H. PYLORI ANTIGEN DEVICE (2–30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADHPG1	20 Tests

Intended Use:
The *H. pylori* Antigen Rapid Test Device (Faeces) 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. 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.
The H. pylori Antigen Rapid Test Cassette (Faeces) is a rapid chromatographic immunoassay for the qualitative detection of H. pylori antigens in human faecal samples, providing results in 10 minutes. The test utilizes antibodies specific for H. pylori antigens to selectively detect H. pylori antigens in human faecal samples.

Test Principle:
In the test, the membrane is pre-coated with anti-H. pylori antibody on the test line region. During the assay, H. pylori antigens, if present in the sample, react with particles coated with anti-H. pylori antibody at the sample well. The mixture migrates upward on the membrane by capillary action where the antigen-antibody complexes further 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.

Materials Provided
Individually pouched test devices
Specimens collection tubes with buffer
Instructions for Use sheet

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

Precautions:
For professional *in vitro* diagnostic use only. Do not use after expiry 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.
• 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.

Reagent Preparation and Stability:
The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through 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 beyond the expiry date.

Specimen Collection and Storage:
• The faeces sample 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.

Assay Procedure:

Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.

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 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 faecal samples:

• 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 sample.

• For Liquid Samples:

Hold the dropper vertically, aspirate faecal specimens, and then transfer 2 drops (approximately 80 µl) into the specimen collection tube containing the extraction buffer.

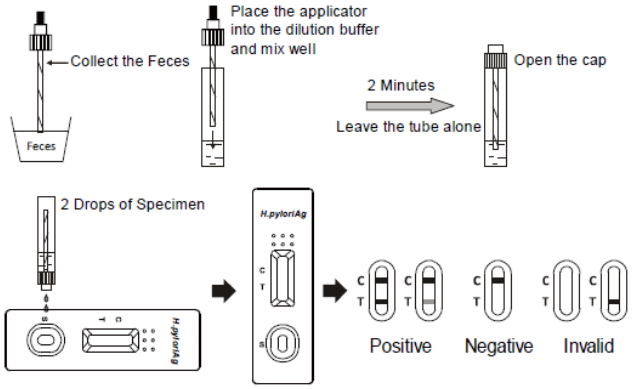
Cap the specimen collection tube, then shake tube vigorously to mix the sample and the extraction buffer. Leave the tube to stand for 2 minutes.

3. Bring the pouch to room temperature before opening it. Remove the test device 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 of the tube. Invert the specimen collection tube and transfer 2 full drops of the extracted specimen (approximately 80 µl) to the sample well (S) of the test device, then start the timer. Avoid trapping air bubbles in the sample well (S). See illustration below.

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

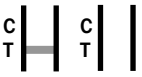
Note: If the specimen does not migrate (presence of particles), centrifuge the extracted specimens contained in the extraction buffer vial. Collect 80 µL of supernatant, dispense into the specimen well (S) of a new test device and start afresh following the instructions mentioned above.



Interpretation of Results:

POSITIVE: Two coloured bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one coloured band appears, in the control region (C). No apparent coloured band appears in the test region (T).



INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read 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.

Quality Controls:
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.
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 Rapid Test Device (Faeces) is for in vitro diagnostic use only. The test should be used for the detection of *H. pylori* antigens in faecal samples 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 Device (Faeces) will only indicate the presence of *H. pylori* in the sample and should not be used as the sole criteria for *H. pylori* as the 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:

Prestige Diagnostics U.K. Ltd 40 Ballymena Business Centre, Galgorm, Co. Antrim, BT42 1FL, United Kingdom. Tel: +44 (0) 28 2564 2100
www.prestigediagnostics.co.uk info@prestigediagnostics.co.uk

The H. pylori Antigen Test Cassette (Faeces) 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 Device (Faeces) 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 Test 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 Test Device (Faeces	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 has been determined by using 15 replicates of four samples: negative, low titer positive, middle titer positive and high titer positive samples. The samples were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on four samples: negative, low titer positive, middle titer positive and high titer positive samples. Three different lots of the *H. pylori* Antigen Test Device (Faeces) have been tested using these samples. The samples were correctly identified >99% of the time.

Cross-reactivity

Cross reactivity with following organisms has been studied at levels of 1.0E+09 organisms/ml. The following organisms were found negative when tested with the *H. pylori* Antigen Test Device (Faeces):

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	

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

Prestige Diagnostics U.K. Ltd 40 Ballymena Business Centre, Galgorm, Co. Antrim, BT42 1FL, United Kingdom. Tel: +44 (0) 28 2564 2100
www.prestigediagnostics.co.uk info@prestigediagnostics.co.uk

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