H. PYLORI ANTIGEN DEVICE (2–30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADHPG1	20 Tests

Intended Use:
The H. pylori Antigen Device is a rapid chromatographic immunoassay for the qualitative detection of *Helicobacter pylori* antigens in human faecal 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. 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. 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. *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 the bacterium.
The H. pylori Antigen Device is a rapid chromatographic immunoassay for the qualitative detection of *H. pylori* antigens in human faecal samples, providing results in 10 minutes. The test uses antibodies specific for *H. pylori* antigens to detect *H. pylori* antigens in human faecal samples.

Test Principle:
In the test, the membrane is coated with anti-H. pylori antibody on the test line and anti-H. pylori antibody conjugated to particles near the sample well. In preparation for the test, faecal specimens are extracted in a specific buffer to generate the samples used in the test. If H. pylori antigens are present in the extracted sample, they react with the particles to form immunocomplexes. The mixture migrates along the membrane by capillary action where the complexes further react with the anti-H. pylori antibody at the Test line. A coloured line forms which indicates a positive result. No colour development at the Test line indicates a negative result. To serve as a procedural control, a coloured band should always appear at the Control line indicating that proper volume of specimen has been added and membrane wicking has occurred.

Materials Provided
Individually pouched test devices
Specimen extraction tubes with extraction buffer
Instructions for Use sheet

Materials not provided: Timer, specimen collection container, pipette and disposable tips (optional), centrifuge, droppers

Precautions:
• For *in vitro* diagnostic use by trained professionals only. Do not use the kit after the expiry date.
• The test should remain sealed in its pouch until use.
• Treat all samples and test components as if infectious and handle and dispose of accordingly.
• 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.

Reagent Preparation and Stability:
The kit can be stored at room temperature or refrigerated (2 - 30°C). The test device is stable up to the expiry date printed on the sealed pouch. The test device must remain in the sealed pouch until use. Do not freeze. Do not use after the expiry date.

Specimen Collection and Storage:
The faecal samples must be collected into clean, dry, waterproof containers without any detergents, preservatives or transport media. Collect 1 – 2 ml or 1 – 2 g of faeces into the container.
Ideally, carry out the rapid test assay within 6 hours of collection. Samples may be stored at 2 – 8°C for testing up to 3 days or for longer term storage, freeze below-20°C.
If specimens are to be transported, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

Assay Procedure:
1. Processing the faecal samples:
Solid Samples
Unscrew the cap of the sample collection tube and randomly poke the sample collection needle into the faecal sample in at least 3 different areas to collect approximately 50 mg of faeces. Do not scoop out excess faecal sample.
Transfer the faeces on the collection needle into the buffer in the extraction tube. Secure the lid on the extraction tube, then shake the tube vigorously to mix the sample and the extraction buffer. Leave the tube to stand for 2 minutes.

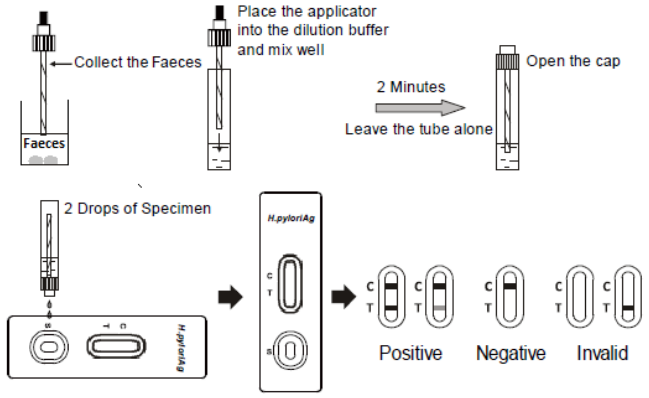
Liquid Samples:
Withdraw liquid faecal sample up into a dropper, and transfer 2 drops (approximately 80 µl) into the specimen extraction tube containing the extraction buffer.
Secure the lid on the extraction tube, then shake the tube vigorously to mix the sample and the extraction buffer. Leave the tube to stand for 2 minutes.

3. Remove the test device from the foil pouch and use it immediately or at least within one hour.

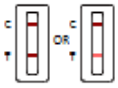
4. Hold the extraction tube upright and remove the cap. Invert the extraction tube and transfer 2 full drops of the extracted specimen (approximately 80 µl) to the sample well of the test device, then start the timer. Avoid trapping air bubbles in the sample well. See illustration below.

5. Read results at 10 minutes after dispensing the specimen. Do not read results after 20 minutes.

Note: If the specimen does not migrate (too much particulate), centrifuge the extracted sample. Use 80 µL of supernatant and dispense it into the sample well of a new test device using the instructions described above.

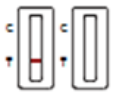


Interpretation of Results:



POSITIVE: Two coloured lines appear. One line develops at the control line (C) and another band appears at the test line (T).

NEGATIVE: Only one coloured line appears, in the control region. No colour development at the test line.



INVALID: Control band fails to appear. Results from any test which has not produced a control line at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of colour at the test line may vary depending on the concentration of analytes present in the sample. Therefore, any shade of colour at the test line should be considered positive. Note that this is a qualitative test only and cannot determine the concentration of analytes in the sample.
2. Insufficient sample volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.

Quality Controls:
A procedural control is included in the test in the form of a coloured line developing at the Control line. Its appearance confirms sufficient sample volume added and correct procedural technique.
Quality Controls 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 Device is for in vitro diagnostic use only. The test should only be used for the detection of *H. pylori* antigens in faecal samples. Neither the quantitative value nor the rate of increase in *H. pylori* antigens can be determined by this qualitative test.
2. The result from this should not be used as the sole criteria for *H. pylori* infection as the etiological agent for gastric conditions but be used in conjunction with other diagnostic procedures and clinical findings.
3. 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.
4. With various 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.

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Performance Characteristics:

Sensitivity and Specificity

The H. pylori Antigen Device 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 Device (Faeces) is 98.8% and the specificity is 98.4% relative to Endoscope-based methods.

Method		Endoscope-based method		Total Result
H. pylori Antigen Device	Results	Positive	Negative	
	Positive	168	3	171
	Negative	2	189	191
Total Result		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%)
Accuracy: 98.6% (95%CI*: 96.8% - 99.5%)

Precision

Intra-Assay

Within-run precision was determined using 15 replicates of four samples: a negative, low positive, middle positive and high positive samples. The samples were correctly identified >99% of the time.

Inter-Assay

Between-run precision was determined in 15 independent assays using the same four samples. Three different batches of the H. pylori Antigen Device were tested using the samples. The samples were correctly identified >99% of the time.

Cross-reactivity

Cross reactivity with following organisms has been studied at levels of $1.0x10^{09}$ organisms/ml. The following organisms were found negative when tested with the H. pylori Antigen Device:

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	

None of the pathogens showed cross reactivity in the H. Pylori Antigen Device assay at the concentration tested.

Interferents

The following substances were added to H Pylori antigen -negative and -positive samples and tested using the *H. pylori* Antigen Test Device (Faeces).

Albumin:	2g/dL	Glucose:	2g/dl
Ascorbic Acid:	20mg/dl	Oxalic Acid:	60mg/dl
Aspirin:	20mg/dl	Urea:	2g/dl
Bilirubin:	100mg/dl	Uric Acid:	60mg/dl
Caffeine:	40mg/dl		

None of the substances interfered in the *H. pylori* Antigen Test Device (Faeces) assay at the concentration tested.

References:

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.

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse

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