CE IVD

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

User Manual

REF **IF1084 for Getein1100**
IF2084 for Getein1600

BACKGROUND

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.

INTENDED USE

Novel Coronavirus (2019-nCoV) IgM/IgG antibody Fast Test Kit (Immunofluorescence Assay) is intended for the quantitative 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.

Novel Coronavirus (2019-nCoV) IgM/IgG antibody Fast Test Kit (Immunofluorescence Assay) 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. This test is only intended for professional and laboratory use, not for home testing. Results from the test should not be used as the sole basis for diagnosis and exclusion of 2019-nCoV infection.

Negative results do not exclude 2019-nCoV infection and should not be used as the sole basis for patient management decisions. IgM antibodies may not be detected in the first few days of infection.

False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions.

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.

Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100 and Getein1600), the concentration of 2019-nCoV IgM and IgG antibody in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 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: 25 tests/kit.
1) Getein Novel Coronavirus (2019-nCoV) IgM/IgG antibody test card in a sealed pouch with desiccant
2) Sample diluent: 25 tubes/kit
3) User manual: 1 piece/kit
4) SD card: 1 piece/kit

2. A kit for Getein1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
1) Sealed cartridge with 24/48 Getein Novel Coronavirus (2019-n-CoV) IgM/IgG antibody test cards
2) User manual: 1 piece/kit

Materials required for Getein1600:
1) Sample diluent: 1 bottle/kit
2) Box with pipette tips: 96 tips/kit
3) Mixing plate: 1 piece/kit

Note: Do not mix or interchange different batches of kits.

3. 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.

4. Sample diluent composition:
Phosphate buffered saline (11 mM PBS)

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test kit at 4~30°C with a valid period of 24 months.

Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

For test card of Getein1600: If the cartridge is opened, it could be stable within 24 hours once exposure to air. 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

1. Do not open pouches until ready to perform the test to protect the test cards from getting damp exposing in air for too long.
2. The test cards can be stored in room temperature with sealed pouches. And the test cards shored in low temperature should reach room temperature before testing.
3. There should be appropriate bio-safety assurance procedure for infectious sources or potential infectious sources. Some relevant precautions are showed below:

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

SPECIMEN COLLECTION AND PREPARATION

1. Sample should be ***human serum, plasma or whole blood***, other body fluid and samples may cause incorrect or inaccurate results.
2. Venous blood should be collected under sterile condition at any time of a day.
3. It is recommended to use serum or plasma for better results.
4. Heparin, sodium citrate and EDTA can be used as anticoagulant for plasma and whole blood sample.
5. 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.
6. 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.
7. SAMPLE VOLUME ***(for Getein1100): 100 μL***.

TEST PROCEDURE

Read the manual carefully before using and operate according to the manual to avoid incorrect results.

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature(15-30°C) before test.

For Getein1100:

1. Confirm SD card lot No. in accordance with test kit lot No. Perform “SD card” calibration when necessary.
2. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
3. Put the test card on a clean table, horizontally placed.
4. Using sample transfer pipette, deliver ***100 μL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100 μL*** of sample mixture into the sample well on the test card.
5. ***Reaction time: 10 minutes.*** Insert the test card into Getein1100 and click on “Start” icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

1. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
2. Put the sample diluent at the correct position in Getein1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Note:

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 for Getein1100.
3. Make sure the test card and the sample insertion is correct and complete.

DISPLAY AND INTERPRETATION OF TEST RESULTS

1. Getein1100/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1600.
2. 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.
3. 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.
4. If the test result is “Positive” for IgM and/or for IgG, the patient is most likely to be infected with 2019-nCoV.
5. If the test result is “Invalid”, there must have been some procedural error or malfunction of test cards and/or analyzers.
6. 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:

1. 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.
2. False positive results may occur due to cross-reacting antibodies from previous infections, such as other coronaviruses, or from other causes.
3. Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made.
4. 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

1. The test is for in vitro diagnostic use only.
2. 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*	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 Novel Coronavirus (2019-nCoV) IgM/IgG antibody Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF76-S-06

Getein Biotech, Inc.
Add.: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

EC REP CMC Medical Devices & Drugs S.L.
Add.: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054