FluA/FluB/SARS-CoV-2 Antigen
Fast Test Kit
(Immunofluorescence Assay)

User Manual

REF **IF1093 for Getein1100**
IF2093 for Getein1600

INTENDED USE

Flu A/Flu B/ SARS-CoV-2 Antigen Fast Test Kit (Immunofluorescence Assay) is intended for the qualitative detection of nucleocapsid protein antigen from Flu A/Flu B/ SARS-CoV-2 in human nasopharyngeal swab or oropharyngeal swab samples from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider within the first five days of the onset of symptoms. This test is only intended for professional and laboratory use, not for home testing.
Flu A/Flu B/ SARS-CoV-2 Antigen Fast Test Kit (Immunofluorescence Assay) is an aid in the differentiate of patients with suspected SARS-CoV-2 infection in conjunction with clinical symptoms and result of other diagnostic methods. Results from the test should not be used as the sole basis for diagnosis and exclusion of SARS-CoV-2 infection.
SARS-CoV-2, influenza A and influenza B viral antigens are generally detectable in upper respiratory specimens during the acute phase of infection. 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 molecular assay test, if necessary for patient management. Negative results do not rule out influenza A, influenza B or SARS-CoV-2 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 influenza A and influenza B and SARS-CoV-2.

BACKGROUND

Influenza viruses are causative agents of highly contagious, acute, viral infections of the respiratory tract. Influenza viruses are immunologically diverse, single-stranded RNA viruses. There are three types of influenza viruses: A, B, and C. Type A viruses are the most prevalent and are associated with most serious epidemics. Type B viruses produce a disease that is generally milder than that caused by type A. Type C viruses have never been associated with a large epidemic of human disease. Both Type A and B viruses can circulate simultaneously, but usually one type is dominant during a given season.
The novel coronaviruses belong to the β genus. SARS-CoV-2 is a generally susceptible acute respiratory infectious disease. The main source of infection is the SARS-CoV-2 infected patients and asymptomatic infected people. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main clinical symptom include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.
Autumn and winter season are the season with high incidence of influenza virus, and the early symptoms of respiratory virus infection are similar, timely differentiate of disease is particularly important.

PRINCIPLE

The test uses recombinant anti-SARS-CoV-2 nucleocapsid protein (N protein) monoclonal antibody I, anti-influenza A nucleocapsid protein (N protein) monoclonal antibody I and anti-influenza B 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, anti-influenza A monoclonal N protein antibody Ⅱ and anti-influenza B 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, anti-influenza A N protein monoclonal antibody I and anti-influenza B N protein monoclonal antibody I bind with influenza A , influenza B and 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 N protein monoclonal antibody Ⅱ, anti-influenza A N protein monoclonal antibody Ⅱ and anti-influenza N protein B monoclonal antibody Ⅱ. The fluorescence intensity of each test line increases in proportion to the amount of Influenza A, Influenza B and SARS-CoV-2 antigen in sample.
Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100)/Automatically inserted by Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to Getein1600), the concentration of Influenza A, Influenza B and SARS-CoV-2 antigen 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/box.
1) Getein Flu A/Flu B/ SARS-CoV-2 antigen test card in a sealed pouch with desiccant
2) Sample extraction solution: 25 tubes/box
3) Sampling Swab: 25 pieces/box
4) Disposable pipette: 25 pieces/box
5) User manual: 1 piece/box
6) SD card: 1 piece/box
2. A kit for Getein1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
1) Sealed cartridge with 24/48 Getein Flu A/Flu B/ SARS-CoV-2 antigen test cards
2) User manual: 1 piece/box
Materials required for Getein1600:
1) Sample extraction solution: 1 bottle/box
2) Box with pipette tips: 96 tips/box
3) Mixing plate: 1 piece/box
Note: Do not mix or interchange different batches of kits.
3. A test card consists of:
A plastic shell and two reagent strip, absorbent paper and liner. The SARS-CoV-2 reagent strip is composed of a sample pad (the sample pad is coated with anti-SARS-CoV-2 N protein monoclonal antibody Ⅰ), nitrocellulose membrane with test line (test line coated with anti-SARS-CoV-2 N protein monoclonal antibody Ⅱ), the control line (coated with rabbit IgG antibody). The Flu A/Flu B reagent strip is composed of a sample pad (the sample pad is coated with anti-influenza A N protein monoclonal antibody I and anti-influenza B N protein monoclonal antibody I), nitrocellulose membrane with test line (test line coated with anti-influenza A N protein monoclonal antibody Ⅱ and anti-influenza B N protein monoclonal antibody Ⅱ), the control line (coated with goat IgG antibody).
4. Sample extraction solution composition (400 μL/tube):
Phosphate buffered saline, protein stabilizer and surfactant.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card 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.
Store the sample extraction solution t at 0-30°C with a valid period of 24 months.
Store the sample extraction solution at 2-8°C for better results.

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 according to relevant local regulations.

SPECIMEN COLLECTION AND PREPARATION

1. Sample should be ***human nasopharyngeal swab or oropharyngeal swab samples***. Samples should be tested immediately after collection for optimal test performance. Inadequate sample collection or improper sample handling/storage/transport may cause 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.htm
2. It is recommended to use a flocked swab with a PP (polypropylene) rod as a sterile swab for sample collection.
3. Sample collection:
1) Nasopharyngeal swab sample:
Carefully insert a sterile swab into the nostril that presents the most secretion under visual inspection. Use gentle rotation, and 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 swab.
2) Oropharyngeal swab sample:
Pass a sterile swab over the base of the tongue and reach the pharyngeal isthmus with the tongue pressure plate. Wipe the posterior wall of the pharynx and the tonsils on both sides. Avoid touching the tongue and oral mucosa when removing.
4. Nasopharyngeal swab or oropharyngeal swab samples should be processed with sample diluent 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 user manual carefully before using and operate according to the user manual to avoid incorrect results.
1. Collect specimens according to user manual.

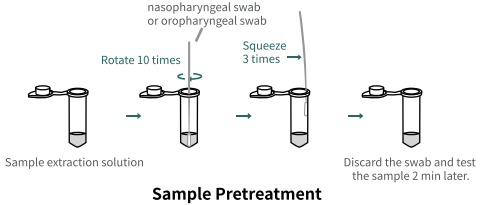
2. Test card, sample and reagent should reach to room temperature (15-30°C) before test.

For Getein1100:

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

1) Take one tube of sample extraction solution, insert the nasopharyngeal swab or oropharyngeal 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) Remove the discard the swab, test it with 2 min after sample pretreated.

7. Select the sample type as "Swab" on Getein1100.
8. Using sample transfer pipette, deliver ***100 uL*** of sample into the sample port on the test card.
9. ***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

For Getein1600:

10. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
11. Put the sample diluent at the correct position in Getein1600.
12. 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 ＜1.0 and positive if COI is ≥ 1.0.

Display	Judgement
COI≥1.0	Positive (+): positive test for Flu A/Flu B/ SARS-CoV-2 (antigen present)
COI<1.0	Negative (-): presumptive negative test for Flu A/Flu B/ 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. It is recommended that each laboratory establish its own expected values for the population it serves.

Note:

1. Positive results indicate the presence of Flu A/Flu B/ 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 cannot 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 Flu A/Flu B/ SARS-CoV-2, 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 Flu A/Flu B/ 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 the test kit 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: 2016.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult 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
CE	CE mark		Do not use if package is damaged
REF	Catalogue number		

Thank you for purchasing Flu A/Flu B/ SARS-CoV-2 Antigen Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF99-S-01

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