 = 100 %
Total agreement: (240+140)/395 =96.2%

Table 2 Comparison with leading commercial Rapid H. Pylori test

		Results of Helicobacter Pylori (*H.Pylori*) Antigen Test		Subtotal
		Positive	Negative	
Results of commercial kits	Positive	235	0	235
	Negative	5	155	160
Subtotal		240	155	395

Positive agreement: 235/235 = 100%
Negative agreement: 155/160 = 96.8%
Overall agreement: (235+155)/395 =98.7%

Interference

The following substances and conditions were found not to interfere with the test. List of potentially interfering chemical analytes and concentrations tested are as follows:

Acetaminophen	20 mg/dl	Atropine	20 mg/dl
Acetylsalicylic acid	20 mg/dl	Ethanol	1%
Ascorbic acid	20 mg/dl	Methanol	1%
Caffeine	20 mg/dl	Heparin	1%
Gentesic acid	20 mg/dl	Citrate	3.2%
Phenylpropanolamine	20 mg/dl	Albumin	2,000 mg/dl
Salicylic acid	20 mg/dl	Glucose	2,000 mg/dl
EDTA	80 mg/dl	Bilirubin	2,000 mg/dl
Benzoylecgonine	10 mg/dl	Hemoglobin	2,000 mg/dl
Atropine	20 mg/dl		

Reproducibility

The precision was determined by replicate assays of both positive and negative samples with devices from three different production lots. The resultant data indicated no appreciable between lot variation when testing both positive and negative samples across three different lots.

12. References

1. Bruce E et al. (1997) Helicobacter pylori. Clin Microbiol Rev 10 (4), 720-741
2. Blaser M J (1998) Helicobacter pylori and gastric diseases. BMJ 316: 1507-1510
3. Gisbert J P et al. (2006) Accuracy of monoclonal stool antigen test for the diagnosis of H. pylori infection: a systematic review and meta-analysis. Am J Gastroenterol 101(8):1921-30.
4. Telford J L et al. (1997) Antonello Covacci, Rino Rappuoli & Paolo Ghiara. Immunobiology of Helicobacter pylori infections.Current Opinion in Immunology 9: 498-503
5. Wu DC, et al (2006) Comparison of stool enzyme immunoassay and immunochromatographic method for detecting Helicobacter pylori antigens before and after eradication. Diagn Microbiol Infect Dis. 56(4):373-8.
6. Kato S et al (2003) Accuracy of the stool antigen test for the diagnosis of childhood Helicobacter pylori infection: a multicenter Japanese study. Am J Gastroenterol. 98(2):296-300.

7. Domínguez J et al (2006) . Comparison of a monoclonal with a polyclonal antibody-based enzyme immunoassay stool test in diagnosing Helicobacter pylori infection before and after eradication therapy. Aliment Pharmacol Ther. 15;23(12):1735-40.
8. Veijola L, et al (2005). Stool antigen tests in the diagnosis of Helicobacter pylori infection before and after eradication therapy. World J Gastroenterol. 11(46):7340-4.

Index of Symbols

	**Attention, see instructions for use**
	**For In-Vitro Diagnostic Use only**
	**Store between 2 – 30 centigrade**
	**Do Not use if package is damaged**
	**Test per kit**
	**Use by**
	**Lot Number**
	**Authorized Representative**
	**Do NOT Reuse**
	**Catalogue No**
	**CE Mark**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