



Novel Coronavirus (2019-nCoV) IgM/IgG antibody Fast Test Kit (Immunofluorescence Assay)

IF1084 for Getein 1100
IF5084 for Getein 1160
IF3084 for Getein 1180
IF2084 for Getein 1600
IF4084 for Getein 1200

REF

User Manual

INTENDED USE

Novel Coronavirus (2019-nCoV) IgM/IgG antibody Fast Test Kit (Immunofluorescence Assay) is intended for the qualitative detection of 2019-Novel Coronavirus IgM and IgG antibody in serum, plasma or whole blood samples from patients suspected of COVID-19 infection by a healthcare provider. The test is an aid in the diagnosis of patients with suspected 2019-nCoV infection in conjunction with clinical presentation and the results of other laboratory tests. Results from the test should not be used as the sole basis for diagnosis and exclusion of 2019-nCoV infection. For professional and laboratory use.

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases. When IgM antibodies are present, it may indicate that a patient has an active or recent infection with 2019-nCoV. And IgG antibodies develop later following infection. When IgG antibodies are present, it often indicates a past infection but does not exclude recently infected patients who are still contagious, especially if detected with IgM antibodies. It is unknown how long IgM or IgG antibodies to 2019-nCoV will remain present in the body after infection and if they confer

immunity to infection. As it is a novel disease diagnosis of which is being explored, please refer to the latest guidelines for diagnosis and treatment of COVID-19.

PRINCIPLE

The test uses mixed recombinant 2019-nCoV nucleocapsid protein (N protein) and spike protein (S protein) both conjugated with fluorescence latex coated on the sample pad and anti-human IgM and IgG antibody coated on different test lines respectively. After the samples has been applied to the test strip, the fluorescence latex-labelled recombinant 2019-nCoV N protein and S protein will bind with 2019-nCoV IgM or IgG antibody in sample and form marked antigen-antibody complexes. These complexes move to the test card detection zone by capillary action. Then marked antigen-antibody complexes will be captured on different test lines by anti-human IgM and IgG antibody. The fluorescence intensity of each test line increases in proportion to the amount of 2019-nCoV IgM and IgG antibody in sample. Fluorescent signals intensity can be analyzed by applicable device thus the 2019-nCoV IgM and IgG antibody in sample be detected qualitatively.

CONTENTS

Materials provided	Getein 1100/Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
Novel Coronavirus (2019-nCoV) IgM/IgG antibody test card*	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	10 pcs	25 pcs	/	/
Sample diluent**	10 tube	25 tube	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

* Novel Coronavirus (2019-nCoV) IgM/IgG antibody test card A test card consists of: A plastic shell and a reagent strip which is composed of a sample pad (coated with recombinant 2019-nCoV N protein and S protein), nitrocellulose membrane with two test lines (these two lines are coated with anti-human IgM and IgG antibody respectively), the control line (coated with anti-recombinant protein tag protein), absorbent paper and

liner.
** Sample diluent

- Sample diluent for Getein 1100/Getein 1160/Getein 1180 is contained in each tube consists of:
 - Sample diluent mainly contains phosphate buffer (20 mmol/L), NaN3 (<0.1%).
- Sample diluent for Getein 1200/Getein 1600 is an independent packing box consists of:
 - Sample diluent mainly contains 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).

APPLICABLE DEVICE

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

STORAGE AND STABILITY

Realtime stability:

Store the 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 the 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

- Do not open pouches until ready to perform the test to protect the test cards from getting damp exposing in air for too long.
- The test cards can be stored in room temperature with sealed pouches. And the test cards stored in low temperature should reach room temperature before testing.
- There should be appropriate bio-safety assurance procedure

for infectious sources or potential infectious sources. Some relevant precautions are showed below:

- Wear disposable gloves to deal with samples, or sterilize reagents.
- Sterilize spilled samples or reagents with sanitizer.
- Sterilize and cope with all of samples, reagents and potential contaminant with relevant local regulations.

SPECIMEN COLLECTION AND PREPARATION

- Sample should be **human serum, plasma or whole blood**, other body fluid and samples may cause incorrect or inaccurate results.
- Venous blood should be collected under sterile condition at any time of a day.
- It is recommended to use serum or plasma for better results.
- Heparin, sodium citrate and EDTA can be used as anticoagulant for plasma and whole blood sample.
- Serum, plasma or whole blood sample should be tested within 4 hours after blood collection in room temperature. If testing is delayed, serum and plasma may be stored up to 5 days at 2-8°C or stored for 6 months at -20°C before testing (whole blood sample may be stored up to 3 days at 2-8°C). Do not heat the samples and discard hemolyzed samples.
- Bring all samples to room temperature (15-30°C) before use. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
- SAMPLE VOLUME (for Getein1100): 100 μ L.**

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.

- Use 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: **10 minutes**. After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button or click on "Start" icon. 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.
- Use 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 (**10 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 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.

Note:

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

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 < 1.00 and positive if COI is ≥ 1.00.
- If the test result is "Negative" for IgM as well as for IgG, the patient may not be infected with 2019-nCoV but follow-up testing with a molecular diagnostic test should be considered to rule out infection in these individuals.
- If the test result is "Positive" for IgM and/or for IgG, the patient is most likely to be infected with 2019-nCoV.
- If the test result is "Invalid", there must have been some procedural error or malfunction of test cards and/or analyzers.
- Cut-off index of Novel Coronavirus (2019-nCoV) IgM/IgG antibody has been determined and validated using 500 samples confirmed as negative and 88 samples confirmed as positive.

Note:

- Due to the limitation of immunochromatography methodology, the negative test result does not exclude 2019-nCoV infection. In the early stage of infection, the lack of IgM/IgG antibody production or very low concentration will lead to false negative results. If COI is 0.80-1.00 for IgM and/or for IgG, the patient may be infected with 2019-nCoV and there is need to combine with other laboratory tests and clinical presentation to confirm.
- False positive results may occur due to cross-reacting antibodies from previous infections, such as other coronaviruses, 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 Novel Coronavirus (2019-nCoV) infection varies considerably and might give different results with assays from different manufacturers. Results of assays from different manufacturers should not be used interchangeably.

LIMITATIONS

- The test is for *in vitro* diagnostic use only.
- The test results of this kit are for clinical reference only. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests, and treatment response.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Novel Coronavirus (2019-nCoV) IgM/IgG 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		<i>In vitro</i> 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 purchasing Novel Coronavirus (2019-nCoV) IgM/IgG antibody Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

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