Stomach Ulcer Test

H.pylori Antigen Rapid Test Cassette (Faeces)

CE 0123 REF IHP-602H ENGLISH

INTENDED USE

The Stomach Ulcer Test (H.pylori Antigen Rapid Test Cassette (Faeces)) is a rapid test for the qualitative detection of Helicobacter pylori (H.pylori) antigens in human faeces to aid the diagnosis of stomach ulcers. For self-testing *in vitro* diagnostic use only.

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 Test (H.pylori Antigen Rapid Test Cassette (Faeces)) 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 (T) 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 (C) indicating that proper volume of specimen has been added and membrane wicking has occurred.

PRECAUTIONS

Please read all the information in the instructions for use before performing the test.

- For self-testing *in vitro* diagnostic use only. Do not use the 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 or touch the test window of the test cassette.
- The kit must not be frozen or used after the expiration date printed on the package.
- The used test should be discarded according to local regulations.
- Keep out of the reach of children.

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
- Instructions for use
- Product summary

MATERIALS REQUIRED BUT NOT PROVIDED

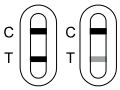
- Timer
- Specimen container

DIRECTIONS FOR USE

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

1. Wash your hands with soap and rinse with clean water. Secure the collection paper to the toilet using the adhesive tabs. Collect the stool sample in the collection paper to avoid contamination with other substances.
2. 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.
3. Screw the applicator back on tightly, then shake the tube to mix the specimen and the extraction buffer. Set aside and wait for 2 minutes. You can now flush the stool and collection paper down the toilet - the paper is biodegradable.
4. Remove the test from the foil pouch and use it as soon as possible. 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. Start the timer. Avoid trapping air bubbles in the specimen well (S). Read results at 10 minutes. Do not read results after 20 minutes.

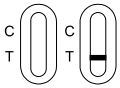
READING THE RESULTS



POSITIVE:* Two coloured lines. Both the test line (T) and control line (C) 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: 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 stool sample was not detectable.



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

Method		Other Rapid Test		Total Results
H. pylori Antigen Rapid Test Cassette	Results	Positive	Negative	
	Positive	83	2	85
	Negative	2	93	95
Total Results		85	95	180

Relative Sensitivity: 97.6% (95%CI:*91.8%-99.7%) *Confidence Intervals
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 Test (H.pylori Antigen Rapid Test Cassette (Faeces)) 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 Stomach Ulcer Test (H.pylori Antigen Rapid Test Cassette (Faeces)):

Acinetobacter calcoaceticus
Candida albicans
E.coli
Group A Streptococcus
Hemophilus influenxa
Neisseria meningitides
Pseudomonas aeruginosa
Staphylococcus aureus
Acinetobacter spp
Chlamydia trachomatis
Enterococcus faecalis
Group B Streptococcus
Klebsiella pneumonia
Proteus mirabilis
Rotavirus
Adenovirus
Branhamella catarrhalis
Enterococcus faecium
Gardnerella vaginalis
Group C Streptococcus
Neisseria gonorrhea
Proteus vulgaris
Salmonella choleraesius

Interfering Substances

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

Ascoribic acid: 20 mg/dL
Uric acid: 60 mg/dL
Glucose: 2000 mg/dL
Oxalic acid: 60 mg/dL
Caffeine: 40 mg/dL
Bilirubin: 100 mg/dL
Urea: 2000 mg/dL
Albumin: 2000 mg/dL

FAQs

1. How does the H.pylori test cassette work?
H.pylori is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum he Stomach Ulcer Test (H.pylori Antigen Rapid Test Cassette (Faeces)) 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 at any time 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 providing the instructions are carefully followed. Nevertheless, the result can be incorrect if the Stomach Ulcer Test (H.pylori Antigen Rapid Test Cassette (Faeces)) 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 specimen drops are fewer than 2 or more than 3. Due to immunological principles involved, false results are possible 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 only means that the test unit is performing well.

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 discuss the test result. 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 the symptoms persist, it is recommended to consult a physician.

BIBLIOGRAPHY
1. Marshall, BJ, McGechie, 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	EC REP	Authorised Representative in EU
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalogue #
	Do not use if package is damaged		Consult Instructions for Use		Non-recyclable
21	Pap 21 recyclable material	22	Pap 22 recyclable material		

EC REP MedNet EC-REP GmbH,
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CE 0123

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