SARS-CoV-2 Antigen Fast Test Kit

(Immunofluorescence Assay)

CE IVD

REF

IF1091 for Getein1100
IF4091 for Getein1200
IF5091 for Getein1160
IF3091 for Getein1180
IF2091 for Getein1600

User Manual

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.

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

INTENDED USE

SARS-CoV-2 Antigen Fast Test Kit (Immunofluorescence Assay) is intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in human nasal swab samples from patients suspected of COVID-19 infection by a healthcare provider.

SARS-CoV-2 Antigen Fast Test Kit (Immunofluorescence Assay) is an aid in the diagnosis of patients with suspected SARS-CoV-2 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 SARS-CoV-2 infection.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.

Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management. Negative results do not rule out COVID-19 and should not be used as the sole basis for patient management decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

PRINCIPLE

The test uses anti-SARS-CoV-2 nucleocapsid protein (N protein) monoclonal antibody I conjugated with fluorescence latex coated on the sample pad and another anti-SARS-CoV-2 N protein monoclonal antibody Ⅱ coated on test line. After the samples have been applied to the test strip, the fluorescence latex-labelled anti-SARS-CoV-2 N protein monoclonal antibody I bind with SARS-CoV-2 antigens 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 test line by anti- SARS-CoV-2 N protein monoclonal antibody Ⅱ. The fluorescence intensity of each test line increases in proportion to the amount of SARS-CoV-2 antigen in sample.

Then insert test card into Getein1100/Getein1160/Getein1180 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1160, Getein1180, Getein1200 and Getein1600), the concentration of SARS-CoV-2 antigens in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/Getein1160/Getein1180 contains:

Package specifications: 25 tests/kit.

1) Getein SARS-CoV-2 antigen test card in a sealed pouch with desiccant
2) Sample extraction solution: 25 tubes/kit
3) Sampling swab: 25 pieces/kit
4) User manual: 1 piece/kit
5) Disposable pipette: 25 pieces/kit
6) SD card: 1 piece/kit

2. A kit for Getein1200/Getein1600 contains:

Package specifications: 2×24 tests/kit, 2×48 tests/kit

Sealed cartridge with 24/48 Getein SARS-CoV-2 antigen test cards

User manual: 1 piece/kit

Materials required for Getein1200/Getein1600:

1) Sample extraction solution: 1 bottle/kit
2) Box with pipette tips: 96 tips/kit
3) Mixing plate: 1 piece/kit
4) Sampling swab: 48 pieces/kit, 96 pieces/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 anti-SARS-CoV-2 N protein monoclonal antibody Ⅰ), nitrocellulose membrane with test line (coated with anti-SARS-CoV-2 N protein monoclonal antibody Ⅱ), the control line (coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

4. Sample extraction solution composition (400 uL/tube):

Phosphate buffered saline, protein stabilizer and surfactant.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer
Getein1180 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/Getein1160/Getein1180 within 1 hour once the foil pouch is opened.

For test card of Getein1200/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 nasal swab sample***. Test samples immediately after collection for optimal test performance. Inadequate sample collection or improper sample handling/storage/transport may yield erroneous results. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) .
   https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html
2. It is recommended to use a flocked swab with a PP (polypropylene) rod as a sterile swab for sample collection.
3. Sample collection:
   Carefully insert a sterile swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Keep the swab in the nasal cavity for 15-30s，rotate the swab 3 times against the nasal wall then remove it from the nostril. If taking samples from two nostrils, use the same sampling swab.
4. Nasal swab samples should be processed with sample extraction solution after collection. If testing is delayed, the sample should be stored in a dry, sterilized and strictly sealed plastic tube immediately, it can be stored up to 8 h at 2-8°C before testing.

TEST PROCEDURE

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

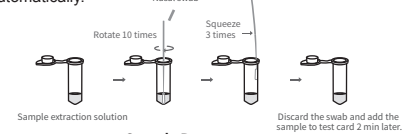
1. Collect specimens according to user manual.
2. Test card, sample and reagent should reach to room temperature (15-30°C) before test.

For Getein1100:

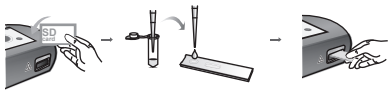
1. Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
2. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
3. Put the test card on a clean table, horizontally placed.
4. Sample pretreatment:

1) Take one tube of sample extraction solution, insert the nasal swab sample into the tube, and rotate the swab 10 times in the solution to make the sample dissolve in the sample extraction solution as much as possible.
2) Squeeze the swab tip along the inner wall of the sample extraction tube 3 times to keep the liquid in the tube as much as possible before taking it out of the tube.
3) Discard the swab and add the sample to test card 2 min later.

5. Select the sample type as "Swab" on Getein1100.
6. Using disposable pipette, deliver ***100 μL*** of sample into the sample well on the test card.
7. ***Reaction time***: ***15 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.



Sample Pretreatment



SD card calibration. Choose sample mode of swab. Reaction time: 15 min

Deliver 100 μL of sample into the sample port on the test card.

Test after reaction time is elapsed.

Test

For Getein1160/Getein1180:

1. Confirm SD card lot No. in accordance with test kit lot No..Perform “SD card” calibration when necessary.
2. Enter testing interface of Getein1160/Getein1180.
3. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
4. Put the test card on a clean table,horizontally placed.
5. Sample pretreatment:

1) Take one tube of sample extraction solution, insert the nasal swab sample into the tube, and rotate the swab 10 times in the solution to make the sample dissolve in the sample extraction solution as much as possible.
2) Squeeze the swab tip along the inner wall of the sample extraction tube 3 times to keep the liquid in the tube as much as possible before taking it out of the tube.
3) Discard the swab and add the sample to test card 2 min later.

6. Using sample transfer pipette, deliver ***100 μL*** of sample into the sample well on the test card.
7. Insert the test card into Getein1160/Getein1180 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 printed automatically.

For Getein1200/Getein1600:

1. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
2. Put the sample diluent at the correct position in Getein1200/Getein1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1200/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/Getein1160/Getein1180.
3. Make sure the test card and the sample insertion is correct and complete.

DISPLAY AND INTERPRETATION OF TEST RESULTS

1. Getein1100/Getein1160/Getein1180/Getein1200/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/Getein1160/Getein1180/Getein1200/Getein1600.
2. The test result is displayed numerically in terms of cut-off index (COI) value. Test result is negative if COI is <1.0 and positive if COI is ≥ 1.0.

Display	Judgement
COI≥1.0	Positive (+): positive test for SARS-CoV-2 (antigen present)
COI<1.0	Negative (-): presumptive negative test for SARS-CoV-2 (no antigen detected)
Invalid Test	Test invalid, repeat the test (some procedural error or malfunction of test cards and/or analyzers)

3. Cut-off index of SARS-CoV-2 has been determined and validated using 500 nasal swab samples from healthy people and 80 nasal swab samples from positive patients.
4. It is recommended that each laboratory establish its own expected values for the population it serves.

Note:

1. Positive results indicate the presence of SARS-CoV-2 antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. A positive result does not rule out co-infections with other pathogens.
2. Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with COVID-19, or in those who have been in contact with the virus. It is recommended that these results be confirmed by a molecular testing method, if necessary, for patient management.
3. The individual immune response following SARS-CoV-2 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 SARS-CoV-2 Antigen Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail 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 SARS-CoV-2 Antigen Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

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