Influenza A/B virus Antigen Rapid Test Kit

(Fluorescence Immunochromatography)

User Manual

（For Medical Professional Use Only）

1.Product Name

Influenza A/B virus Antigen Rapid Test Kit (Fluorescence Immunochromatography)

2.Package Specification

20 T/box

3.Intended Use

The rapid detection kit for influenza A/influenza B antigen aims to qualitatively detect influenza A/influenza B antigen in oropharyngeal swab or nasopharyngeal swab samples in vitro.

4.Summary

Influenza viruses include type A, type B and type C. Type A is the most likely to cause epidemics, followed by type B, and type C rarely occurs. Influenza A virus can infect humans, poultry and other mammals, while influenza B virus and influenza C virus can only spread among people. The nucleotide sequence of influenza A virus encoding HA and/or NA is prone to mutation, resulting in the change of antigen epitopes of HA and/or NA. Therefore, influenza A virus has strong variability and is highly likely to cause epidemic. The antigenic variation of influenza B virus is very slow. There are also variations among viruses, and there are no subtypes among viruses. Although the mutation of influenza B virus will produce new mainstream strains, there is cross-immunity between the new and old strains, that is, the immune response to the old strain is still effective against the new strain, so it is unlikely to cause epidemic. The antigenicity of influenza C virus is very stable, so it rarely causes influenza.

According to the difference of antigenicity between hemagglutinin (HA) and neuraminidase (NA) proteins, influenza A virus can be divided into 16 subtypes H (H1-H16) and 9 subtypes N (N1-N9). Almost all subtypes can infect poultry. There are at least 8 different subtypes in pigs, while there are mainly 3 HA subtypes and 2 NA subtypes in humans, namely H1N1, H2N2 and H3N2. However, birds and pigs can be infected with different subtypes of virus. When mixed infection occurs, different segments of the virus will match again, resulting in virus mutation. These mutated viruses can cross species barriers and infect people under specific circumstances, leading to influenza pandemic in people.

5.Test Principle

The rapid detection kit of influenza A/influenza B antigen uses immunochromatography. Fix the marker containing anti-influenza A antibody 1/anti-influenza B antibody 1 on the binding pad, and coat the anti-influenza A antibody 2/anti-influenza B antibody 2 on the corresponding nitrocellulose membrane detection line. The goat anti-rabbit IgG was coated on the quality control line (line C) of nitrocellulose membrane. When the concentration of influenza A/B in the sample is higher than that of influenza LoD (minimum detection limit), influenza A/B in the sample can form a complex with anti-influenza antibody 1/anti-influenza B antibody 1 of the labeled particles. The complex moves to the test line under the action of chromatography, where it will be captured by the anti-influenza A antibody 2/anti-influenza B antibody 2, and combined on the test line to form a "labeled particle - anti-influenza A antibody 1 - (influenza A) - anti-influenza A antibody 2"/"labeled particle - anti-influenza B antibody 1 - (influenza B) - anti-influenza B antibody 2" complex.

Detection principle of the supporting instrument: insert the reaction detection card into the supporting fluorescence immunoassay quantitative analyzer, and the measuring system of the instrument will automatically scan the binding area of the fluorescent marker and the object to be measured and obtain the optical signal. The instrument quantitatively obtains the concentration of the measured substance by analyzing and processing the obtained optical signal.

6.Components

This test kit consist of :

① Individually Packaged Test Cassette

a. One kit device

b. One desiccant

② Sample buffer: 1.5mL/bottle/test

③ ID Card

④ Quick Reference Instructions

7.Materials Required but not Provided

(1)Timer or watch

(2)Fluorescent Immunoanalyzer

(Model type: GTF2600, GTF3000B. Manufactured for International Biomedical Supplies INC.)

8.Storage and Expiration Date

It is stored at 2~30℃, and its validity period is 24 months. After the aluminum foil bag is opened, the test card should be used within 60 minutes. See the product label for the

production date and expiration date.

9.Specimen Requirements

1. Nasal swab: let the patient's head relax naturally, slowly rotate the swab against the wall of the nostril into the patient's nostril to the nasal palate, and then slowly rotate and take it out when wiping. Wipe the other nostril with the same cotton swab and use the same method; Put the swab sample into the extraction tube, roll the swab 3 to 5 times (3-5 times), and leave the swab in the extraction tube for 1 minute. Pinch and pull out the tube with your fingers, and take out the solution from the cotton swab as much as possible.
2. Pharyngeal swab: make the patient's head slightly backward, open his mouth, and make a "ah" sound. Gently wipe both sides of the patient's pharyngeal tonsils with a hand swab that exposes the tonsils, and then rub at least three times on the back wall of the pharynx. Put the specimen into the extraction tube with a mop, roll the cotton swab 3 to 5 times (3-5 times), and leave the cotton swab in the extraction tube for 1 minute. Pinch the tube with your fingers and take out as much solution as possible from the cotton swab.
3. Nasopharyngeal swab: put the nasal swab into the sampling tube of the collected pharyngeal swab. In this way, there are throat swabs and nasal swabs in the sampling tube, namely the so-called nasopharynx swab tube. Put the swab sample into the extraction tube, roll the swab 3 to 5 times (3-5 times), and leave the swab in the extraction tube for 1 minute. Pinch and pull out the tube with your fingers, and take out the solution from the cotton swab as much as possible.
4. Samples should be used as soon as possible after collection (within half an hour).
5. The sample should not be inactivated.

10.Testing Procedures

Open the test bag after the test is ready. It is recommended to conduct a one-time test at low ambient humidity (RH ≤ 70%) within 1 hour. Before the test, the room temperature is required to reach 18 ° C~26 ° C. Remove the test card from the aluminum foil bag and place it on a clean and dry surface.

- Machine operate

1. Before the experiment, take out the samples and test reagents to be tested from the storage conditions and balance them to room temperature.
2. Take out the kit ID card and store the kit data in the fluorescence immunoassay analyzer.
3. Put the test card in the card warehouse.
4. Remove the soft glue plug from the buffer tube.
5. Put the swab sample into the extraction buffer tube, roll the swab 3 to 5 times.
6. Break the swab head in the test tube.Press the cover tightly on the tube to avoid any leakage.
7. Shake the specimen collection tube vigorously to mix the specimen and the dilution buffer.
8. The main end of the swab tube is down,make sure the liquid soak the swab,leave the tube alone for 2 minutes.
9. The specimen collection tube was shaken, placed on the test tube rack, and tested by machine.
10. Select the sample type on the machine, establish the test task, and give the results after 15 min.

- Manual operate

1. Before the experiment, take out the samples and test reagents to be tested from the storage conditions and balance them to room temperature.
2. Take out the kit ID card and store the kit data in the fluorescence immunoassay analyzer.
3. Remove the soft glue plug from the buffer tube.
4. Put the swab sample into the extraction buffer tube, roll the swab 3 to 5 times.
5. Leave the head of the swab inside the tube.Press the cover tightly on the tube to avoid any leakage.
6. Shake the specimen collection tube vigorously to mix the specimen and the dilution buffer. Make sure the liquid soak the swab,leave the tube alone for 2 minutes.
7. Shake the specimen collection tube and add 100 μ L, put the liquid into the sample hole of the test card and start the timing.
8. React at room temperature for 15 minutes, use fluorescence immunoassay analyzer to test, read or print the test results.

11.Expected Value

Negative judgment value: Flu A<0.5ng/ml, Positive judgment value: ≥0.5ng/ml.

Negative judgment value: Flu B<1.0ng/ml, Positive judgment value: ≥1.0ng/ml.

The test results of this reagent are only for reference, and the patient's diagnosis results need to be judged in combination with clinical diagnosis.

12.Interpretation of Test Result

1. Use fluorescent immunoanalyzer to analyze the test card and issue quantitative test results. Professional personnel are responsible for the review and analysis of test results, which are usually considered normal within the reference range and are influenced by age, sex, diet and region.

2. The test results of this reagent are for clinical reference only, and the clinical diagnosis and treatment of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment response.

13.Limitation of Test Method

1. This kit is only used for in vitro diagnosis, and only for detecting influenza A/influenza B antigen in oral and nasopharyngeal swab samples.
2. This kit is only used for qualitative detection of influenza A/B antigen, and cannot determine the quantity of influenza A/B antigen in the sample.
3. If the clinical symptoms persist, but the test result is negative, it is recommended to re-sample or use other methods for testing. Negative results cannot completely rule out the possibility of infection with influenza A/influenza B.
4. The test results of this kit are only for the reference of clinicians and should not be used as the only basis for clinical diagnosis. The clinical diagnosis should be combined with the patient's symptoms/signs, medical history, other laboratory test results, treatment response, etc.
5. Due to the limitations of the detection method, the LOD of this kit is generally lower than that of nucleic acid reagent. Therefore, the tester should pay more attention to the negative results and make a comprehensive judgment in combination with other test results. In case of doubt, it is recommended to use nucleic acid reagent or virus isolation and culture identification method to recheck negative.
6. Analysis of the possibility of false negative results:
(1) The sample collection, transportation and treatment are unreasonable, the virus concentration in the sample is low, and the long-term storage of the sample or repeated freezing and thawing of the sample may lead to false negative results.
(2) The mutation of virus gene may lead to the change of antigen factor, which may lead to false negative results.
(3) In some new type A/B influenza outbreaks, the virus may mutate, resulting in differences in the best sampling time (peak virus titer) and sampling location. Therefore, multiple site sampling or multiple follow-up of the same patient can reduce the possibility of false negative results.

14.Warnings and Precautions

For *in Vitro* Diagnostic Use

1. The reagent is a disposable diagnostic reagent in vitro, which is only used to detect human nasal swabs, nasopharyngeal swabs or oropharyngeal swabs. The operation shall be carried out in strict accordance with the instructions. Do not use expired and damaged products.
2. The reagent shall be sealed and kept away from moisture. Reagents or samples stored at low temperature should be taken out and balanced to room temperature before use.
3. The reagent should be used as soon as possible after being taken out of the aluminum foil bag to avoid long-term exposure to the air and affect the test results due to humidity.
4. Do not use samples that have been stored for too long or contaminated.
5. Please follow the infectious disease laboratory testing procedures. The waste after use shall be treated as infectious substances and shall not be discarded anywhere.
6. Incorrect operation may affect the accuracy of the results, such as insufficient sample mixing, insufficient quantity, inaccurate detection time, etc.
7. Components of different batches shall not be mixed.
8. It is recommended to use "fresh samples" for testing. If the test cannot be carried out on the same day, the samples collected with cotton swabs should be kept at minus 20 ℃, stored and transferred under dry conditions.
9. There should be appropriate biosafety assurance procedures for substances containing and suspected sources of infection. The following are relevant considerations:
1) Wear gloves to handle samples and reagents;
2) Do not suck the sample with your mouth:
3) When handling these items, do not smoke, eat, drink, make up or handle contact lenses;
4) Disinfect the spilled sample or reagent with disinfectant;
5) Disinfect all samples, reagents and potential pollutants according to relevant local regulations;
6) Within the validity period of the reagent, each component shall be stable under proper handling and storage conditions. Do not use expired reagents.

15.Reference

1, Peaper DR, Landry ML. Rapid diagnosis of influenza: state of the art. Clin Lab Med. 2014;34(2):365–385. doi:10.1016/j.cll.2014.02.009
2. Patel J, Sharma P. Design of a novel rapid immunoassay for simultaneous detection of hepatitis C virus core antigen and antibodies. Arch Virol. 2020;165(3):627–641. doi:10.1007/s00705-019-04518-0
3. Chafekar A, Fielding BC. MERS-CoV: Understanding the Latest Human Coronavirus Threat. Viruses. 2018;10(2):93. Published 2018 Feb 24. doi:10.3390/v10020093