H.PYLORI Ag Rapid Test (Stool)

The H.PYLORI Ag Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of Helicobacter Pylori Antigen human Stool specimens.

For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
	Device
01 Test	PHPA 01
10 Tests	PHPA 10
25 Tests	PHPA 25

CLINICAL SIGNIFICANCE

Helicobacter pylori (*H. pylori*) were initially isolated by Warren and Marshall from biopsy samples taken from patients suffering from active chronic gastritis. In fact, it is now clear that *H. pylori* is the principle etiologic agent in type B gastritis (chronic active antral gastritis) pathology for which it appears to be the triggering and perhaps aggravating factor. Increasing data are being accumulated regarding the fundamental role of *H. pylori* in active chronic gastritis, in gastric ulcer and in duodenal ulcer and its close correlation with gastric lesions. *H. pylori* is isolated in culture medium and examined by microscopy after staining or is detected by urease test. 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 antibodies specific to *H. pylori* has substantially resolved these problems, ensuring a serological monitoring in a very short space of time using simple, highly specific technology without recourse to invasive techniques. The stool test for *H. pylori* can be utilized as a rapid screening process for large populations of patients and highly indicated 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 stool-level antigen against *H. pylori* must be interpreted as an indication of type B asymptomatic gastritis.

PRINCIPLE

The H.PYLORI Ag Rapid Test Kit (Stool) detects H.PYLORI Ag in human stool sample through visual interpretation of color development on the strip. This test kit is intended as an aid in the diagnosis of *H. pylori* infection in patients with gastrointestinal symptoms. The *H. pylori* test contains a membrane strip, which is pre-coated with *H. pylori* capture monoclonal antibodies on test band region. The *H. pylori* antibody– colloid gold conjugate and extracted stool sample move along the membrane chromatographically to the test region (T) and form a visible line as the antibody-antigen-antibody gold particle complex forms with high degree of sensitivity and specificity. This test device is marked with the letters T (Test Line) and C (Control Line) on the surface of the case. Both the Test Line and Control Line in result window are not visible before applying any samples. The Control Line is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working.

KIT COMPONENTS

- Test Cassettes
- Droppers
- Package Insert
- Sample Extraction tube with buffer

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

PRECAUTIONS

1. For professional *In-vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens and tested device/strip.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Read the Instruction for use carefully before performing the test.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

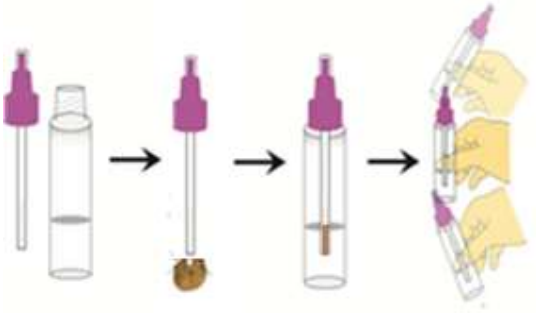
1. Stool samples must be taken as soon as the symptoms appear.
2. Stool specimens should be collected in containers that do not contain media, preservatives, animal serum or detergents as any of these additives may interfere with the test.
3. Specimens may be stored at 2-8ºC for 2 days without interfering with the assay performance.
4. For long-term storage of specimens,-20ºC or colder is recommended. Repeated freezing and thawing of specimens is not recommended and may cause erroneous results. Do not store specimens in self-defrosting freezers.

5. If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

DIRECTIONS FOR USE

Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before testing.

1. Allow test device, Assay Buffer and specimen equilibrates to room temperature (15-30°C) prior to testing.
2. Remove the test device from the aluminum foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
3. Unscrew the cap of the specimen collection tube with extraction buffer, then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites. Take the dab of stool sample using applicator and add in to the 1 ml buffer in sample extraction tube. Mix well then kept for 10 minute. Add 2 drops (80 to 100µL) into the sample well.
4. Allow reaction to occur and read the results at 20 minutes. Do not interpret results after 30 minutes.



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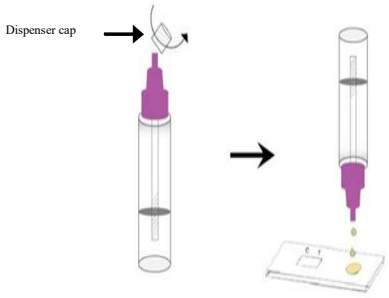

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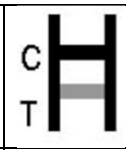
INTERPRETATION OF RESULTS

Negative Result	

Positive Result	

1) Negative

The control line is the only visible line on the test device.

2) Positive

The control line and Test line is visible line on the test device.

3) 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.

Quality Control

Internal procedural controls are included in the test individually. A colored line appearing in control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Test

1. The H. Pylori Ag Rapid Test (Stool) is for professional in vitro diagnostic use, and should be only used for the qualitative detection of H. Pylori Antigen.
2. Test will only indicate the presence of H. pylori antigen in the specimen and should not be used as the sole criteria for the diagnosis of H. pylori infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of H. pylori infection.

Performance characteristics

Diagnostic Performance

Commercial H. Pylori Ag Rapid Test Results	**H. Pylori Ag Rapid Test**		**Total**
	Positive	**Negative**	
Positive	35	0	35
Negative	0	50	50
Total	35	50	85

Relative sensitivity: 100%, Relative Specificity: 100.0%, Overall agreement: 100.0 %

BIBLIOGRAPHY

1. Marshall B.J. et al. Pyloric Campylobacter infection and gastroduodenal disease. Med. J. Aust. 142: 439-444 (1985).
2. Varia, D. and Holton, J. Serum immunoglobulin G antibody levels for *Campylobacter pylori* diagnosis, *Gastroenterology*. 97: 1069–1071 (1989).
3. Lambert, J.r., Lin, S.K. and Aranda-Michel, J. *Helicobacter pylori,* Scand. J. *Gastroenterol*. 30 suppl 208: 33-46 (1995).
4. Evans, D.J., Evans, D.G., Graham, D.Y. and Klein, P.D. A, Sensitive and specific serologic test for detection of *Campylobacter pylori* infection. *Gastroenterology*. 96: 1004–1008 (1989).

GLOSSARY OF SYMBOL

	Consult Instruction for Use
REF	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

India office
BIOBOON BIOTECH INDIA LLP
207. Regent Square
2nd floor, Above D'mart shopping mall
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