ZOAN™

H.pylori Antigen Test Kit

User Instruction Guide

【PREPARATION】

1. Follow the below steps for preparation.
2. Ensure the test kit is at room temperature for at least 30 minutes prior to use.
3. A timing device (clock, phone or timer) is required but not provided.

Step 1

- 1a Wash hands before and after the test, either using soap and water or hand sanitizer.
- 1b Make sure hands are dry before starting.

Step 2

- Read the instructions for use carefully before using the ZOAN™ H.pylori Antigen test kit.

Step 3

- 3a Check the expiration date on the label of foil pouch and extraction buffer cap.
- 3b Do not use if it is beyond expiration date or if it is damaged.

Test Device

Extraction Buffer cap

Step 4

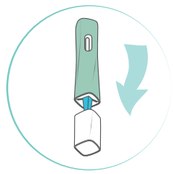
- 4a Open the test device foil pouch.
- 4b Place the test device and extraction buffer cap on a dry and clean surface.
- 4c Check the result window and specimen well on the test device.

【OPERATION PROCEDURE】

Sample stool should be fresh

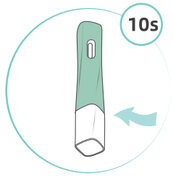
Step 5

- 5a Put the clean collection paper in the toilet before sample collection;
- 5b Make sure no water to the sample;
- 5c Use the test device (tip part) to fully collect sample on the clean collection paper, back and forth ;



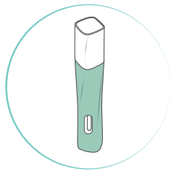
Step 6

- 6a Insert the test device into the extraction buffer cap downward;



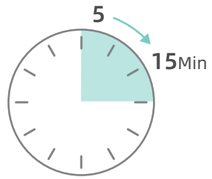
Step 7

- 7a Make sure the test device and extraction buffer cap are fully screwed so that the sample can be completely extracted;
- 7b Wait for 10 seconds;



Step 8

- 8a Put the test device vertically on the flat surface with extraction buffer cap up;



Step 9

- 9a Wait for 5-15 minutes to read the results ;
- 9b Do not read results after 15 minutes .

【Q&A】

Q: What is H.pylori?

A: H.pylori is a bacterium that lives in various areas of the stomach and duodenum.

It can cause mild chronic inflammation of the gastric mucosa, and even lead to gastric and duodenal ulcers and gastric cancer.

Q: What is purpose to test H.pylori?

A: Detection of H.pylori can be used for early warning of gastric cancer.

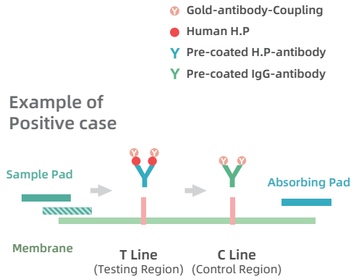
Infection with H.pylori causes chronic inflammation and significantly increases the risk of developing duodenal and gastric ulcer disease and gastric cancer. Infection with H.pylori is the strongest known risk factor for gastric cancer, which is the second leading cause of cancer-related deaths worldwide.

Q: What are symptoms of H.pylori infection?

A: After H.pylori infection, patients often show discomfort in the upper part of the stomach, as well as pain, flatulence, anorexia, nausea, vomiting, and dark or tar colored stool, among which more than 70% of infected people have no obvious symptoms.

Q: The principle of H.pylori antigen detection?

A: Applying colloidal gold test technology, H.pylori antigen test kit immunochemical methodology to detect H.pylori levels in human feces sample.



When the stool sample contains antigens of H.pylori, it will react with with the colloidal gold-antibody-coupling, then become colloidal gold antibody conjugate. The colloidal gold antibody conjugate migrates upward on the membrane chromatographically by capillary action to react with pre-coated H.P-aitibody, then combined to a mixture, which will generate a colored Test line (T).

If the sample does not have H.pylori, the testing region will not generate any colored Test line.

Colloidal gold-antibody-coupling migrates upward on the membrane chromatographically to the control line region, it will react with pre-coated IgG-antibody, then combined to a mixture, which will generate a colored Control line (C).

The control line should generate a red colored line when testing. This indicates the test strip is working properly.

Q: I have symptoms of flatulence, nausea and stomachache, but why is the test result negative?

A: H.pylori is only one of the causes of flatulence, nausea and stomachache.

Not all stomach discomfort is caused by H.pylori.

Q:During operation of test, is there a high risk of leaking or peculiar smell?

A:No. The sampler is designed fully sealed. This can allow the extra liquid to go to the waste buffer thoroughly.In addition, Zoan™ also has function of odor removal, which can avoid peculiar smell.

Q: Who should be tested for H.pylori antigen?

A: H.pylori infection is the cause of more than 90% duodenal ulcer and 70-80% gastric ulcer. Eradicating H.pylori can promote ulcer healing and significantly reduce the incidence of ulcer recurrence and complications. In 1994, the International Cancer Research Center under the World Health Organization identified Hp as a Class I carcinogen of gastric cancer.

The incubation period of H.pylori infection is about one week; People with poor living habits have a great chance to be infected with H.pylori.

Therefore, patients with duodenal ulcer, gastric ulcer and normal people should be tested for H.pylori antigen, to prevent and monitor H.pylori infection.

Q:What should I do if I get an invalid result?

A:Manual operating error may cause invalid result.

It is suggested to use a new one to re-test.

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ENGLISH

H.pylori

H.pylori Antigen Test Kit
(Colloidal Gold Method)
Instructions for Use

Version: A/0

REF :HP-H.P-1/HP-H.P-2/HP-H.P-5/HP-H.P-7/HP-H.P-20/HP-H.P-25

Manufacturer

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[PRODUCT NAME]

H.pylori Antigen Test Kit (Colloidal Gold Method)

[INTENDED USE]

The ZOAN™ H.pylori Antigen Test Kit is a single use immunochromatographic assay for the qualitative detection of H. pylori antigen in unpreserved human stool specimens.

Test results are intended to aid in the initial diagnosis and treatment of H. pylori infection. Test results should be taken into consideration by the physician in conjunction with the patient history and symptoms.

For in vitro diagnostic use only. For prescription use.

[PRINCIPLE]

To perform the test, a small portion of stool sample is diluted and mixed in the extraction buffer cap, and the diluted sample is added onto the sample well of test cassette.

The sample flows through a labeled pad containing red-colored antibody-coated latex particles. If the sample contains H. pylori antigen, the antigen will bind to the antibody to form antigen-antibody latex complexes which flow through the nitrocellulose membrane by capillary action. The complexes bind H. pylori specific antibodies at the test area to form a pink-red line.

Another pink-red line at the control area position serves as an internal control to show that adequate flow of the sample has occurred, and that active components have been employed during a test run.

For a positive result, a pink-red test line (next to the letter T)along with pink-red control line (next to the letter C) must be visible in the "Result Window".
If H. pylori antigen is not present or is present at very low levels in the stool sample, only a pink-red control line will be visible, and the test result is negative.
If the pink-red control line does not develop within 10 minutes, the test result is invalid.

[MATERIALS PROVIDED-Pen Shape]

Components	1 Kit	2 Kits	5 Kits	7 Kits	20 Kits	25 Kits
REF	HP-H.P-1	HP-H.P-2	HP-H.P-5	HP-H.P-7	HP-H.P-20	HP-H.P-25
Test Device	1	2	5	7	20	25
Extraction Buffer Cap	1	2	5	7	20	25
Clean Collection Paper	1	2	5	7	20	25
Instructions for Use	1	1	1	1	1	1

Test Device

Extraction Buffer Cap

Clean Collection Paper

Instructions for Use

[MATERIALS REQUIRED BUT NOT PROVIDED]

• Clock, timer or stopwatch

[STORAGE AND STABILITY]

- Store in a dry place at 2-30°C . Do not freeze or damp the test kit.
- Please use it within 1 hour after opening the inner sealing pouch.
- Validity: 24 months.
- Please refer to the label for LOT number and expiration date.

[WARNINGS AND PRECAUTIONS]

1. For in vitro diagnostic use only.
2. Do not use after expiration date.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Observe established precautions against microbiological hazards throughout the testing and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
6. Humidity and temperature can adversely affect results.
7. Please read the Instructions for Use seriously before using the kit.
8. Do not use the kit with an obviously damaged package.
9. Do not reuse any kit components.
10. Do not use with multiple specimens.
11. Avoid menstrual period,haemorrhoid bleeding and blood urine while collecting samples.

H.pylori Antigen Test Kit Instruction Guide

BEFORE YOU BEGIN

Cautions :
1.Follow the below steps for preparation.
2.Ensure the test kit is at room temperature for at least 30 minutes prior to use.
3.A timing device (clock, phone or timer) is requested but not provided

1a Wash hands before and after the test, either using soap and water or hand sanitizer

1b Make sure hands are dry before starting

Test Device

Extraction Buffer Cap

Clean Collection Paper

Instructions for Use

2a Take all the items out of the test box and lay them on a well-cleaned flat surface. Identify each item in the test kit.

2b Read the instructions for use carefully before using the ZOAN™ H.pylori Antigen test kit.

2c Check the expiration date on the label of test device foil pouch and extraction buffer cap.

2d Do not use if it is beyond expiration date or if it is damaged.

3a Open the test device and extraction buffer cap foil pouch and place them on the dry and clean surface.

3b Check the result window and specimen well on the test device.

TEST PROCEDURE

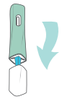
Sample stool should be fresh

4a Unfold the clean collection paper and put it on the toilet before sample collection.

4b Make sure no water to the collection paper or sample.

4c Use the test device (tip part) to fully collect sample back and forth on the collection paper.

TEST PROCEDURE



5a Insert the test device with collected sample into the extraction buffer cap as the direction shown.

5b Make sure the test device and buffer cap are tightly and fully screwed to let the sample and buffer completely mix.

5c Put the test device on a dry, clean and flat surface with buffer cap down Wait for 10 seconds.

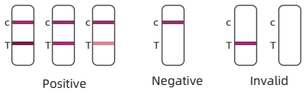
6a Invert the test device with buffer cap up.

6b Place the test device on a flat and clean surface.

6c Wait and read the results at 5 minutes (no longer than 15 minutes)

6d Dispose the waste test device into the trash after reading results.

INTERPRETATION OF RESULTS



POSITIVE: Two distinct colored lines appear. One line should be in the control region (C) and another line should be in the test region (T).

*NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of hemoglobin present in the specimen. Therefore, any shade in the test region indicates positive result.

NEGATIVE: One colored line appears in the control region (C). No apparent red or pink line appears in the test region (T).

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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

! The user should not take any decision of medical relevance without first consulting his or her medical practitioner.

[LIMITATIONS]

1.This test kit is to be used for the qualitative detection of H. pylori antigen in fecal samples. A positive result suggests the presence of H. pylori antigen in fecal samples.

2.The ZOAN™ H.pylori Antigen Test Kit is for in vitro diagnostic use only. It is only for qualitative detection, not for quantitative measurement of H.pylori antigen in fecal samples.

3. The ZOAN™ H.pylori Antigen Test Kit is not suitable for detection after treatment.

4.Urine and excessive dilution of sample with water from toilet bowl may cause erroneous test results.

5.As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

6.Other clinically available tests are required if questionable results are obtained.

[QUALITY CONTROL]

An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability. The use of an external control is recommendedto verify proper kit performance. Quality control samples should be tested according to quality control requirements

[HAZARDOUS INGREDIENTS]

The Extraction buffer contains potentially harmful chemicals (see table below). If the test solution contacts the skin or eye, flush with copious amounts of water.

Chemical Name	Harms (GHS Code) for each ingredient	Concentration
Disodium Hydrogen Phosphate Dodecahydrate	Harmful if swallowed (H302) Cause skin irritation(H315) Cause serious eye damage (H318)	0.58%
ProClin® 300	Harmful if swallowed (H302) Harmful if inhaled (H332) Causes severe skin burns and eye damage (H314) May cause an allergic skin reaction (H317)	0.05%
Sodium dihydrogen-phosphate dihydrate	Harmful if swallowed (H302) Cause skin irritation(H315) Cause serious eye damage (H318)	0.03%

[PERFORMANCE]

LoD: The lowest LoD should be

≤3×10^4CFU/mL

Positive Percent Agreement (PPA)
The PPA should be ≥90%

Negative Percent Agreement (NPA)
The NPA should be ≥90%

Interference
Below interferents were used as interferent study for ZOAN™ H.pylori Antigen test kit. Specimen containing the following substances at the standard concentration were tested on both positive and negative controls with no effect on test results.

Interferent	Concentration
Vitamin C	20mg/dL
Fat	500mg/mL
Bilirubin	60mg/dL
Ranitidine	2mg/g
Omeprazole	2mg/g
Mucin	2000mg/dL
Sodium hydroxide aluminum	20mg/g
hemameba	10000个/mL
famotidine	2mg/g
Hemoglobin	20mg/g

Cross-reactivity
The potential cross reactivity and microbial interference of the ZOAN™ H. pylori Antigen Test Kit was assessed.

Microorganism	Source	Concentration
Bacillus sp.	ATCC6896	1×10^7CFU/mL
Campylobacter jejuni	ATCC3329	1×10^7CFU/mL
Escherichia coli	ATCC8739	1×10^7CFU/mL
Candida albicans	ATCC10231	1×10^7CFU/mL
Enterococcus faecalis	ATCC19433	1×10^7CFU/mL
Enterobacter aerogenes	CMCC45103	1×10^7CFU/mL
Klebsiella pneumoniae	CMCC46117	1×10^7CFU/mL
Bacillus subtilis	ATCC6633	1×10^7CFU/mL
acinetobacter calcoaceticus	ATCC23055	1×10^7CFU/mL
Pseudomonas aeruginosa	ATCC9027	1×10^7CFU/mL
Staphylococcus aureus	ATCC6538	1×10^7CFU/mL
Proteus mirabilis	ATCC35659	1×10^7CFU/mL
Shigella flexneri	ATCC12022	1×10^7CFU/mL
Salmonella Choleraesuis	ATCC13312	1×10^7CFU/mL

No cross reactivity was observed while detecting the above microorganism at 1×10^7 CFU/mL

Prozone Effect
There is no hook effect if H.pylori is ≤1×10^8CFU/mL.

Other
- Strip width: ≥2.5MM
- Liquid flow speed: ≥10mm/min

[SYMBOLS]

	Use-By date		Consult Instructions for use
LOT	Batch code		Do not freeze
	Manufacturer		Biological risks
	Keep Away from Sunlight		Contains sufficient for <n> tests
2°C 30°C	Temperature Limit		Do not use if package is damaged
IVD	In Vitro Diagnostic Medical device		Date of manufacture
CE	CE Mark		Do Not Reuse
EC REP	Authorized Representative in the European Community		

[Approval date and date of revision]

Approval Date: Jul.15, 2022

CE IVD