MONOCENT
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ENGLISH

# H. PYLORI ANTIGEN RAPID TEST SYSTEM

CE

REF RT27-2143 Σ 25 TESTS IVD

## INTENDED USE

The Monocent, Inc.'s H. pylori Antigen Rapid Test System 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 AND EXPLANATION

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 (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.

## PRINCIPLE OF THE TEST

The H. pylori Antigen Rapid Test System 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.

## REAGENTS

The test cassette contains monoclonal anti-H. pylori antibodies coated particles and monoclonal anti-H .pylori antibodies coated on the membrane.

## MATERIALS AND COMPONENTS

- Test cassettes
- Specimen collection tubes with extraction buffer
- Package insert

## MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection containers
- Pipette and disposable tips (optional)
- Centrifuge
- Droppers
- Timer

## STORAGE AND STABILITY

Store as packaged in the sealed pouches 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.

## PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- The test cassette should remain in the sealed pouch until 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 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.

## SPECIMEN COLLECTION AND PREPARATION

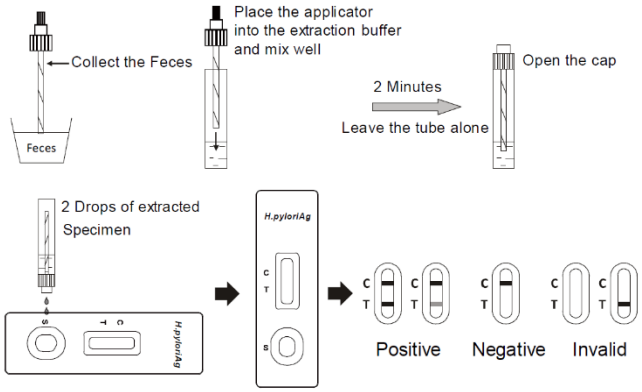
- The feces specimen must be collected in clean, dry, waterproof container containing no detergents, preservatives or transport media.
- Bring the necessary reagents to room temperature before use.
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

## TEST PROCEDURE

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 transferapproximately 80 µL into the specimen collection tube containing the extraction buffer.
     Tighten the cap onto the specimen collection tube, then 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 within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
4. Hold the specimen collection tube upright and open the cap onto the specimen collection tube. Invert the specimen collection tube and transfer 2 full drops of the extracted specimen (approximately 80 µL) to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
5. Read results at 10 minutes after dispensing the specimen. Do not read results after 20 minutes.

Note: If the specimen does not migrate (presence of particles), centrifuge the extracted specimens contained in the extraction buffer vial. Collect 80 µL of supernatant, dispense into the specimen well (S) of a new test cassette and start afresh following the instructions mentioned above.




## INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

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.

## QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal valid 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 Antigen Rapid Test System 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 System 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

The H. pylori Antigen Rapid Test System has been compared with Endoscope-based methods, demonstrating an overall accuracy of 98.6%.

## PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The H. pylori Antigen Rapid Test System 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 System is 98.8% and the specificity is 98.4% relative to Endoscope-based methods.

| Method | | Latex Agglutination | | Total Results |
|---|---|---|---|---|
| H. pylori Rapid Test | Results | Positive | Negative | |
| | Positive | 168 | 3 | 171 |
| | Negative | 2 | 189 | 191 |
| Total Results | | 170 | 192 | 362 |

Relative Sensitivity: 98.8% (95%CI*:95.8%-99.9%) *Confidence Interval
Relative Specificity: 98.4% (95%CI*: 95.5%-99.7%)
Overall Accuracy: 98.6% (95%CI*: 96.8%-99.5%)

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 5 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 Rapid Test System 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 Rapid Test System:

| | | |
|---|---|---|
| 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: 20mg/dl | Oxalic acid: 60mg/dl | Bilirubin: 100mg/dl |
| Uric acid: 60mg/dl | Aspirin: 20mg/dl | Urea: 2000mg/dl |
| Glucose: 2000mg/dl | Caffeine: 40mg/dl | Albumin: 2000mg/dl |

## REFERENCES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