Rapid Response®

***H. pylori* Antigen Test**
(Feces)

REF HPY-9P10, HPY-9P20, HPY-9P25 Product Insert

A rapid, one step test for the qualitative detection of *Helicobacter pylori (H. pylori)* antigens in human feces.
For professional laboratory *in vitro* diagnostic use only.

Intended Use

The Rapid Response® *H. pylori* Antigen Test is a rapid chromatographic immunoassay for the qualitative detection of *H. pylori* antigens in human feces to aid in the diagnosis of *H. pylori* infection.

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] 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.[3]
Helicobacter pylori (H. pylori) infection underlies gastric ulcer disease, gastric cancer and duodenal ulcer disease. The disease expression reflects the pattern and extent of gastritis/gastric atrophy (i.e., duodenal ulcer with non-atrophic and gastric ulcer and gastric cancer with atrophic gastritis).[4]
The Rapid Response® *H. pylori* Antigen Test 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.

Principle

The Rapid Response® *H. pylori* Antigen Test 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* antibody on the test line region of the test. During testing, the specimen reacts with the particle coated with anti-*H. pylori* antibody. The mixture migrates upward on the membrane by capillary action to react with anti-*H. pylori* antibody 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.

Reagents

The test contains monoclonal anti-*H. pylori* antibody coated particles and monoclonal anti-*H. pylori* antibody coated on the membrane.

Precautions

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

- For professional laboratory *in vitro* diagnostic use only.
- Do not use after the expiration date. Do not reuse the test.
- Store in a dry place at 2-30 °C (35.6-86 °F), avoiding areas of excess moisture. If the foil packaging is damaged or has been opened, please do not use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature may adversely affect results.
- Wash hands thoroughly before and after handling.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority.
- Use the test only once. **Keep the test upright while testing. Do not move or turn the test upside down.**
- The kit must not be frozen or used after the expiration date printed on the package.
- Components provided in the kit are approved for use in the Rapid Response® *H. Pylori* Antigen Test. Do not use any other commercial kit component.

Storage and Stability

The kit can be stored at room temperature or refrigerated (35.6°F to 86°F; 2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.
Note: It is recommended to use the test within one hour after removing it from the foil pouch.

Specimen Collection and Preparation

- The feces specimen must be collected in a clean, dry, waterproof container containing no detergents, preservatives or transport media.
- No dietary restrictions are necessary before using the Rapid Response® *H. pylori* Antigen Test.
- Bring the necessary reagents and feces specimen to room temperature before use.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

Materials

Materials provided

- Test Cups (with dilution buffer)
- Product Insert

Materials required but not provided

- Timer
- Specimen Containers
- Droppers

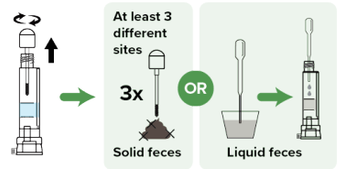
Test Procedure

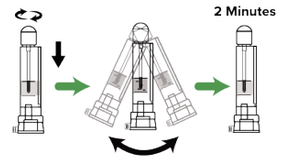
Before performing the test, allow the test specimen and cup to reach room temperature (15-30°C), stool samples must be collected following the instruction below.

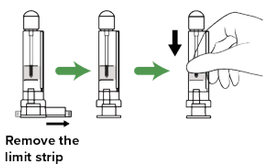
1. Wash your hands with soap and rinse with clear water.
2. **Fecal Specimen Collection:**
   Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container. Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8 °C if not tested within 6 hours. For long term storage, specimens should be kept below -20 °C.
3. Bring the pouch to room temperature before opening it. Remove the test cup 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.
4. **Fecal Specimen Preparation:**
   For Solid Specimens:
   Unscrew the cap of the test cup and take out the specimen collection applicator.
   Randomly insert the specimen collection applicator into the fecal specimen in at least 3 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
   For Liquid Specimens:
   Hold the dropper vertically, aspirate fecal specimens, and then transfer 2 drops of the liquid specimen (approximately 80 µL) into the test cup containing the dilution buffer.
5. Insert the specimen collection applicator back into the test cup and tighten the cap.
6. Shake the test cup for about 10-15 seconds to mix well. Leave the cup for reaction for 2 minutes.
7. Remove the plastic limit strip of the test cup.
8. Put the test cup on a clean and level surface, press the cup body from the top to the bottom and start the timer.

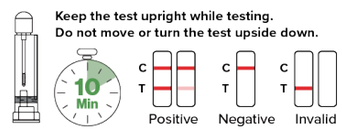
NOTE: If the specimen does not migrate (presence of particles), open a new test cup, repeat step 4 and centrifuge the diluted specimen contained in the test cup with a clean tube. Pipette 1-1.5 mL of supernatant, dispense into the test cup and insert the specimen collection applicator back into the test cup and tighten the cap. Continue from step 7-8 onwards in the above instructions for use and start the timer.

9. Read results at 10 minutes. Do not read results after 20 minutes.



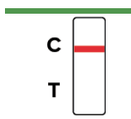




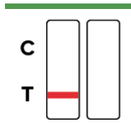


Results Interpretation

POSITIVE:* Two colored lines appear.
One colored line should be in the control region (C) and another colored line should be in the test region (T). This result indicates the presence of *H. pylori* antigens in feces. Consultation with a physician is advised.
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 colored 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.

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Quality Control

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Limitations

1. The Rapid Response® *H. pylori* Antigen Test is for professional laboratory *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 Rapid Response® *H. pylori* Antigen Test 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

Accuracy

The Rapid Response® *H. pylori* Antigen Test has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. The result shows that the sensitivity of the Rapid Response® *H. pylori* Antigen Test is 98.5% and the specificity is 99.0% relative to other rapid test.

Method		Other Rapid Test		Total Results
	Results	Positive	Negative	
Rapid Response® *H. pylori* Antigen Test	Positive	64	1	65
	Negative	1	99	100
Total Results		65	100	165

Relative Sensitivity: 98.5% (95%CI:*91.7%-99.9%)
*Confidence Intervals
Relative Specificity: 99.0% (95%CI:*94.6%-99.9%)
Relative Accuracy: 98.8% (95%CI:*95.7%-99.9%)

Sensitivity

The Rapid Response® *H. pylori* Antigen Test can detect *H. pylori* antigen at concentrations as low as 5 ng/mL.

Dose Hook Effect

No high-dose hook effect was detected at concentration up to 2.5 mg/mL.

Precision-Repeatability

Precision-repeatability has been determined by using three specimens: negative, low positive and middle positive specimens. The study was performed with 5 replicates per day for 5 consecutive days by one operator using one lot of Rapid Response® *H. pylori* Antigen Test. No difference was detected in intralot.

Precision-Reproducibility

Precision-reproducibility has been determined by using three specimens: negative, low positive and middle positive specimens. The study was performed 5 replicates per day for 5 consecutive days in 3 different sites using 3 separate lots of Rapid Response® *H. pylori* Antigen Test (one lot per site), and three operators per site. All values were correctly identified >99% of the time.

Cross-Reactivity

Cross reactivity with following organisms has been studied at 1.0E+07 org/mL. The following organisms were found negative when tested with the Rapid Response® *H. pylori* Antigen Test:

Acinetobacter calcoaceticus	*Klebsiella pneumoniae*
Candida albicans	*Proteus mirabilis*
E. coli	*Salmonella choleraesuis*
Group A Streptococcus	*Branhamella catarrhalis*
Haemophilus influenzae	*Enterococcus faecium*
Neisseria meningitidis	*Gardnerella vaginalis*
Pseudomonas aeruginosa	*Group C Streptococcus*
Acinetobacter spp	*Neisseria gonorrhoeae*
Chlamydia trachomatis	*Proteus vulgaris*
Enterococcus faecalis	*Staphylococcus aureus*
Group B Streptococcus	

Cross reactivity with following organisms has been studied at TCID50: 5E+03 per/mL. The following organisms were found negative when tested with the Rapid Response® *H. pylori* Antigen Test:

Rotavirus	*Adenovirus*

Interfering Substances

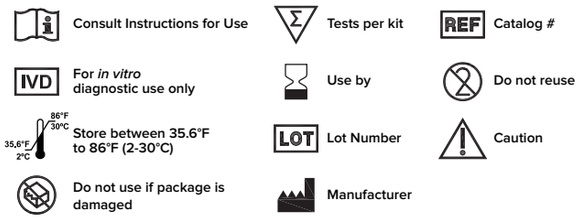
The following potentially interfering substances were added to *H. pylori* antigen negative and positive specimens. It does not interfere with the normal results.

Ascorbic acid: 20 mg/dL	Caffeine: 40 mg/dL
Uric acid: 60 mg/dL	Bilirubin: 100 mg/dL
Glucose: 2000 mg/dL	Urea: 2000 mg/dL
Oxalic acid: 60 mg/dL	Albumin: 6000 mg/dL
Aspirin: 60 mg/dL	

Bibliography

1. Marshall, BJ, McGechie, DB, Rogers, PAR and Glancy, RG. Pyloric Campylobacter infection and gastroduodenal disease. Med. J. Australia. (1985), 149: 439-444.
2. Soll, AH. Pathogenesis of peptic ulcer and implications for therapy. New England J. Med. (1990), 322: 909-916.
3. Cutler AF. Testing for Helicobacter pylori in clinical practice. Am j. Med.(1996), 100: 35S-41S.
4. David, Y, Graham. History of Helicobacter pylori, duodenal ulcer, gastric ulcer and gastric cancer. World J Gastroenterol. (2014), 20(18): 5191-5204.

Glossary of Symbols



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Part Number	14603507501	***Description***	(彩色)BTNX Rapid Response IHP-607 英语说明书(For A0028)(新地址)		
Size	355x216mm	***Material***	80g铜版纸，彩色双面， 折好到货，折后88.75x108mm, 露出首页logo		
Designer	HouHou	***Design Date/Version***	Apr 17 2026/A	***Mold Num.***	
Confirmation and Signature of Customer/Date					