™Stomach Health (*H. pylori*) Rapid Test

Package Insert

REF	IHP-N602H-01/IHP-N602H-02/ IHP-N602H-05/IHP-N602H-10	English

【INTENDED USE】

The test is a rapid chromatographic immunoassay for the qualitative detection of *H. pylori* antigens in human feces to aid in the diagnosis of *H. pylori* infection. Not for detection of gastric cancer.

The test is for self-testing use. It is not automated. For *in vitro* diagnostic use only.

【MATERIALS】

Materials Provided

Components	Kit size	1T/kit	2T/kit	5T/kit	10T/kit
	Test cassette(s)	1	2	5	10
	Package insert	1	1	1	1
	Stool collection paper(s)	1	2	5	10
	Specimen collection tube(s) (with dilution buffer) 2 mL (0.02% Proclin 300, ≤0.02% NaN_3)	1	2	5	10

Materials Required But Not Provided

- Timer

【WARNINGS AND PRECAUTIONS】

Please read all the information in this package insert before performing the test.

- For self-testing *in vitro* diagnostic use only.
- Do not use after the expiration date. Do not reuse the test.
- Store in a dry place at 2-30 °C (36-86 °F), avoiding areas of excess moisture. Do not use if any of the test kit content or packaging is damaged or opened.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Carefully handle the buffer - do not ingest and avoid contact with skin or eyes. If contact does occur, immediately rinse with running water.
- It is important that the timings are strictly followed to ensure accurate results.
- Do not dismantle and touch the test window of the test cassette.
- Keep the kit out of the reach of children. An adult may perform the test on a child.
- The used test should be discarded according to local regulations.
- Wash hands thoroughly before and after handling.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority.
- Components provided in the kit are approved for use in the Stomach Health (*H. pylori*) Rapid Test. Do not use any other commercial kit component.
- This test provides only a preliminary test result, it could not replace medical advice. Always seek guidance from a qualified healthcare provider before making any health-related decisions.

【SPECIMEN COLLECTION AND PREPARATION】

- The fecal specimen may be collected in a clean and dry container.
- No dietary restrictions are necessary before using the Stomach Health (*H. pylori*) Rapid Test.

Collected with stool collection paper as follows:



Unfold the stool collection paper and peel off the liner covering the adhesive tape on each end of the collection paper.



Lift toilet seat and secure the adhesive tabs of the stool collection paper to the sides of the toilet rim.



Make bowel movement onto stool collection paper. Avoid urinating on the paper. If needed, urinate in the front of the bowl, missing the collection paper.

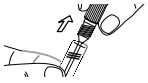
- Test should be performed immediately after the feces have been collected.

【DIRECTIONS FOR USE】

Before performing the test, allow the test cassette, buffer to equilibrate to room temperature (15-30 °C).

- Wash your hands with soap and rinse with clean water.
- The fecal specimen should be collected in the stool collection paper. Remove the test cassette from the foil pouch and use it within 1 hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.

1



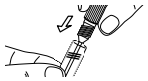
Unscrew the cap of the specimen collection tube and take out the sampling stick.

2



Randomly stab the sampling stick into the fecal specimen in **3 different sites.** Do not scoop the fecal specimen.

3



Insert the sampling stick back into the specimen collection tube and tighten the cap.

4



Shake the specimen collection tube vigorously to mix the specimen and the dilution buffer.

5



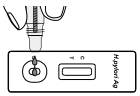
Leave the specimen collection tube for reaction for **2 minutes**.

6



Open the cap of the specimen collection tube.

7



Put the test cassette on a clean and level surface.

Invert the specimen collection tube and **transfer 2 full drops** of the diluted specimen to the specimen well (S) of the test cassette.

8



Read results at 10 minutes. Do not read results after 20 minutes.

Note: Do not move the test cassette during the waiting time.

【READING THE RESULTS】



POSITIVE

***Two colored lines appear.** One colored line should be in the control region (C) and the other colored line should be in the test region (T).

This result means that there is the presence of the *H. pylori* antigens in feces and that you should consult a physician.

***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of *H. pylori* antigen present in the specimen.



NEGATIVE

One colored 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 feces 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 test. If the problem persists, discontinue using the test kit immediately and contact the local distributor.

【LIMITATIONS】

1. The Stomach Health (*H. pylori*) Rapid Test should be used for the detection of *H. pylori* antigens in fecal 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 Health (*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 etiological agent for peptic or duodenal ulcer.
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. Following certain antibiotic treatments, the concentration of *H. pylori* antigens may decrease to the concentration below the minimum detection level of the test, leading to false negative results. Therefore, diagnosis should be made with caution during antibiotic treatment.

【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.[1,2] 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.[3] *Helicobacter pylori* (*H. pylori*) infection underlies gastric ulcer disease, gastric cancer and duodenal ulcer disease. The disease expression reflects the pattern and extent of gastritis/gastric atrophy (i.e., duodenal ulcer with non-atrophic and gastric ulcer and gastric cancer with atrophic gastritis).[4] 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*.[5]

The Stomach Health (*H. pylori*) Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of *H. pylori* antigens providing results

in 10 minutes. The test utilizes antibodies specific for *H. pylori* antigens to selectively detect *H. pylori* antigens in human feces.

【PRINCIPLE】

The Stomach Health (*H. pylori*) Rapid Test is a qualitative, lateral flow immunoassay for the detection of *H. pylori* antigens in human feces. In this test, the membrane is pre-coated with monoclonal anti-*H. pylori* antibody on the test line region of the test. During testing, the specimen reacts with the latex particle coated with anti-*H. pylori* antibody. The mixture migrates upward on the membrane by capillary action to react with monoclonal anti-*H. pylori* antibody on the membrane and generate a colored line. The presence of this red line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, the specimen migrates upward through the capillary action to drive the mouse IgG coated colloid gold particle to react with goat anti-mouse IgG on the membrane and generate a red line, which will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

【STORAGE AND STABILITY】

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

Note: It is suggested to use the test cassette within one hour after removing it from the foil pouch.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control line region(C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

【PERFORMANCE CHARACTERISTICS】

LOD	Sensitivity	Specificity	Overall Accuracy
5ng/mL	98.4%	100.0%	99.1%

Performance data obtained by clinical study with 111 participants enrolled. PCR has been utilized as reference method.

Hook Effect

No high-dose hook effect was detected at the concentration up to 2.5 mg/mL.

Precision-Repeatability

No difference was detected in intra lot.

Precision-Reproducibility

No difference was detected between days, sites, lots and operators.

Cross-Reactivity

No cross-reactivity was observed when tested with following organisms:

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

Interfering Substances

The following potentially interfering substances do not interfere with the test results.

Name	Concentration	Name	Concentration
Ascorbic acid	20 mg/dL	Oxalic acid	60 mg/dL
Uric acid	60 mg/dL	Aspirin	60 mg/dL
Glucose	2000 mg/dL	Urea	2000 mg/dL
Bilirubin	100 mg/dL	Albumin	6000 mg/dL
Caffeine	40 mg/dL	Omeprazole	2 mg/g
Sodium	20 mg/g	Bismuth potassium aluminum hydroxide	3 mg/g
Mucin	2000 mg/dL	Famotidine	2 mg/g
Ranitidine	2 mg/g	Cholesterol	150 mg/dL
		cirtrate	

【QUESTION&ANSWER】

1. How does the Stomach Health (*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 Health (*H. pylori*) Rapid Test detects specifically the antigens in feces 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 (gastro-esophageal reflux disease, gastritis etc.).

3. Can the result be incorrect?

The results are accurate as far as the instructions are carefully respected. Nevertheless, the result can be incorrect if Stomach Health (*H. pylori*) Rapid Test gets wet before performing the test or if the quantity of feces dispensed in the dilution buffer is too much or not sufficient.

Besides, due to immunological principles involved, there exist the chances of false positive or false negative results in rare cases under proper use and normal conditions. A consultation with the doctor is always recommended for such tests based on immunological principles.

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

The color and intensity of the lines have no importance for result interpretation. The test should be considered as positive whatever the color 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 is a false positive result?

A false positive test result means the *H.pylori* antigen is not present but shows detected by the device. The most common causes of a false positive test are cross reactants or unknown interference in the sample.

7. What is a false negative result?

A false negative test means the *H.pylori* antigen is present but is not detected by the device. False negative results may occur if the specimen is improperly collected or handled.

8. 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 feces and that you should consult a doctor to show the test result. Then, the doctor will decide whether additional analysis should be performed.

9. 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 see a doctor.

【BIBLIOGRAPHY】

1. Marshall, BJ, McGechie, DB, Rogers, PAR and Glancy, RG. Pyloric Campylobacter infection and gastroduodenal disease. Med. J. Australia. (1985), 142: 439-444.
2. Soll, AH. Pathogenesis of peptic ulcer and implications for therapy. New England J. Med. (1990), 322: 909-916.
3. Cutler AF. Testing for Helicobacter pylori in clinical practice. Am j. Med. (1996), 100: 35S-41S.
4. David,Y, Graham. History of Helicobacter pylori, duodenal ulcer, gastric ulcer and gastric cancer. World J Gastroenterol. (2014), 20(18): 5191-5204.
5. Anand, BS, Raed, AK, Malaty, HM, et al. Low point prevalence of peptic ulcer in normal individuals with Helicobacter pylori infection. Am J Gastroenterol. (1996), 91: 1112-1115.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests	30°C 2°C	Temperature limit
IVD	*In vitro* diagnostic medical device		Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community/European Union		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer	UDI	Unique device identifier

CE 0123

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Summary of safety and performance is available on website: https://ec.europa.eu/tools/eudamed/

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