

A rapid test for the qualitative detection of *Helicobacter pylori* (H. pylori) antigens in human faeces. For self-testing *in vitro* diagnostic use only.

INTENDED USE

The Stomach Ulcer (H. pylori) Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of H. pylori antigens in human stool specimens. The test utilises antibodies specific for H. pylori antigens to selectively detect H. pylori antigens in human faeces specimens.

SUMMARY

H. pylori is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. It plays a role in 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. Some diagnostic methods are specimen-dependent and can be invasive, such as gastric or duodenal biopsy, 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 testing is the inability to distinguish current and past infections. An antibody may still 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 for monitoring the efficacy of the treatment. 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

PRINCIPLE

The Stomach Ulcer (H. pylori) Rapid Test 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 a proper volume of specimen has been added and membrane wicking has occurred.

PRECAUTIONS

Please read all the information in this Instructions for use before performing the test

- For self-testing *in vitro* diagnostic use only. Do not use after the expiration date
- Do not eat, drink or smoke in the area where the specimens or kits are handled
- Store in a dry place at 2-30°C (36-86°F), avoiding areas of excess moisture. If the foil packaging is damaged or has been opened, please do not use
- Use a clean container to collect your stool specimen
- Follow the indicated time strictly
- Use the test only once. Do not dismantle and touch the test window of the test cassette
- The kit must not be frozen or used after the expiration date printed on the package
- Keep out of the reach of children
- The used test should be discarded in your general household waste

STORAGE AND STABILITY

The kit should be stored at room temperature or refrigerated (2-30°C). The test cassette is stable until the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use after the expiration date.

MATERIALS PROVIDED

- Test cassette • Specimen collection tube with extraction buffer • Stool collection paper • Product summary leaflet • Instructions for use

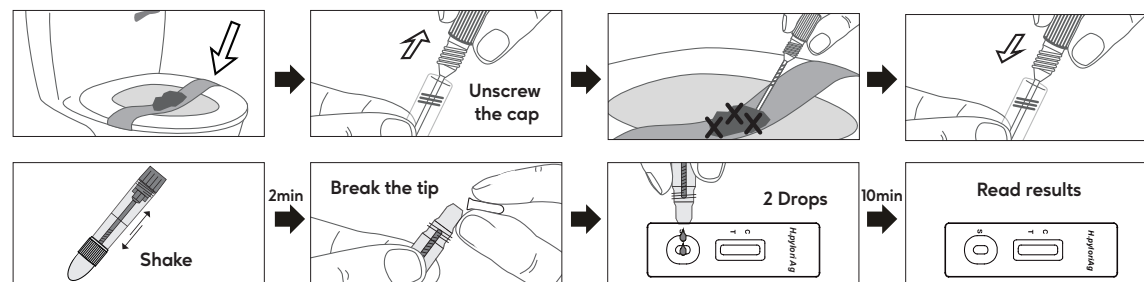
MATERIALS REQUIRED BUT NOT PROVIDED

- Timer • Specimen container




INSTRUCTIONS

Before performing the test, stool samples must be collected following the instruction below:

1. Wash your hands with soap and rinse with clear water.
2. Secure the collection paper to the toilet using the adhesive tabs. Collect the stool sample in the collection paper.
3. Unscrew the cap of the specimen collector tube, then insert the applicator into the stool in at least 3 different places. You only need a small sample, about the size of a grain of rice. Screw the applicator back on tightly, then shake the tube to mix the specimen and the extraction buffer and wait for 2 minutes.
4. You can now flush the stool and collection paper down the toilet - the paper is biodegradable.
5. Remove the test from the foil pouch and use it as soon as possible..
6. Unscrew the lid of the extraction buffer, break off the tip of the dropper then transfer 2 full drops of the extracted specimen to the specimen well (S) of the test cassette. Then with arrows pointing towards the extraction buffer, then start the timer. Avoid trapping air bubbles in the specimen well (S).
7. Read results at 10 minutes. Do not read results after 20 minutes.



READING THE RESULTS

Positive 	Positive Two coloured lines. Both T (Test) line and C (Control) line appear. This result means that there is the presence of the H. pylori antigen in faeces and that you should consult a physician. *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.
Negative 	Negative One coloured line appears in the control line region (C). No line appears in the test line region (T). This result means that the presence of the H. pylori antigen in the stool sample was not detectable.
Invalid 	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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The Stomach Ulcer (H. pylori) Rapid Test is for *in vitro* diagnostic use only. The test should be used for the detection of H. pylori antigens in stool 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 Stomach Ulcer (H. pylori) Rapid Test 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 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.

PERFORMANCE CHARACTERISTICS

Sensitivity and specificity

The H. pylori Antigen Rapid Test Cassette (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 Rapid Test Cassette (Faeces) is 97.6% and the specificity is 97.9% relative to other rapid tests.

Method	Other rapid test			Total Results
	Results	Positive	Negative	
Stomach Ulcer (H. pylori) Rapid Test	Positive	83	2	85
	Negative	2	93	95
	Total Results	85	95	180

*Confidence Intervals

Relative Sensitivity: 97.6% (95%CI:*91.8%-99.7%)

Relative Specificity: 97.9% (95%CI:*92.6%-99.7%)

Overall accuracy: 97.8% (95%CI:*94.4%-99.4%)

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 Stomach Ulcer (H. pylori) Rapid Test 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 Test Cassette (Faeces):

Acinetobacter calcoaceticus
Candida albicans
E.coli
Group A *Streptococcus*
Hemophilus influenza
Neisseria meningitidis
Pseudomonas aeruginosa
Staphylococcus aureus

Acinetobacter spp
Chlamydia trachomatis
Enterococcus faecalis
Group B *Streptococcus*
Klebsiella pneumonia
Proteus mirabilis
Rotavirus
Adenovirus

Branhamella catarrhalis
Enterococcus faecium
Gardenerella vaginalis
Group C *Streptococcus*
Neisseria gonorrhoea
Proteus vulgaris
Salmonella choleraesuis

Interfering Substances

The following potentially Interfering Substances were added to HPG negative and positive specimens.

Ascorbic acid: 20 mg/dL
Uric acid: 60 mg/dL
Glucose: 2000 mg/dL

Oxalic acid: 60 mg/dL
Aspirin: 20 mg/dL
Caffeine: 40 mg/dL

Bilirubin: 100 mg/dL
Urea: 2000 mg/dL
Albumin: 2000 mg/dL

FAQs

1. How does the Stomach Ulcer (H. pylori) Rapid Test work?

H. pylori is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. The Stomach Ulcer (H. pylori) Rapid Test detects specifically the antigens in faeces to ascertain the presence of the bacterium.

2. When should the test be used?

The test can be performed anytime of the day. The test can be performed in case of repeated stomach and intestinal troubles (GERD, gastritis etc.).

3. Can the result be incorrect?

The results are accurate as far as the instructions are carefully followed. Nevertheless, the result can be incorrect if the test cassette gets wet before performing the test or if the quantity of faeces dispensed in the sample well is too much or not sufficient, or if the number of extracted specimens drops are less than 2 or more than 3. Due to immunological principles involved, there exist the chances of false results in rare cases. A consultation with the doctor is always recommended for such tests based on immunological principles.

4. How to interpret the test if the colour and the intensity of the lines are different?

The colour and intensity of the lines have no importance for result interpretation. The lines should only be homogeneous and clearly visible. The test should be considered as positive whatever the colour intensity of the test line is.

5. What is the line that appears under the mark C (control) for?

When this line appears, it confirms that the test was performed correctly.

6. What do I have to do if the result is positive?

If the result is positive, it means that the H. pylori antigens were detected in faeces and that you should consult a doctor to show the test result. Then, the doctor will decide whether additional analysis should be performed.















7. What do I have to do if the result is negative?

If the result is negative, it means that it was not possible to detect the H. pylori antigens. However, if symptoms persist, it is recommended to consult a physician.

BIBLIOGRAPHY

1. Marshall, BJ, McGeachie, DB, Rogers, PAR and Glancy, RG. Pyloric Campylobacter infection and gastroduodenal disease. Med. J. Australia. (1985), 149: 439-444.
2. Soll, AH. 'Pathogenesis of peptic ulcer and implications for therapy.' New England J. Med.(1990), 322: 909-916.
3. Hazell, SL, et al. 'Campylobacter pylori is and gastritis I: Detection of urease as a marker of bacterial colonization and gastritis.' Amer. J. Gastroenterology. (1987), 82(4): 292-296.
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		Tests per kit		Authorised Representative in EU
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalogue #
	Do not use if package is damaged		Consult Instructions for Use		Non-recyclable
	PAP 21 recyclable material		PAP 22 recyclable material		



Hangzhou AllTest Biotech Co.,Ltd.
#550, Yinhai Street,
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China



MedNet EC-REP GmbH, Borkstrasse 10, 48163
Muenster, Germany

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