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H. pylori Antigen
Fast Test Kit
(Immunofluorescence Assay)

Instructions for Use

REF IF1047 for Getein1100
IF5047 for Getein1160
IF3047 for Getein1180

INTENDED USE

H. pylori Antigen Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative detection of *H. pylori* antigen in human stool specimen. It is a useful aid in the diagnosis of a number of gastrointestinal disorders. For professional and laboratory use.

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* infection causes more than 90% of duodenal ulcers and up to 80% of gastric ulcers. Clinically, detecting *H. pylori* antigen can be used as an adjunct diagnosis for *H. pylori* infection in the gastrointestinal tract.

PRINCIPLE

H. pylori Antigen Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After the sample has been applied to the test strip, the fluorescence latex-labelled HP monoclonal antibody binds with the *H. pylori* antigen in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by another HP monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of *H. pylori* antigen in sample. Fluorescent signals intensity can be analyzed by applicable device thus the *H. pylori* antigen in sample be detected quantitatively.

CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180	
	10 T/kit	25 T/kit
H. pylori Antigen test card*	10 pcs	25 pcs
Sample diluent**	10 tube	25 tube
Instructions for use	1 pc	1 pc
SD card	1 pc	1 pc

* *H. pylori* Antigen test card
A test card main consists of: Fluorescence latex-labelled HP monoclonal antibody, HP monoclonal antibody and polyclonal IgG antibody.
** Sample diluent main consists of: phosphate buffer (20 mmol/L), NaN3 (＜0.1%).

Note:

1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
2. Do not mix or interchange different batches of kits.

APPLICABLE DEVICES

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

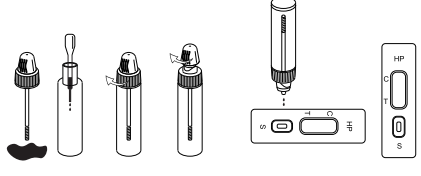
Store the test kit at 4~30℃ with a valid period of 24 months.
Use the test card within 1 hour once the foil pouch is opened.

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 instructions for use 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 2~8℃ 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 should be no 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 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. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.

For Getein1100:

1) Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
4) 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 μL) of the mixture without bubbles to the test card.
5) Reaction time: ***10 minutes.*** After reaction time is elapsed, insert the test card into Getein1100 and press "ENT" button (click on "Start" icon for Android Getein1100). The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:

1) Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
4) 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 μL) of the mixture without bubbles to the test card.
5) Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time ***(10 minutes)*** and automatically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

EXPECTED VALUE

The expected normal value for *H. pylori* antigen 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/Getein1160/Getein1180 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1160/Getein1180.

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 limit of detection. In this case, further tests are required if signs of symptom persisted.

PERFORMANCE CHARACTERISTICS

Measuring Range	1.0 ng/mL~200.0 ng/mL
Limit of Detection	≤1.0 ng/mL
Repeatability	≤10%
Between-lot Precision	≤15%

REFERENCES

1. Ye Yingwu, etc. National Clinical Laboratory Procedures (3rd Edition). Southeast University Press, 2006: 347-351.
2. Sirin Goktug, Sezikli Mesut, Eruyar Ahmet Tuğrul, et al. Duodenal bulb infection may be a risk factor for Helicobacter pylori eradication insuccess.. 2021, 32(2):303-304.
3. Bradbury Richard. Helicobacter pylori: Molecular genetics and cellular biology [Book Review]. 2012, 33(2):65-66
4. Khalil Hanan. Evidence summaries: The effectiveness of eradicating Helicobacter pylori in reducing gastric cancer. 2015, 34(9):36-37.
5. A. L. Korkin, S. V. Gasanova. ASSESSMENT OF SYMPTOMS OF DYSPEPSIA SYNDROME IN NEWLY DIAGNOSED GASTRIC AND DUODENAL ULCERS, HELICOBACTER PYLORI ASSOCIATED. 2015, 6(1):25-28.Blaser M J. Science, Medicine, and the Future: Helicobacter pylori and Gastric Diseases[J]. Bmj British Medical Journal, 1998, 316(7143):1507-1510.
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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 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult *instructions for use* or consult electronic *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/ European Union
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		

Thank you for purchasing *H. pylori* Antigen Fast Test Kit (Immunofluorescence Assay).
Please read this instructions for use carefully before operating to ensure proper use.

Version: WIF45-S-06

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