



H. pylori Antibody Fast Test Kit (Immunofluorescence Assay)

IF1140 for Getein 1100
IF5140 for Getein 1160
IF3140 for Getein 1180
IF4140 for Getein 1200
IF2140 for Getein 1600



Instructions for Use

INTENDED USE

H. pylori antibody Fast Test Kit (Immunofluorescence Assay) is intended for the *in vitro* qualitative detection of *Helicobacter pylori* (*H. pylori*) antibody in human serum, plasma and whole blood samples. It is used as an adjunctive diagnosis for *H. pylori* infection and related conditions such as gastritis, gastroduodenal ulcers, gastric cancer, and non-ulcer dyspepsia. For professional and laboratory use only.

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 a major cause of gastritis and peptic ulcer, and it is also strongly associated with functional dyspepsia, mucosa-associated lymphoid tissue (MALT) lymphoma, and gastric cancer. *H. pylori* infection can cause bacterial growth, changes in the gastric mucosa, and a decrease in gastric acidity, making it one of the pathogenic factors of gastric cancer. Its main symptoms include acid reflux, heartburn and stomach pain. Therefore, detecting the antibody content of *H. pylori* in human blood samples is of significant importance for assisting in the diagnosis of *H. pylori* infection.

PRINCIPLE

H. pylori antibody Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunochromatographic assay for the detection of *H. pylori* antibody in human serum, plasma and whole blood samples. After the sample has been applied to the test card, the fluorescence latex-labelled *H. pylori* antigen binds with *H. pylori* antibody in the sample and forms a marked antigen-antibody complex. The complex moves to the detection area by capillary action, then it is captured by anti-human IgG antibody coated on

the detection area of nitrocellulose membrane, forming a sandwich complex. The fluorescence intensity of the test line increases in proportion to the amount of *H. pylori* antibody in the sample.

CONTENTS

Materials provided	Getein 1100/Getein 1160/ Getein 1180			Getein 1200/ Getein 1600	
	5 T/kit	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
<i>H. pylori</i> antibody test card*	5 pcs	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	5 pcs	10 pcs	25 pcs	/	/
Sample diluent**	5 tube	10 tube	25 tube	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

* *H. pylori* antibody test card

A test card main consists of: Fluorescence latex-labelled *H. pylori* antigen, anti-human IgG antibody.

** Sample diluent

(1) Sample diluent for Getein 1100/Getein 1160/Getein 1180 in each tube main consists of: phosphate buffer (20 mmol/L), NaN3 (<0.1%).

(2) Sample diluent for Getein 1200/Getein 1600 is an independent packing box main consists of:

- Phosphate buffer (20 mmol/L), NaN3 (<0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),
- Box with pipette tips (96 tips/box),
- Mixing plate (1 piece/box).

Note:

- 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".
- Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Realtime stability:

Store the test kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

In-use stability:

-For the test card of Getein 1100/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.

-For test card of Getein 1200/Getein 1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional and laboratory use only, not for near-patient test and self-testing.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches until performing the test.
- Handle all specimens as potentially infectious. The foil bag is nondegradable. Proper handling and disposal methods should be followed in accordance with local regulations.
- It is recommended that operators take necessary self-protection measures (work clothes, goggles and disposable gloves, etc.) when touching kits or samples.
- Proper handling and disposal methods should be followed in accordance with local regulations.

SPECIMEN COLLECTION AND PREPARATION

- Serum, plasma and whole blood can be used as samples in the assay.
- Heparin, sodium citrate and EDTA can be used as the anticoagulants for plasma and whole blood. Do not use hemolytic specimens.
- This assay is designed and validated for use with human blood, other specimens or body fluids may not get accurate results.
- It is recommended to test the sample within 4 hours after collection. Serum and plasma are stable for 5 days when stored at 2~8°C and 6 months when stored at -20°C. Whole blood is stable for 3 days when stored at 2~8°C.
- Refrigerated or frozen samples should reach room

temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.

TEST PROCEDURE

- User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
- Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

- Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- Using disposable pipet or pipette, deliver **100 µL** of sample into one tube of sample diluent, mix thoroughly. Then drop **100 µL** of sample mixture into the sample well on the test card.
- Reaction time: **15 minutes**. After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button (click on "Start" icon for Android Getein 1100). The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

- Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- Using disposable pipet or pipette, deliver **100 µL** of sample into one tube of sample diluent, mix thoroughly. Then drop **100 µL** of sample mixture into the sample well on the test card.
- Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (**15 minutes**) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

For Getein 1200/Getein 1600:

- Each cartridge for Getein 1200/Getein 1600 contains a

specific RFID card (SD card) which can calibrate automatically.

- Place the sample diluent at the correct position in Getein 1200/Getein 1600.
- Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1200/Getein 1600 will do the testing and print the result automatically.

Notes:

- It is required to perform "SD card" calibration when using a new batch of kits for Getein 1100/Getein 1160/Getein 1180.
- It is suggested to calibrate once for one batch of kits for Getein 1100/Getein 1160/Getein 1180.
- Make sure the test card and the sample insertion are correct and complete.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.50-100.00 S/CO
Within-run Precision	≤ 10%
Between-lot Precision	≤ 15%

DISPLAY AND INTERPRETATION OF TEST RESULTS

- Getein 1100/Getein 1160/Getein 1180/Getein 1600/Getein 1200 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein 1100/Getein 1160/Getein 1180/Getein 1600/Getein 1200.
- The test result is displayed numerically in terms of cut-off index (COI) value. Test result is negative if COI is <1.0 S/CO and positive if COI is ≥1.0 S/CO.

Display	Judgment
COI≥1.0 S/CO	Positive test for <i>H. pylori</i> antibody (antibody present)
COI<1.0 S/CO	Presumptive negative test for <i>H. pylori</i> antibody (no antibody detected)
Invalid Test	Test invalid, repeat the test (some procedural error or malfunction of test cards and/or analyzers)

- Cut-off index of *H. pylori* antibody has been determined and validated using 300 negative samples and 100 positive samples.
- It is recommended that each laboratory establish its own expected values for the population it serves.

Note:

- Due to the limitation of immunochromatography methodology, the negative test result does not exclude *H. pylori* infection. In the early stage of infection, the lack of IgG antibody production or very low concentration will lead to false negative results.
- False positive results may occur due to cross-reacting antibodies from previous infections, or from other causes.
- Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made.
- The individual immune response following *H. pylori* infection varies considerably and might give different results with assays from different manufacturers. Results of assays from different manufacturers should not be used interchangeably.
- H. pylori* antibody detection has certain limitations, such as the inability to distinguish between current and past infections. Therefore, a clinical diagnosis usually requires a comprehensive evaluation combined with other testing methods and clinical symptoms.

LIMITATIONS

- 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.
- Patient samples may contain heterophilic antibodies (e.g. human anti-mouse antibodies (HAMA) and rheumatoid factors) that could react in immunoassays to give a falsely elevated or depressed result. This assay has been designed to minimize interference from heterophilic antibodies. Nevertheless, complete elimination of this interference from all patient specimens cannot be guaranteed.

REFERENCES

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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on *H. pylori* antibody Fast Test Kit (Immunofluorescence Assay) 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		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community/European Union
	CE mark		Do not use if package is damaged and consult instructions for use
	Catalogue number		Caution

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

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