One Step®

H.pylori Antigen Rapid Test Cassette (Faeces)
Package Insert
For Self-testing

REF IHP-602H	English

A rapid test for the qualitative detection of Helicobacter pylori (H.pylori) antigens in human faeces. For self-testing in vitro diagnostic use only.

【SUMMARY】

H.pylori is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. It is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis.[1,2] Both invasive and non-invasive methods are used to diagnose *H.pylori* infection in patients with symptoms of gastrointestinal disease. Specimen-dependent and costly invasive diagnostic methods include gastric or duodenal biopsy followed by urease testing (presumptive), culture, and/or histologic staining.[3] A very common approach to the diagnosis of *H.pylori* infection is the serological identification of specific antibodies in infected patients. The main limitation of serology test is the inability to distinguish current and past infections. Antibody may be present in the patient's serum long after eradication of the organisms.[4] HpSA (H. pylori Stool Antigen) testing is gaining popularity for diagnosis of H. pylori infection and also for monitoring the efficacy of the treatment of H. pylori infection. Studies have found that more than 90% of patients with duodenal ulcer and 80% of patients with gastric ulcer are infected with *H.pylori*.[5]

The *H.pylori* Antigen Rapid Test Cassette (Faeces) is a rapid chromatographic immunoassay for the qualitative detection of *H.pylori* antigens in human faeces specimens, providing results in 10 minutes. The test utilizes antibodies specific for *H. pylori* antigens to selectively detect *H.pylori* antigens in human faeces specimens.

【PRECAUTIONS】

Please read all the information in this package insert before performing the test.

- For self-test in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Store in a dry place at 2-30°C (36-86°F), avoiding areas of excess moisture. If the foil packaging is damaged or has been opened, please do not use.
- Use either the stool collection paper or a clean container to collect your faecal specimen.
- Follow the indicated time strictly.
- Use the test only once. Do not dismantle and touch the test window of the test cassette.
- The kit must not be frozen or used after the expiry date printed on the package.
- After use, all components can be disposed of with your normal household waste.
- Keep out of the reach of children.

【STORAGE AND STABILITY】

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【MATERIALS PROVIDED】

• Test Cassette • Specimen collection tube with extraction buffer • Package insert • Stool collection paper

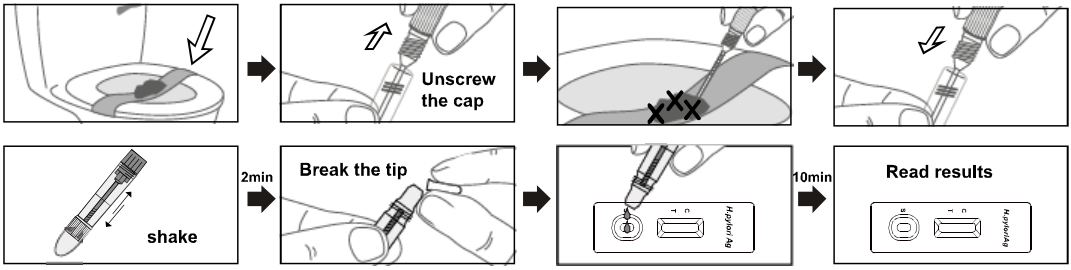
【MATERIALS REQUIRED BUT NOT PROVIDED】

- Timer
- Specimen containers

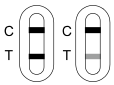
【DIRECTIONS FOR USE】

Before performing the test, stool samples must be collected following the instruction below.

1. Wash your hands with soap and rinse with clear water.
2. To collect faecal specimens:
   The stool specimen should be collected in the stool collection paper, avoiding contamination of the specimen by taking precautions that the specimen or the side of the paper containing specimen does not come in contact with any contaminating objects including toilet cleaners. Please read the instructions on the collection paper for how to collect your specimen. Alternatively, you can use a clean specimen container, but again must make sure that neither the specimen nor the cup come into contact with any contaminating objects.
3. To process faecal specimens:
   Unscrew the blue cap of the specimen collection tube with extraction buffer, then randomly stab the specimen collection applicator into the faecal specimen in at least **3 different sites**. **Do not scoop the faecal specimen.**
   Re-fasten the blue cap onto the specimen collection tube, then **shake** the specimen collection tube vigorously to mix the specimen and the extraction buffer.
4. Bring the pouch to room temperature before opening it. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
5. Open the white cap of the specimen collection tube with extraction buffer and then break off the tip. Invert the specimen collection tube and transfer **2 full drops of the extracted specimen** to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S).
6. Read results at **10 minutes**. Results obtained after this time may be inaccurate.

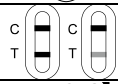


【READING THE RESULTS】



POSITIVE:* **Two lines appear.** Both T (Test) and C (Control) lines appear.
This result means that there is the presence of the *H.pylori* antigen in faeces and that you should consult a physician.
***NOTE**: The intensity of the colour in the test line region (T) will vary depending on the concentration of *H.pylori* antigen present in the specimen. Therefore, any shade of colour in the test line region (T) should be considered positive.

NEGATIVE: **One coloured line appears in the control line region (C)**. No line appears in the test line region (T).
This result means that the presence of the *H.pylori* antigen in faeces was not detectable.



INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【LIMITATIONS】

1. The *H.pylori* Antigen Test Cassette (Faeces) is for in vitro diagnostic use only. The test should be used for the detection of *H.pylori* antigens in faeces specimens only. Neither the quantitative value nor the rate of increase in *H.pylori* antigens concentration can be determined by this qualitative test.
2. The *H.pylori* Antigen Test Cassette (Faeces) will only indicate the presence of *H.pylori* in the specimen and should not be used as the sole criteria for *H.pylori* to be etiological agent for peptic or duodenal ulcer.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *H.pylori* infection.
5. Following certain antibiotic treatments, the concentration of *H.pylori* antigens may decrease to the concentration below the minimum detection level of the test. Therefore, diagnosis should be made with caution during antibiotic treatment.

【FAQs】

1. How does the *H. pylori* test work?
H.pylori is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. The *H. pylori* Test specifically detects the antigens in faeces to ascertain the presence of the bacterium.

2. When should the test be used?
The test can be performed any time of the day. The test can be performed in case of repeated stomach and intestinal troubles (GERD, gastritis etc.).

3. Can the result be incorrect?
The results are accurate as far as the instructions are carefully respected. Nevertheless, the result can be incorrect if *H. pylori* Test gets wet before performing the test or if the quantity of faeces dispensed in the sample well is too much or not sufficient, or if the number of diluted specimen drops are fewer than 2 or more than 3. In addition, due to immunological principles involved, there is the possibility of false results in rare cases. A consultation with the doctor is always recommended for such tests based on immunological principles.

4. How to interpret the test if the colour and the intensity of the lines are different?
The colour and intensity of the lines have no importance for result interpretation. The lines should only be homogeneous and clearly visible. The test should be considered as positive whatever the colour intensity of the test line.

5. What is the line that appears under the mark C (control) for?
When this line appears, it only means that the test has worked.

6. What do I have to do if the result is positive?
If the result is positive, it means that the *H. pylori* antigens were detected in faeces and that you should consult a doctor to discuss the test result. Then, the doctor will decide whether additional analysis should be performed.

7. What do I have to do if the result is negative?
If the result is negative, it means that it was not possible to detect the H.pylori antigens. However, if the symptoms persist, it is recommended to consult a physician.

【BIBLIOGRAPHY】

1. Marshall, BJ, McGechie, DB, Rogers, PAR and Glancy, RG. Pyloric Campylobacter infection and gastroduodenal disease. Med. J. Australia. (1985), 149: 439-44.
2. Soll, AH. Pathogenesis of peptic ulcer and implications for therapy. New England J. Med.(1990), 322: 909-16.
3. Hazell, SL, et al. Campylobacter pylori is and gastritis I: Detection of urease as a marker of bacterial colonization and gastritis. Amer. J. Gastroenterology. (1987), 82(4): 292-96.
4. 4. Cutler AF. Testing for Helicobacter pylori in clinical practice. Am j. Med. 1996; 100:35S-41S.
5. Anand BS, Raed AK, Malaty HM, et al. Loe point prevalence of peptic ulcer in normal individual with Helicobacter pylori infection. Am J Gastroenterol. 1996,91:1112-1115.

Index of Symbols

	Attention, see instructions for use		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #
	Do not use if package is damaged		Consult Instructions For Use		Manufacturer

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CE 0123

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