GP

CE IVD

RSV/Influenza A/B Fast Test Kit (Immunofluorescence Assay)

Instructions for Use

REF IF1085 for Getein1100
IF5085 for Getein1160
IF3085 for Getein1180

INTENDED USE

RSV/Influenza A/B Fast Test Kit (Immunofluorescence Assay)is intended for *in vitro* qualitative detection of influenza A and influenza B antigens and respiratory syncytial virus (RSV) antigen in human nasal swab. The test is indicated to be used as an auxiliary diagnostic of influenza virus and respiratory syncytial virus infections in conjunction with clinical and epidemiological risk factors. For professional and laboratory use.

SUMMARY

Influenza, commonly known as the flu, is a contagious viral respiratory infection. The primary mode of transmission for influenza is through the air (i.e., coughing or sneezing), with peak transmission typically occurring in the winter. Common symptoms include fever, chills, headache, fatigue, cough, and nasal congestion. Symptoms usually appear within two days after exposure to an infected individual. Influenza infection can develop into pneumonia (a complication), increasing morbidity and mortality rates among children, the elderly, and individuals with compromised immune systems.

Influenza viruses are immunologically diverse and single-stranded RNA viruses. There are three types of infuenza 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.

Respiratory Syncytial Virus (RSV) is the most common virus that causes lower respiratory tract infection. RSV mainly invades human body through respiratory tract and spreads through air (droplets and dust). RSV mainly proliferates in nasopharyngeal epithelial cells. Symptoms of RSV infection mainly include cough, nasal congestion, runny nose, throat discomfort and other local symptoms of respiratory tract and general symptoms such as fever, fatigue, headache and muscle soreness.

The epidemic season of RSV is similar to that of influenza, with infections typically increasing from the fall and continuing through early spring. The test can rapidly identify the type of seasonal virus infecting a patient, effectively control viral infections, and aid in the selection of appropriate treatment plans, thereby preventing large-scale outbreaks.

PRINCIPLE

RSV/Influenza A/B Fast Test Kit(Immunofluorescence Assay) is a lateral flow immunoassay based on the double antibody sandwich principle. After the sample has been applied to the test strip, the fluorescence latex-labelled Flu A/Flu B/RSV monoclonal antibody bind with the Flu A/Flu B/RSV antigen in sample and forms a marked antigen-antibody complex.This complex moves to the test card detection zone by capilary action.Then marked antigen-antibody complex is captured on the test line by another Flu A/Flu B/RSV antibody.The fluorescence intensity of the test line increases in proportion to the amount of Flu A/Flu B/RSV antigen in sample. Fluorescent signals intensity can be analyzed by applicable device thus the Flu A/Flu B/RSV antigen in sample can be detected qualitatively.

CONTENTS

Materials provided	Main Components	Getein 1100/ Getein 1160/ Getein 1180	
		10 T/kit	25 T/kit
RSV/Influenza A/B test card	Fluorescence latex-labelled Flu A / Flu B / RSV monoclonal antibody, Flu A / Flu B / RSV monoclonal antibody and polyclonal IgG antibody	10 pcs	25 pcs
Disposable pipet	/	10 pcs	25 pcs
Sterile swab	/	10 pcs	25 pcs
Sample extraction solution	phosphate buffer (20 mmol/L), NaN3 (＜0.1%)	10 tube	25 tube
Instructions for use	/	1 pc	1 pc
SD card	/	1 pc	1 pc

Note:

1. 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".
2. Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

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

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 stored 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

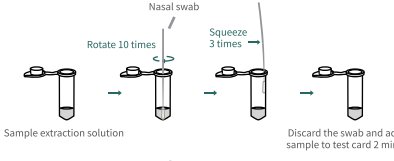
1. Sample should be ***human nasal swab sample.*** Samples should be tested immediately after collection for optimal test performance. Inadequate sample collection or improper sample handling/storage/transport may cause erroneous results.
2. Sample collection:
   Carefully insert a sterile swab into the nostril that presents the most secretion under visual inspection. Gently rotate the swab, and push the swab until resistance is met at the level of the turbinate (less than one inch into the nostril). Keep the swab in the nasal cavity for 15-30 s. Rotate the swab 3 times against the nasal wall then remove it from the nostril. If taking samples from two nostrils, use one swab for each.
3. Nasal swab samples should be processed with sample extraction solution after collection. The processed samples can be stored up to 8 h at 2-8°C before testing.

TEST PROCEDURE

User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.

1. Collect samples according to the instructions for use.
2. Test card, sample and reagent should be returned to room temperature (15~30°C) before testing.
3. 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 mins later.



Sample Pretreatment

For Getein1100:

1) Confirm SD card lot No. in accordance with test kit lot No. Read the relevant information in the SD card for calibration.
2) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
3) Select the sample type as “Swab” on Getein1100.
4) Using disposable pipette, deliver ***100 uL*** of sample into the sample well on the test card.
5) ***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.

For Getein1160/Getein1180:

1) Confirm SD card lot No. in accordance with test kit lot No. Read the relevant information in the SD card for calibration.
2) Enter testing interface of Getein1160/Getein1180.

3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
4) Using disposable pipette, deliver ***100 μL*** of sample into the sample well on the test card.
5) Insert the test card into Getein1160/Getein1180 **immediately** after sample loading. The analyzer will count down the reaction time and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

Note:

1. It is suggested to calibrate once for each batch of kits for Getein1100/Getein1180/Getein1160.
2. Make sure the test card and the sample insertion are correct and complete.

DISPLAY AND INTERPRETATION OF TEST RESULTS

1. Getein1100/Getein1180/Getein1160 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1180/Getein1160.
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.

Display	Judgement
COI≥1.00	Positive: positive test for Flu A, Flu B and RSV (antigen present)
COI<1.00	Negative: presumptive negative test for Flu A, Flu B and RSV (no antigen detected)
Invalid Test	Test invalid, repeat the test (some procedural error or malfunction of test cards and/or analyzers).

Note:

1. Positive results indicate the presence of Flu A, Flu B and RSV 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 and RSV antigens 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 and RSV antigens 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.
3. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected improperly.
4. Positive test results do not identify specific influenza A virus subtypes.
5. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.

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: 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 RSV/Influenza A/B Fast Test Kit (Immunofluorescence Assay). Please read this Instructions for Use carefully before operating to ensure proper use.


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