Influenza B（FluB）Virus Antigen Rapid Test Kit (Colloidal Gold)
User manual

【Product name】
Influenza B （FluB）Virus Antigen Rapid Test Kit (Colloidal Gold)

【Package specification】
25 Tests/kit

【Intended use】
It is used for qualitative detection of influenza B virus antigens in human nasopharyngeal swab and oropharyngeal swab samples. It is applicable to the auxiliary diagnosis of influenza B virus infection.

【Inspection principle】
Double antibody sandwich method was used to detect influenza B virus antigens by immunochromatography. During detection, the treated extract is added to the sample adding hole of the test card. When the sample to be tested contains influenza B virus antigen and the antigen concentration is higher than the minimum detection limit, influenza B virus antigen first forms a reaction complex with the labeled antibody, and the reaction complex moves forward along the nitric acid fiber membrane under the action of chromatography, It is captured by the monoclonal antibody of influenza B virus nucleoprotein pre coated in the detection areas on the nitric acid fiber membrane, and a red reaction line is finally formed in the detection areas. At this time, the result is positive; On the contrary, when the sample does not contain influenza B virus antigen or the antigen concentration is lower than the minimum detection limit, there is no red reaction line in the detection area, and the result is negative. No matter whether the sample contains influenza B virus antigen, a red reaction line will be formed in the quality control area (c). The red reaction line displayed in the quality control area (c) is not only the standard to judge whether the chromatographic process is normal, but also the internal control standard of the reagent.

【Components】

Name	Quantity	Component
Test cards	25	a) Monoclonal antibodies against influenza B virus nucleoprotein (fixed in the T region of nitrocellulose membrane); b) Sheep anti mouse immunoglobulin G (IgG) polyclonal antibody (fixed in region C of nitrocellulose membrane); c) Colloidal gold labeled monoclonal antibody against influenza B virus nucleoprotein (fixed on glass fiber); d) Other test strip supports.
Sample diluent	25（400μL/tube）	Phosphate buffer
Swabs	25	Flocking

The components in different batches of kits cannot be used interchangeably.

【Storage conditions and validity】
The kit should be stored at 4℃~30℃, out of direct sunlight. It is valid for 18 months. The test card should be used within 15 minutes after unsealing under the environment of 15℃~30℃ and 20% ~ 90% relative humidity.
The production date, batch number and expiration date are shown in the outer package of the product.

【Sample requirements】
1. Collection of nasal secretions: when collecting nasal exudates, insert the swab into the place with the most secretions in the nasal cavity, gently rotate and move the swab towards the inside of the nasal cavity until the turbinate (about 2.0cm ~ 2.5cm away from the nostril) is blocked, stick to the nasal wall, rotate the swab three times, and take out the swab.

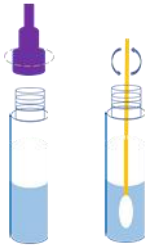
2. Collection of throat secretions: insert the throat completely from the mouth, take the throat wall and the red part of the maxillary amygdala as the center, wipe the bilateral pharyngeal tonsils and the posterior pharyngeal wall with moderate force, avoid touching the tongue, and take out the swab.

3. After the collection of samples, the virus sampling solution or the sample extraction solution provided by this kit shall be used for treatment as soon as possible. If the specimen cannot be processed immediately, it shall be stored immediately in a dry, sterilized and tightly sealed plastic tube. It can be stored for 8 hours at 2℃ ～8℃ and for a long time at - 70℃.

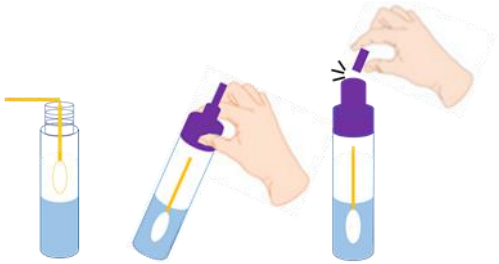
【Test procedure】

Please read the operating instructions carefully before testing. Please restore all tests to room temperature before the test. The test shall be carried out at room temperature.

1. Insert the swab after sampling into the sample buffer and rotate it close to the inner wall of the test tube for about 10 times to make the sample dissolve in the solution as much as possible.

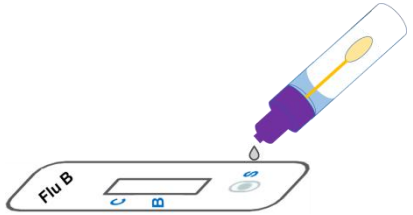


2. Squeeze the cotton swab head of the swab along the inner wall of the extraction tube to keep the liquid in the tube as much as possible. Break the tail of the swab, cover the extraction tube cover, and break the upper part of the extraction tube after mixing.

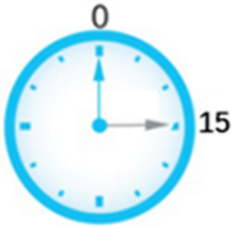


3. Open it along the opening of the aluminum foil bag, take out the reagent card and place it flat.

4. Drop 80 μL (about 3-4 drops) of treated sample extract into the sampling hole of the test card or directly add 80 μL of treated virus culture medium.



5. Observe the displayed results within 15 ～ 20 minutes, and the results displayed after 30 minutes have no clinical significance.



【Interpretation of results】

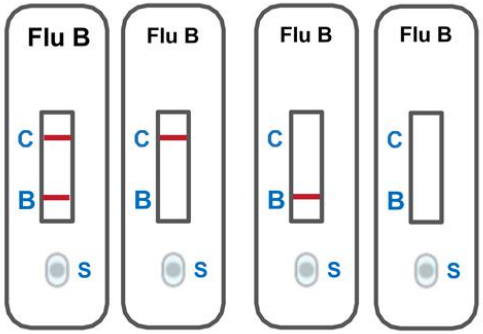
1. FluA positive: two red reaction lines appear, one in zone B and one in Zone C (quality control area).

2. Negative: only one red reaction line appears in area C of quality control area, and no visible red / pink band appears in B area

5. Invalid: there is no red reaction line in the quality control area (c), and the inspection is invalid. It is recommended to retest with a new test card at this time

Note: the color development depth of the reaction line is related to the content of the tested substance contained in the extracted sample. Regardless of the color intensity, the result shall be determined according to whether the reaction line is color developed or not.

This reagent contains quality control process. When a red reaction line appears in Zone C, it indicates that the operation is correct and effective, otherwise the detection is invalid.



【Limitations of methods】

1. This reagent is only used to detect respiratory secretions of nasopharyngeal swabs and oropharyngeal swabs.

2. The test card only provides qualitative detection for influenza B virus in the sample. If you need to test the specific content of a certain index, please use relevant professional instruments.

3. The test results of this reagent are only for clinical reference and shall not be used as the only basis for clinical diagnosis and treatment. The clinical management of patients shall be comprehensively considered in combination with their symptoms / signs, medical history, other laboratory tests and treatment reactions.

4. Possibility analysis of false negative results

① Unreasonable sample collection, transportation and treatment, and low virus titer in the sample may lead to false negative results.

② Viral gene variation may lead to changes in antigenic determinants, resulting in false results.

③ The optimal sample type and the optimal sampling time (peak virus titer) after infection have not been verified. Therefore, collecting samples in multiple parts and times in the same patient may avoid false infection.

5. Cross reactivity:

(1) Influenza A virus and influenza B virus do not interact with each other.

(2) Influenza C virus, parainfluenza virus, adenovirus, respiratory syncytial virus, herpes simplex virus, epidemic virus, fan virus, respiratory Chlamydia, mycoplasma, Mycobacterium tuberculosis, pertussis, Candida albicans, diphtheria, Haemophilus influenzae, Legionella pneumoniae, Mycobacterium tuberculosis, Staphylococcus aureus, enterovirus 71 (EV71) bacteria Coronavirus, etc.

6. Interfering substances:

The common interfering substances in the sample, such as blood, mucin and pus, have no effect on the test results. Drugs used to treat or alleviate influenza symptoms, such as nasal corticosteroids, analgesics and antipyretics, decongestants, antitussive drugs, antihistamines and antiviral drugs, have no effect on the test results.

7. Hook effect:

When the concentration of influenza B virus in the sample is less than $5.1 \times 10^6 TCID_{50}$ / ml, there was no hook effect. When the concentration of influenza B virus is less than $5.6 \times 10^6 TCID_{50}$ / ml, there was no hook effect.

【Performance】

1. Limits of detection

No higher than $1.0 \times 10^2 TCID_{50}$ /ml.

2. Sensitivity:

95.24% (91.75%～97.14%)

3. Specificity:

100.00% (96.34%～100.00%)

【Note】

1. This product is a disposable in vitro diagnostic reagent. Do not use expired products.

2. There is no color band on the quality control line and inspection line, indicating that there is an error and the detection should be retried.

3. Avoid the high temperature of the test environment. The test card stored at low temperature needs to be restored to room temperature and then opened to avoid moisture absorption.

4. It is recommended to use fresh samples instead of repeated freeze-thaw samples.

5. For sampling, please use the sub sample and sample extract provided by this test box. Do not mix different batches of test cards and sample buffer.

6. If the virus sampling solution is used to treat the sample, it can be detected directly without diluting the sample extraction solution.

7. For the detection of influenza B virus or subtypes, the small change of antigen epitope caused by small-scale mutation of nucleic acid sequence may lead to the reduction of clear results or the analytical sensitivity of reagents.

8. Pay attention to safety measures during operation, such as wearing protective clothing, gloves, etc. The used swabs, test cards and extraction tubes shall be decontaminated before being discarded. It is recommended to disinfect them with high-pressure steam.

【Interpretation of signs】

	Storage temperature		Non reusable
	Avoid light	IVD	In vitro diagnostic reagents
	moisture-proof		See instruction manual

【Reference】

[1] Fraser C. WHO Rapid Pandemic Assessment Collaboration. Pandemic Potential of a Strain of Influenza B (H1N1) [J]. Early Findings. Science, 2009, 324.

[2] Yuan, Liu, Aihua, et al. Detection of 3-phenoxybenzoic acid in river water with a colloidal gold-based lateral flow immunoassay [J]. Analytical Biochemistry, 2015.

【Essential information】

Registered/manufacturer name: WWHS Biotech. Inc

Address: Rm505, 1st building, Shenzhen Biomedical Innovation Industrial Park, No. 14th, Jinhui Road, East Jinxiu Road, Kengzi Street, Pingshan District, Shenzhen

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