

# PathFlow™ h.pylori Antigen (EN)

## Instructions for Use

### INTENDED USE

The Pathflow™ h.pylori Antigen Cassette is a rapid chromatographic immunoassay for the qualitative detection of H.pylori antigens in human faeces 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.<sup>1,2</sup> 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.<sup>3</sup> 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.<sup>4</sup> 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*.<sup>5</sup>

The Pathflow™ h.pylori Antigen Cassette 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.

### PRINCIPLE

The Pathflow™ h.pylori Antigen Cassette is a qualitative, lateral flow immunoassay for the detection of H.pylori antigens in human faeces 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 coloured line. The presence of this coloured line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a coloured 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

**Provided:** Test cassettes, Package Insert, Specimen collection tube with extraction buffer.

**Not Provided:** Specimen collection container, timer, Pipette and disposable tips (optional), Centrifuge and droppers.

### WARNINGS AND 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 use test if pouch is damaged.
- 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 can adversely affect results.

### STORAGE AND STABILITY

- Store as packaged at room temperature or refrigerated (2°C - 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 until use.
- **DO NOT FREEZE.**
- Do not use beyond the expiration date.

### SPECIMENS

- The faeces 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.

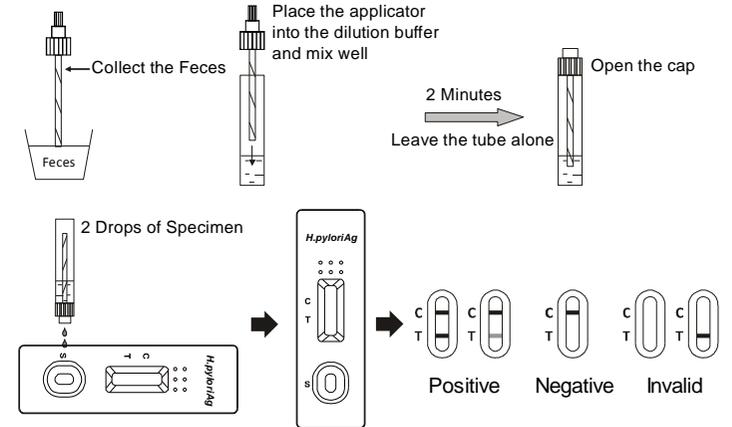
### DIRECTIONS FOR USE / INSTRUCTIONS FOR USE

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

1. To collect faecal specimens:  
Collect sufficient quantity of faeces (1-2 ml or 1-2 g) in a clean, dry specimen collection container to obtain enough virus particles. 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°C - 8°C if not tested within 6 hours. For long-term storage, specimens should be kept below -20°C.
2. To process faecal specimens:  
  - **For Solid Specimens:**  
Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the faecal specimen in at least 3 different sites to collect approximately 50 mg of faeces (equivalent to 1/4 of a pea). Do not scoop the faecal specimen.
  - **For Liquid Specimens:**  
Hold the dropper vertically, aspirate faecal 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, 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 the 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.

MICROGEN  
BIOPRODUCTS



### INTERPRETATION OF RESULTS

<p>Positive</p>	<p><b>POSITIVE:</b> * Two lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T). *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.</p>
<p>Negative</p>	<p><b>NEGATIVE:</b> One coloured line appears in the control line region (C). No line appears in the test line region (T).</p>
<p>Invalid</p>	<p><b>INVALID:</b> 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.</p>

### QUALITY CONTROL

Internal procedural controls are included in the test. A coloured 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

- The Pathflow™ h.pylori Antigen Cassette 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.
- The Pathflow™ h.pylori Antigen Cassette 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.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- 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.
- 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.

## CLINICAL SENSITIVITY, SPECIFICITY AND ACCURACY

The Pathflow™ h.pylori Antigen Cassette has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. The result shows that the sensitivity of the Pathflow™ h.pylori Antigen Cassette is >98.8% and the specificity is 98.4% relative to Endoscope-based methods.

Method	Results	Endoscope-based method		Total Results
		Positive	Negative	
Pathflow™ h.pylori Antigen Cassette	Positive	168	3	<b>171</b>
	Negative	2	189	<b>191</b>
Total Results		<b>170</b>	<b>192</b>	<b>362</b>

Relative Sensitivity: 98.8% (95%CI\*: 95.8%-99.9%) \*Confidence Interval

Relative Specificity: 98.4% (95%CI\*: 95.5%-99.7%)

Accuracy: 98.6% (95%CI\*: 96.8%-99.5%)

## 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 Pathflow™ h.pylori Antigen Cassette:

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 gonorrhoea
Neisseria meningitidis	Proteus mirabilis	Proteus vulgaris
Pseudomonas aeruginosa	Rotavirus	Salmonella choleraesuis
Staphylococcus aureus	Adenovirus	

## EXPECT VALUE

The Pathflow™ h.pylori Antigen Cassette has been compared with Endoscope-based methods, demonstrating an overall accuracy of 98.6%.

## 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 Pathflow™ h.pylori Antigen Cassette have been tested using these specimens.

The specimens were correctly identified >99% of the time.

## BIBLIOGRAPHY

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- 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.
- Cutler AF. Testing for Helicobacter pylori in clinical practice. Am j. Med. 1996; 100:35S-41S.
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## TABLE OF SYMBOLS

SYMBOL	DEFINITION
	Batch Code/Lot Number
	In Vitro Diagnostic Medical Device
	Catalogue Reference
	Upper and Lower Temperature Limit
	Expiry Date
	Manufacturer and Address Details
	Date of Manufacture
	Please consult Instructions for Use
	Sufficient for
	Do not use if package is damaged
	CE Mark
	Caution

This document applies to the following product codes:

M587CE / M587a / M587b



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