# *H. pylori* Antigen Rapid Test Cassette (Feces)

**Package Insert**

| REF L031-10711 | English |
|---|---|

*A rapid test for the qualitative detection of Helicobacter pylori (H. pylori) antigens in human feces*
*For professional 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 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] 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 to *H. pylori* infection.

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. The test utilizes antibodies specific for *H. pylori* antigens to selectively detect *H. pylori* antigens in human feces specimens.

## 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 cassette. 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 line 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 anti-*H. pylori* antibodies coated particles and anti-*H. pylori* antibodies coated on the membrane.

## PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

## STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch containing desiccant until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

## MATERIALS

### Materials Provided

- Test Cassettes
- Specimen collection tubes with extraction buffer
- Package insert
- Droppers

### Materials Required But Not Provided

- Specimen collection containers
- Centrifuge and pipette to dispense 80 µL if required
- Timer

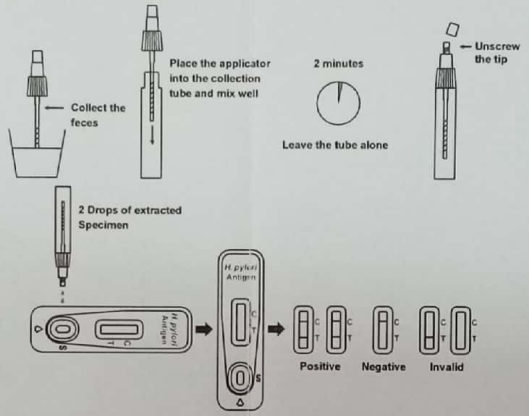
## DIRECTIONS FOR USE

**Allow the test, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing**

1. To collect fecal specimens:
   Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). 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
2. To process fecal specimens:
   - For Solid 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 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 (approximately 80 µL) into the specimen collection tube containing the extraction buffer.

   Tighten the cap onto the specimen collection tube, shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Leave the tube alone for 2 minutes.
3. 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.
4. Hold the specimen collection tube upright and unscrew the tip of the specimen collection tube. Invert the specimen collection tube and transfer 2 full drops of the extracted specimen (approximately 90 µL) to the specimen well (S) of the test cassette, then start the timer. Avoid air bubbles. See illustration below.
5. Read results at 10 minutes after dispensing the specimen. Do not interpret results after 20 minutes.

**Note:** If the specimen does not migrate (presence of particles), centrifuge the extracted specimens in the specimen collection tube. Collect 80 µL of supernatant, dispense into the specimen well (S) of a new test cassette and repeat the step 5 mentioned above.




## INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**POSITIVE:* Two distinct colored lines appear.** One colored line should be in the control line region (C) and another colored line should be in the test line region (T).

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of *H. pylori* antigens 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).

**INVALID: Control line (C) 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 Cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

## QUALITY CONTROL

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

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.

## EXPECTED VALUES

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 (Feces) has been compared with Elisa methods, demonstrating an overall accuracy of 99%.

## PERFORMANCE CHARACTERISTICS

### Clinical Sensitivity, Specificity and Accuracy

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 99.0% and the specificity is 98.9% relative to Elisa methods.

***H. pylori* Antigen Rapid Test Cassette vs. Elisa methods**

| Method | | Elisa methods | | Total Results |
|---|---|---|---|---|
| | Results | Positive | Negative | |
| *H. pylori* Antigen Test Cassette | Positive | 104 | 3 | 107 |
| | Negative | 1 | 273 | 274 |
| Total Results | | 105 | 276 | 381 |

Relative Sensitivity: 99.0% (94.8%-99.8%)*
Relative Specificity: 98.9% (96.9%-99.6%)*
Relative Accuracy: 99.0% (97.3%-99.6%)*
*95% Confidence Intervals

### Precision

**Intra-Assay**

Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The specimens were correctly identified >99% of the time.

**Inter-Assay**

Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. The specimens were correctly identified >99% of the time.

### Cross-Reactivity

Cross reactivity with following organisms has been studied at $1.0 \times 10^8$ organisms/mL. The following organisms were found negative when tested with the *H. pylori* Antigen Rapid Test Cassette (Feces).

| | | |
|---|---|---|
| *Staphylococcus aureus* | *Proteus mirabilis* | *Neisseria gonorrhea* |
| *Pseudomonas aeruginosa* | *Acinetobacter spp* | *Group B Streptococcus* |
| *Enterococcus faecalis* | *Salmonella choleraesius* | *Proteus vulgaris* |
| *Group C Streptococcus* | *Gardnerella vaginalis* | *Enterococcus faecium* |
| *Klebsiella pneumoniae* | *Acinetobacter calcoaceticus* | *Hemophilus influenzae* |
| *Branhamella catarrhalis* | *E.coli* | *Neissena meningitidis* |
| *Candida albicans* | *Chlamydia trachomatis* | *Rotavirus* |

## 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 pyloridis and gastritis I: Detection of urease as a marker of bacterial colonization and gastritis. Amer. J. Gastroenterology. (1987), 82(4): 292-96.
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 | 30°C / 2°C | Store between 2-30°C |
| IVD | For *in vitro* diagnostic use only | | Use by | | Do not reuse |
| | Consult instructions for use | LOT | Lot Number | REF | Catalog # |


**ACON Laboratories, Inc.**
10125 Mesa Rim Road,
San Diego, CA 92121, USA



Number: 1150992401
Effective Date: 2018-04-09