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Influenza A/B Fast Test Kit (Immunofluorescence Assay)

User Manual

REF IF1086 for Getein1100
IF5086 for Getein1160
IF3086 for Getein1180

INTENDED USE

Influenza A/B Fast Test Kit (Immunofluorescence Assay) is intended for the qualitative detection of nucleocapsid protein antigen from influenza A and influenza B in human nasal swab samples from individuals suspected of respiratory viral infection consistent with influenza A and influenza B by their healthcare provider. This test is intended for professional and laboratory use.

Influenza A/B Fast Test Kit (Immunofluorescence Assay) is an aid in the differentiate of patients with suspected influenza A and influenza B virus 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 influenza A and influenza B infection.

BACKGROUND

Influenza viruses are causative agents of highly contagious and acute viral infections of the respiratory tract. Influenza viruses are immunologically diverse and 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.

Autumn and winter season are the seasons with high incidence of influenza virus, and the early symptoms of respiratory virus infection are similar. Therefore, timely differentiation of diseases is particularly important.

PRINCIPLE

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 anti-influenza A and anti-influenza B nucleocapsid protein monoclonal antibody bind with the influenza A, influenza B antigen in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by another anti-influenza A and anti-influenza B nucleocapsid protein monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of influenza A and influenza B antigen in sample. Fluorescent signals intensity can be analyzed by applicable device thus the Influenza A/B antigen in sample can be detected qualitatively.

CONTENTS

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

Package specifications: 1 tests/kit, 3 tests/kit, 5 tests/kit, 10 tests/kit, 25 tests/kit, 50 tests/kit, 100 tests/kit.

1) Getein Influenza A/B test card in a sealed pouch with desiccant
2) Sample extraction solution
3) Sterile swab
4) Disposable pipette
5) User manual: 1 piece/kit
6) SD card: 1 piece/kit

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

2. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane, absorbent paper and liner. The test card contains fluorescence latex-labelled anti-influenza A and anti-influenza B nucleocapsid protein monoclonal antibody, another anti-influenza A and anti-influenza B nucleocapsid protein monoclonal antibody and goat anti-mouse IgG antibody.

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

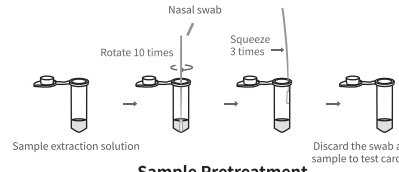
1. Sample should be ***human nasal swab sample***. Samples should be tested immediately after collection for optimal test performance. Inadequate sample collection or improper sample handling/storage/transport may cause erroneous results.
2. Sample collection:
   Carefully insert a sterile swab into 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

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

1. Collect samples according to user manual.
2. Test card, sample and reagent should be returned to room temperature (15~30°C) before testing.
3. Sample pretreatment:

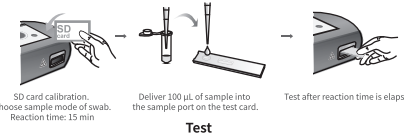
1) Take one tube of sample extraction solution, insert the nasal swab sample into the tube, and rotate the swab 10 times in the solution to make the sample dissolve in the sample extraction solution as much as possible.
2) Squeeze the swab tip along the inner wall of the sample extraction tube 3 times 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 min 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. Label the test card with patient identification.
3) Put the test card on a clean table horizontally.
4) Select the sample type as “Swab” on Getein1100.
5) Using disposable pipette, deliver ***100 uL*** of sample into the sample well on the test card.
6) ***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.



Test

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. Label the test card with patient identification.
4) Put the test card on a clean table, horizontally placed.
5) Using disposable pipette, deliver ***100 µL*** of sample into the sample well on the test card.
6) 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 ＜1.0 and positive if COI is ≥ 1.0.

Display	Judgement
COI≥1.0	Positive (+): positive test for influenza A and influenza B (antigen present)
COI<1.0	Negative (-): presumptive negative test for influenza A and influenza B (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 influenza A and influenza B 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 influenza A and influenza B 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 influenza A and influenza B 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: 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 Influenza A/B Fast Test Kit (Immuno-fluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

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