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

REF IHP-602H	English

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

【INTENDED USE】

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

【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]

【PRINCIPLE】

The *H. pylori* Antigen Rapid Test Cassette (Feces) is a qualitative, lateral flow immunoassay for the detection of *H. pylori* antigens in human feces specimens. In this test, the membrane is pre-coated with anti-*H. pylori* antibodies on the test line region of the test. During testing, the specimen reacts with the particle coated with anti-*H. pylori* antibodies. The mixture migrates upward on the membrane by capillary action to react with anti-*H. pylori* antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

【PRECAUTIONS】

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

- For self-testing *in vitro* diagnostic use only. Do not use the 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 a clean container to collect your fecal 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 expiration date printed on the package.
- The used test should be discarded according to local regulations.
- 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

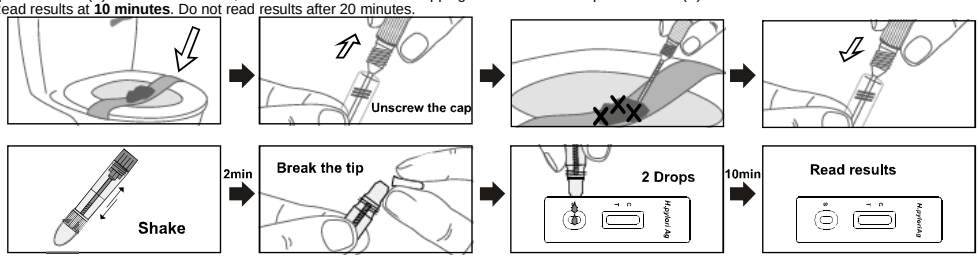
【MATERIALS REQUIRED BUT NOT PROVIDED】

• Timer • Specimen container

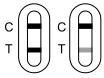
【DIRECTIONS FOR USE】

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

1. Wash your hands with soap and rinse with clear water.
2. To collect fecal specimens:
   The stool specimen should be collected in the stool collection paper or clean collection containers.
   Please use the stool collection paper, avoiding contamination of the specimen by taking precautions that the specimen or side of paper containing specimen does not come in contact with any contaminating objects including toilet cleaners.
3. To process fecal specimens:
   Unscrew the cap of the specimen collection tube，then randomly stab the specimen collection applicator into the fecal specimen in at least **3 different sites**. **Do not scoop the fecal specimen.**
   Screw on and tighten the 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 cap of the specimen collection tube and break 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**. Do not read results after 20 minutes.

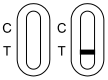


【READING THE RESULTS】



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

NEGATIVE: **One colored 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 feces 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 Rapid Test Cassette (Feces) is for *in vitro* diagnostic use only. The test should be used for the detection of *H. pylori* antigens in feces 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 Rapid Test Cassette (Feces) 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.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The *H. pylori* Antigen Rapid Test Cassette (Feces) has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. The result shows that the sensitivity of the *H. pylori* Antigen Rapid Test Cassette (Feces) is 97.6% and the specificity is 97.9% relative to other rapid test.

Method		Other Rapid Test		Total Results
***H. pylori* Antigen Rapid Test Cassette**	**Results**	Positive	Negative	
	Positive	83	2	85
	Negative	2	93	95
Total Results		85	95	180

Relative Sensitivity: 97.6% (95%CI:*91.8%-99.7%)
Relative Specificity: 97.9% (95%CI:*92.6%-99.7%)
Overall accuracy: 97.8% (95%CI:*94.4%-99.4%)

*Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of four specimens: negative, low titer positive, middle titer positive and high titer positive specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same four specimens: negative, low titer positive, middle titer positive and high titer positive specimens. Three different lots of the *H. pylori* Antigen Test Cassette (Feces) have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

Cross reactivity with following organisms has been studied at 1.0E+09 organisms/mL. The following organisms were found negative when tested with the *H. pylori* Antigen Test Cassette (Feces):

Acinetobacter calcoaceticus	*Acinetobacter spp*	*Branhamella catarrhalis*	*Candida albicans*
Chlamydia trachomatis	*Enterococcus faecium*	*E.coli*	*Enterococcus faecalis*
Gardnerella vaginalis	*Group A Streptococcus*	*Group B Streptococcus*	*Group C Streptococcus*
Hemophilus influenza	*Klebsiella pneumonia*	*Neisseria gonorrhea*	*Neisseria meningitides*
Proteus mirabilis	*Proteus vulgaris*	*Pseudomonas aeruginosa*	*Rotavirus*
Salmonella choleraesius	*Staphylococcus aureus*	*Adenovirus*	

Interfering Substances

The following potentially Interfering Substances were added to HPG negative and positive specimens.

Ascoribic acid: 20 mg/dL	Oxalic acid: 60 mg/dL	Bilirubin: 100 mg/dL	Uric acid: 60 mg/dL	Aspirin: 20 mg/dL
Urea: 2000 mg/dL	Glucose: 2000 mg/dL	Caffeine: 40 mg/dL	Albumin: 2000 mg/dL	

【EXTRA INFORMATION】

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

2. When should the test be used?
The test can be performed anytime 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* Antigen Rapid Test Cassette gets wet before performing the test or if the quantity of feces dispensed in the sample well is too much or not sufficient, or if the number of extracted specimens drops are less than 2 or more than 3. Besides, due to immunological principles involved, there exist the chances 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 color 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 is.

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

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 feces and that you should consult a doctor to show 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】

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2. Soll, AH. Pathogenesis of peptic ulcer and implications for therapy. New England J. Med.(1990), 322: 909-916.
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): 292-296.
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

	Manufacturer	Σ	Tests per kit	EC REP	Authorized representative in EU
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
30°C 2°C	Store between 2-30°C	LOT	Lot number	REF	Catalog #
	Do not use if package is damaged		Consult instructions for use		

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CE 0123

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