No.IFU-HPAg-FEST-01,Ver.A/1

CE 3018

H.Pylori Antigen Test Kit

Operational Use Video

For in vitro diagnostic use only. For self-testing.
Please read the instruction carefully before use.

[Intended use]
This product is used for the qualitative detection of Helicobacter pylori antigen in human fecal specimens. It is a non-automated rapid test designed for infection diagnosis, specifically to aid in diagnosing Helicobacter pylori infection in individuals. The test is authorized for non-prescription home use with self-collected fecal specimens.

[Model]
Cassette

[Summary]
Helicobacter pylori (also known as Campylobacter pylori) is a spiral-shaped with a typical flagellum,Gram negative bacteria, infecting gastric mucosa. It causes several gastro-enteric diseases such as non-ulcerous dyspepsia, gastric and duodenal ulcer, active gastritis and can even increase the risk of stomach adenocarcinoma, so as to be classified as carcinogen agent type I. It transmission through the digestive tract.

[Principle]
The H.Pylori Antigen Test kit has been designed to detect Helicobacter pylori through visual interpretation of color development in the internal strip. The membrane was immobilized with anti-H.pylori monoclonal antibody on the test region. During the test, the specimen is allowed to react with colored anti-H. pylori monoclonal antibody colloidal gold conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interact with reagents on the membrane. If there were enough H. pylori antigens in specimens, a colored line will form at the test region of the membrane. Presence of this colored line indicates a positive result, while its absence indicates a negative result. Appearance of a colored line at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

[Warnings and Precautions]
1. This kit is for in vitro use only. Please read the instructions carefully before use and strictly control the reaction time. Failure to follow the instructions may result in erroneous results.
2. Operational errors, insufficient or excessive sample size may cause biased test results.
3. Negative results may occur if the antigen concentration is below the detection limit of the product.
4. Protect from moisture. Do not open the aluminum foil pouch prior to preparing for testing. Do not use if the aluminum foil pouch is damaged or the reagents are moist.
5. Strictly adhere to the instruction. Do not mix reagent tubes/test cassette or sample collection tubes from different batches.
6. The results of this kit are determined visually. To ensure accuracy, avoid reading in dimly lit areas.
7. The test results should be interpreted within 10 minutes under the conditions of temperature of 15-30 ℃ and humidity of 20% -80%. The interpretation is invalid after 20 minutes. Use within one hour after opening, avoid leaving it in the air for too long, which may cause moisture and affect the test results.
8. Use before the expiration date. This kit is for single use only. Used kits and samples may pose potential infection risks and should be disposed of properly according to relevant regulations.
9. Within the specified reading time, a positive result is indicated by the presence of a red band in both the test line (T) and control line (C), regardless of band intensity.
10. The package contains desiccant—do not ingest.
11. After testing, do not self-medicate based solely on the test results.
12. Following certain antibiotic treatments, Helicobacter pylori antigen levels may fall below the test's detection limit. Therefore, exercise caution when diagnosing during antibiotic therapy.

[Materials and Components]
Materials provided

Test device	Instruction
Specimen collection tube with extraction buffer	
Stool collection paper	

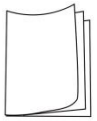
Materials required but not provided

Specimen collection container	Timer

[Storage and Stability]
1. The kit should be stored at 2-30 ℃ and the humidity at 20%-80% until the expiry date printed on the sealed pouch.
2. After the foil pouch is unsealed, the test device should be used as soon as possible within one hour.
3. The test device should be kept away from direct sunlight, moisture and heat.
4. Do not freeze the test kit.
5. When the sample diluent is stored at 2℃ to 30℃, the stability of the product will not be affected after opening for 30 days.

[Preparation before the test]

1. Clean your hands, make sure they are dry before starting the test.



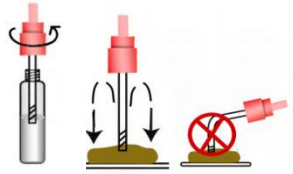
2. Read the instructions carefully.

3. Check all parts of the test kit to make sure that all parts are complete and not damaged.

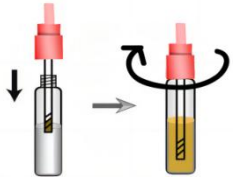
4. Check the Expiration Date printed on the foil pouch of the test device.

[Specimen Collection and Preparation]

1.Keep Stool collection paper on the toilet.



2.Unscrew and remove the specimen collection tube applicator. Be careful not to spill or spatter solution from the tube. Collect specimens by inserting the applicator stick into at least 5 different sites of the feces. Insert depth for sample covering applicator stick helix root.



3.Place the applicator back into the tube and screw the cap tightly. Be careful not to break the tip of the specimen collection tube.

5. Shake the specimen collection tube left and right for 10 seconds to mix the specimen and the extraction buffer.

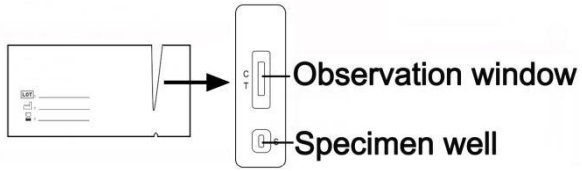
[Sample Storage]

1. Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 24 hours.
2. Best results will be obtained if the assay is performed within 1 hour after collection.
3. Store frozen at -20°C or below for no more than 7 days, and the sample can be subjected to repeated freeze-thaw cycles for a maximum of 3 times. Both refrigerated and frozen samples must be allowed to return to room temperature (15-30°C) before testing.

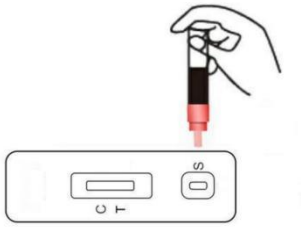
[Test Procedure]

Carefully read the reagent instruction before using the test kit and strictly operate according to the instruction to ensure reliable results. Bring test device, buffer and specimens were restored to room temperature 15-30℃（59-86℉）.

Please keep the temperature at 15-30 ℃ and the humidity at 20%-80% during the whole test.



1. Remove the test device from the sealed foil pouch and place it on a flat surface. Know the observation window and specimen well (S). It should be used within one hour.



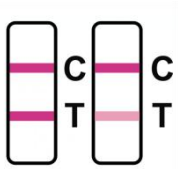
2. Dispense 2 drops processed samples into the specimen well (S) on the test.

3. Start the timer. Read the result within 10 minutes. Do not interpret results after 20 minutes.

[Interpretation of Test Results]

Two colored lines should be observed in the observation window.

Positive result:

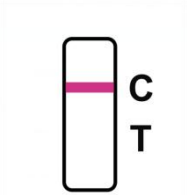


Note: The red line in the test line (T) can show different shades of color. However, even a very weak ribbon should be judged as a positive result during the specified observation period, regardless of the color of the ribbon.

This positive result indicates that you may have been infected with Helicobacter pylori. However, this is only a preliminary screening result and cannot be used as the basis for final diagnosis. You must consult a doctor immediately and must not purchase or use any antibiotics for treatment on your own.

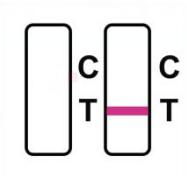
Negative result:

The control line(C) appears in the observation window, but the test line (T) is not visible.



Note: This negative result means no Helicobacter pylori antigen was detected in your sample. However, if you have symptoms like stomach discomfort, pain, bloating, or acid reflux, you should consult a doctor for professional testing to rule out other digestive conditions or a false negative due to improper sampling or medication use.

Invalid result:



If the control line (C) is not observed, the test is considered to be invalid whether the test line (T) (as shown in the figure) is visible or not. A new test needs to be performed using a new test device.

[Quality Control]

A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume.

[Limitations of Procedure]

1. This kit is a qualitative in vitro diagnostic product intended for auxiliary diagnosis. For confirmation of Helicobacter pylori infection or post-treatment eradication efficacy, further examinations should be conducted in conjunction with the physician's clinical diagnosis.
2. This kit is solely for the qualitative detection of Helicobacter pylori antigens in human fecal samples.
3. A positive result only indicates the possible presence of Helicobacter pylori antigens and should not be used as the sole criterion for diagnosing Helicobacter pylori infection.
4. A negative result does not entirely rule out the possibility of Helicobacter pylori infection, as it may be due to antigen levels below the detection limit of this kit or other factors causing false-negative results.
5. Inconsistent or erroneous results may arise due to technical or procedural operational errors, sample contamination, or the presence of drugs that interfere with detection.
6. The collection and processing methods of samples significantly impact antigen detection, and improper operations may lead to incorrect results.
7. If you have been diagnosed and are undergoing treatment, please strictly follow your doctor's advice to complete the entire course of treatment. Generally, a test should be conducted about four weeks after stopping the medication. If the test result is negative, it indicates that Helicobacter pylori may have been successfully eradicated. If the result remains positive, it may be necessary to further evaluate the treatment plan or identify the cause of treatment failure.

[Performance index]

1. Physical characters

1.1 Appearance**:** The test should be clean and complete, no burr, no damage and no pollution. Material attachment is good. The shell of the detection card should be flat, the upper and lower covers should be closed evenly, and there should be no obvious gap. The extraction buffer (1mL 0.85% NaCl) should be clear and free of foreign matter.

1.2 Size: the size of test strip should not be less than 2.5mm.

1.3 Liquid migration speed should not be less than 10mm/min.

2. Limit of detection

The limit of detection is not higher than 5.0×10^4 CFU/mL.

3.Hook effect

When Hp≤$5x10^8$CFU/mL, the test results of this product do not produce hook effect. If the concentration is exceeded, false negative results may occur. This situation is relatively rare. It is recommended that users seek professional medical assistance.

4. Specificity

Campylobacter jejuni, Enterobacter aerogenes, Proteus mirabilis, Klebsiella pneumoniae, Bacillus subtilis, Escherichia coli, Candida albicans, Shigella fowleri, Enterococcus faecalis and Acinetobacter calcoaceticus were not cross-reacted with this product at a concentration of $1x10^7$CFU/mL.

White blood cells (10000/mL), Haemoglobin (20mg/g), Lipids(500mg/mL), Intestinal mucus (2000mg/dL), Norfloxacin(10μg/mL), Ascorbic acid (10mg/dL), Bilirubin, Aluminium hydroxide (20mg/g), Ranitidine (2mg/g), Famotidine(2mg/g), Omeprazole (2mg/g), Bismuth potassium citrate (3mg/g) did not interfere with this product.

5. Precision

During the 20-day test period, there were two rounds of tests per day on average, and the test results on different dates were consistent. The difference in band color intensity was ≤1 gradient, indicating high intra-day, inter-day, intra-batch and inter-batch precision.

The test results of the three operators at three different test sites were consistent, and the difference in band color intensity was ≤1 gradient, indicating high precision among personnel and locations.

[Clinical performance]

The results obtained by trained technicians using the H.Pylori Antigen Test kit produced by InTec Products, Inc. (Xiamen) are compared with the results of this test kit:

Reference Assay							95% Wilson Score CI	
							LCI	UCI
H.Pylori Antigen Test Kit		POS	NEG	Total	PPA	99.46%	98.05%	99.85%
	POS	367	0	367	NPA	100.00%	99.36%	100.00%
	NEG	2	598	600	PPV	Total compliance rate		99.79%
	TOTAL	369	598	967	NPV			

Specificity: 100.00%; Sensitivity: 99.46%; Accuracy: 99.79%

[Instruction of symbols]

CE 3018	CE mark	LOT	Batch number
	Consult instructions for use	IVD	*In vitro* diagnostic medical device
	Do not re-use		Date of manufacture
30°C 2°C	Storage temperature		Contains sufficient for <n> tests
	Manufacturer		Use before the date
EC REP	Authorized Representative in European Community		Keep dry
	Keep away from sunlight		Do not use if package is damaged and consult instructions for use

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ul. Obrzeżna 5XIP/1, 02-691, Warsaw, Poland

Packaging Specification	Catalogue Number
	HPAg1FEST Cassette
1 pc/box	HPAg1FEST-1
2 pcs/box	HPAg1FEST-2
5 pcs/box	HPAg1FEST-5
25 pcs/box	HPAg1FEST-25
30 pcs/box	HPAg1FEST-30

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