CE IVD

H. pylori
Fast Test Kit
(Immunofluorescence Assay)

User Manual REF IF1047 for Getein1100

INTENDED USE
H. pylori Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative detection of H. pylori specific antigen in human stool specimen. It is a useful aid in the diagnosis of a number of gastrointestinal disorders.

SUMMARY
H.pylori is a spiral-shaped, flagellated, gram-negative bacterium that can be found in the gastric mucus layer or attached to the gastric epithelium. It is considered as a major cause of gastritis and peptic ulcer, and it is also closely related to functional dyspepsia, mucosa-associated lymphoid tissue (MALT) lymphoma, and gastric cancer. The World Health Organization's International Agency for Research on Cancer identified H. pylori as a "group 1 (definite carcinogen)". *H. pylori* causes more than 90% of duodenal ulcers and up to 80% of gastric ulcers. Clinically, the detection of *H. pylori* infection in the gastrointestinal tract can be used as an auxiliary diagnosis for gastritis, gastric ulcer, and gastric cancer.

PRINCIPLE
The test uses an anti-human *H. pylori* monoclonal antibody I conjugated with fluorescence latex coated on the sample pad and another anti-human *H. pylori* monoclonal antibody II coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human *H. pylori* monoclonal antibody binds with the *H. pylori* specific antigen in sample and forms a marked antigen-antibody complex. This complex moves to the test detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by anti-human *H. pylori* antibody II. The fluorescence intensity of test line increases in proportion to the amount of *H. pylori* specific antigen in sample.

Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100), the concentration of H. pylori specific antigen in sample will be measured and displayed on the screen. The value will be stored in Getein1100 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

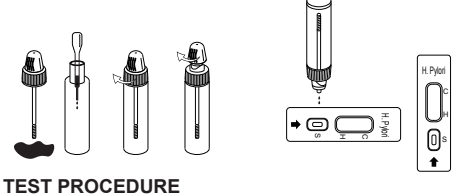
CONTENTS
1. A kit for Getein1100 contains:
Package specifications: 10 tests/box, 25 tests/box.
1)Getein *H. pylori* test card in a sealed pouch with desiccant.
2)Sample diluent
3)User Manual:1 piece/box
4)SD card: 1 piece/box
2.Sample diluent composition:
Phosphate buffered saline, proteins, detergent, preservative, and stabilizer.
3. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, a sample pad (coated with fluorescence latex-labeled anti-human *H. pylori* monoclonal antibody I), nitrocellulose membrane (the test line is coated with anti-human *H. pylori* monoclonal antibody II, and the control line C is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.
Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICES
Getein1100 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY
Store the test card at 4~30℃ with a valid period of 24 months.
Use the test card within 1 hour once the foil pouch is opened.
Store the sample diluent at 0~30℃ with a valid period of 24 months.
Store the sample diluent at 2~8℃ for better results.

PRECAUTIONS
1.For in vitro diagnostic use only.
2.Do not use the kit beyond the expiration date.
3.Do not use the test card if the foil pouch is damaged.
4.Do not open pouches until ready to perform the test.
5.Do not reuse the test card.
6.Do not reuse the sample diluent.
7.Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8.Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION
1.This test can be used for ***stool specimen***.
2.Stool specimen should be stored in a clean container and detected immediately after sampling. If testing is delayed, stool specimen may be stored up to 2 days at 2~4℃ or stored at -20℃ for 1 year.
3.Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles. The proposed sample freeze-thaw is not more than 1 time.
4.Sample preparation:
Open sample diluent and take out the sample stick, insert it into the stool specimen and then return the fecal sampling stick into the tube. Tighten the tube and shake it gently. Totally do above action 3 times and take different sites of stool specimen and try to avoid obtaining clumps of fecal matter each time.
Or use a sample stick to pick 10-50 mg stool specimen, and put into the tube, tighten and shake gently and thoroughly to use.



TEST PROCEDURE
1.Collect specimens according to user manual.
2.Test card, sample and reagent should be brought to room temperature before testing.
3.Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
4.Enter testing interface of Getein1100.
5.Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6.Put the test card on a clean table, horizontally placed.
7.Take out the treated sample mixture, clockwise turn off the cap lid, invert the mixture, discard the first 3 drops, and drip

vertically 3 drops (about 100 ul) of the mixture without bubbles to the test card.

8.Reaction time: **10 minutes.** Insert the test card into Getein1100 and start test after reaction time is elapsed. The result will be shown on the screen and printed automatically.

Notes:

1.It is required to perform SD card calibration when using a new batch of kits.

2.It is suggested to calibrate once for one batch of kits.

Make sure the test card insertion is correct and complete.

EXPECTED VALUE

The expected normal value for *H. pylori* is determined by testing samples from 199 healthy individuals. The upper limit (95th percentile) of the reference range is 5.0 ng/mL.

It is recommended that each laboratory establish its own expected values for the population it serves.

TEST RESULTS

Getein1100 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100.

LIMITATIONS

1.For in vitro diagnosis only.

2.As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.

3.A false-negative result could occur if the concentration of H. pylori antigen is below the lower limit of detection. In this case, further tests are required if signs of symptom persisted.

PERFORMANCE CHARACTERISTICS

Linearity Range	1.0 ng/mL~200.0 ng/mL
Lower Detection Limit	≤1.0 ng/mL
Repeatability	≤10%
Between-run Precision	≤15%

REFERENCES

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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2016.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged
REF	Catalogue number		

Thank you for purchasing *H. pylori* Fast Test Kit (Immunofluorescence Assay).

Please read this user manual carefully before operating to ensure proper use.

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