One Step Influenza A&B Test

Catalog No. W71-CH

Wondfo One Step Influenza A&B Test is a qualitative test that detects influenza type A and influenza type B nucleoprotein antigen extracted from the nasal swab and throat swab specimens. The device can help you to determine whether you have infected the influenza type A and B viruses.

For *in vitro* use only. For self-testing use.

HOW DOES IT WORK?

Influenza (commonly known as 'flu') is a highly contagious, acute viral infection of the respiratory tract. It is a communicable disease that is easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus. Influenza outbreaks occur each year during the autumn and winter months. There are three types of influenza viruses: A, B, and C. The influenza A virus is associated with the most serious influenza epidemics. Influenza B is milder and slower in infection rate than the A virus, yet more serious and faster in infection rate than the C virus. Influenza producing symptoms such as headache, chills, dry cough and fatigue.

In the meantime some medicaments are in use for the treatment of an influenza infection, they strongly reduce the virulence and the symptoms of the disease but only if they are used in the first 24 to 30 hours after the first appearance of symptoms. Especially for high risk groups, it is useful having a home test within reach to be able to make a diagnosis at the appearance of the first symptoms. Having a positive test result, you can immediately get medical aid and a treatment can be started.

Wondfo One Step Influenza A&B Test is a rapid immunochromatographic test for the visual detection of influenza type A and B nucleoprotein antigens extracted from the nasal swab or throat swab specimen.

When specimen is dropped into cassette, capillary action carries the specimen to migrate along the membrane. When the influenza type A antigen levels are equal to or above the target cutoff, there is a visible colored band in the test region "2" close to control region. Absence of this test colored band in the test region close to control region suggests a negative result.

When the influenza type B antigen levels are equal to or above the target cutoff, there is a visible colored band in the test region "1" away from control region. Absence of this test colored band in the test region away from control region suggests a negative result.

To serve as a procedure control, a colored line will appear at the Control Zone region, if the test has been performed properly.

CONTENT OF THE TEST KIT

1. 1 Individual sealed pouch, each containing:
   - Test device
   - Desiccant pouch
2. 1 Extraction tube
3. 1 Sterile swab CE 0197 MDD 93/42/EEC
   The swab is for collecting sample. The information from supplier is listed below:
   Manufacturer: Shenzhen Miraclean Technology Co., Ltd
   3 FL, 18 Rongshuxia Industry, Tongle Community, Long Gang District, Shenzhen, P.R.China
4. One bottle of extraction buffer (0.4 mL): 0.1M phosphate buffer saline (PBS).
5. Leaflet with instructions for use.

WHAT ELSE DO YOU NEED?

Timer (watch or clock)
Spoon (optional)
Medical gloves

PRECAUTIONS

1. This kit is for in vitro diagnostic use only. Do not swallow.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.
6. Discard after use. The test device cannot be used more than once.
7. The extraction tube and sample collection swab are single use items – do not use with multiple specimens.
8. Wear protective gloves while handling specimens.
Wash hands thoroughly afterwards.
9. Be careful not to spill the extraction buffer when placing the specimen swab in the tube. Negative results can occur from inadequate specimen collection and/or handling.
10. The used device, swab and extraction tube have the infectious risk, disposing them as if they were infectious waste, in a biohazard container.

STORAGE AND STABILITY

1. Store 4ºC to 30ºC in the sealed pouch up to the expiration date.
2. Keep away from direct sunlight, moisture and heat.
3. DO NOT FREEZE.
4. The test device should be used within 1 hour once opened.

SPECIMEN COLLECTION AND PREPARATION

Nasal swab sample:

1. As shown in the Figure 1: Take out the sterile swab provided. Tilt your head backwards to the angle of 70°.
2. Gently insert the swab into the nostril which shows the most secretion. Turn the swab twice to complete 360-degree rotation. Press firmly against the nasal mucosa to ensure adequate sample is taken.

Throat swab sample:

1. As shown in the Figure 2: Take out the sterile swab provided. Open your mouth and stick your tongue out, press the tongue downward with spoon if necessary.
2. Rub the swab on both tonsillar surfaces and the posterior pharynx. Avoid touching the tongue, cheeks and teeth.

Figure 1

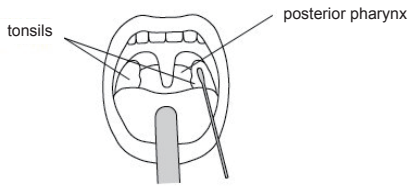


Figure 2

Your samples perform best if tested immediately after collection.

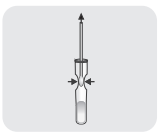
HOW TO DO THE TEST?

The test device, specimen, and extraction buffer have to be at room temperature (10~30°C) prior to testing.

1. Use an extraction tube (provided) for each specimen to be tested, and label each tube appropriately. Transfer all of the extraction buffer (0.4mL) to the extraction tube.

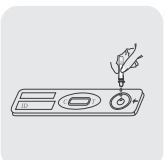
2. Place the specimen swab in the tube and swirl the swab for 10 times while pressing the swab head against th e inside of the tube to release the specimen in the swab.
   Note: Be careful not to spill the extraction buffer.

3. Remove the swab while squeezing the swab head against the inside of the collection tube as you remove it to expunge as much liquid as possible from the swab. Discard the swab.



4. Cap the tube and mix contents by gently swirling. **The extraction specimen must be tested immediately.**

5. Rmove the test device from its sealed foil pouch by tearing at the notch. Dispense 3~4 drops (80 µl~100µl) of extraction specimen from the extraction tube into the sample well (with an arrow marked) of the test device by inverting and squeezing the tube as shown.



6. Read the test results at 15~20 minutes. **Do not read test results after 30 minutes.**

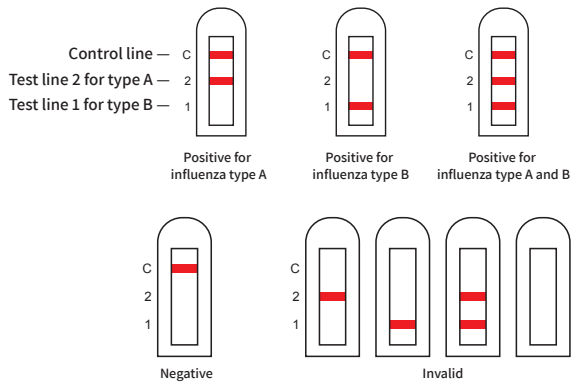
HOW TO READ THE RESULTS?

Positive (+)
A colored band is visible in the control region and one or two bands in the appropriate test region. It indicates a positive result for the influenza type A/B of that specific test zone.

1. Type A positive: One color band presents in test region "2" close to control region and one band in control region indicates influenza type A positive.
2. Type B positive: One color band presents in test region "1" away from control region and one band in control region indicates influenza type B positive.
3. Type A and B positive: both two test bands present in the two test regions ("1"+"2") and one band in control region indicate influenza type A and B positive.

Negative (-)
A colored band is visible only in the control region. No color band appears in the test region. It indicates that the concentration of the influenza type A/B antigen is zero or below the detection limit of the test.

Invalid
No visible band at all or there is a visible band only in the test region but not in the control region. Repeat with a new test kit. If test still fails, please contact the distributor or the store, where you bought the product, with the lot number.



Note: There is no meaning attributed to line color intensity or width.

PERFORMANCE CHARACTERISTICS

Analytical reactivity
Wondfo One Step Influenza A&B Test was tested with the following influenza A and influenza B subtypes, all showed positive results:

Viral Type	Viral Subtype
A	H1N1
A	H3N2
A	H5N1
B	Victoria Lineage
B	Yamagata Lineage

Note: *The performance of this test has not been evaluated for specific influenza A/B subtypes other than above subtypes. Additional testing is required to differentiate any other specific influenza A/B subtypes or strains.*

LIMITATIONS

1. This test has been developed for testing nasal swab or throat swab specimen only.
2. As it is with any diagnostic procedure, a confirmed Influenza A/B infection diagnosis should only be made by a physician after evaluating all clinical and laboratory findings.
3. Taking some prescription and non-prescription medicines with high concentration such as nasal spray may affect this test.
4. Negative test results may occur if the level of antigen in a sample is below the detection limit of the test, or from improper sample collection, and the negative results are not intended to exclude other non-influenza viral infections.
5. Positive test results do not exclude co-infections with other pathogens and does not identify specific influenza A/B virus subtypes.

QUESTIONS &ANSWERS

1. Can Wondfo One Step Influenza A&B Test detect other types of influenza viruses?
No. The influenza type A and B monoclonal antibodies were coated in the membrane of the test device, which are specific to detect the influenza type A and B nucleoprotein antigens.

2. There is much difference between the control lines of two tests. Is that a concern?
No. Variations in the color of the control band will not affect the test result.

3. When should I do the test?
When you have symptoms of sudden high fever, severe generalized muscle pain, and other symptoms similar to influenza viruses, you are supposed to do the test.

4. If the test result is positive, what should I do?
A positive test indicates you may be infecting the influenza A /B viruses. Please see a doctor for medical aid.

5. If my test result is negative, does it mean I have not got influenza A/B viruses infected?
No, negative results do not preclude influenza A/B viruses infection and should not be used as the sole basis for treatment or other patient management decisions. If you are experiencing some of the common symptoms associated with influenza, you should consult with your doctor.

BIBLIOGRAPHY

1. Kristi A. Covalciuc, Kenneth H. Webb, Curtis A. Carlson. Comparison of Four Clinical Specimen Types for Detection of Influenza A and B Viruses by Optical Immunoassay (FLU OIA Test) and Cell Culture Methods. Journal of Clinical Microbiology. 1999, 37(12):3971-3974
2. Marita Smit, Kirsten A. Beynon, David R. Murdoch, et al. Comparison of the NOW Influenza A & B, NOW Flu A, NOW Flu B, and Directigen Flu A+B assays, and immunofluorescence with viral culture for the detection of influenza A and B viruses. Diagnostic Microbiology and Infectious Disease, 2007, 57:67-70
3. Uyeki, Timothy M., Prasad Ramakrishna, Vukotich Charles, et al. Low Sensitivity of Rapid Diagnostic Test for Influenza. Brief Repotr CID, 2009, 48: 89-92
4. L. J. R. van Elden, M. Nijhuis, P. Schipper, et al. Simultaneous Detection of Influenza Viruses A and B Using Real-Time Quantitative PCR. Journal of Clinical Microbiology, 2001, 39(1): 196-200
5. Templeton, K. E., Scheltinga, S. A., Beersma, M. F. C, et al. Rapid and Sensitive Method Using Multiplex Real-Time PCR for Diagnosis of Infections by Influenza A and Influenza B Viruses, Respiratory Syncytial Virus, and Parainfluenza Viruses 1, 2, 3, and 4. Journal of Clinical Microbiology, 2004, 41(4): 1564-1569

MEANING OF SYMBOLS ON PACKAGE

IVD *For In Vitro* Diagnostic Use Only	See Instruction for Use	Expiry Date
Tests per Kit	Manufacturing Date	Keep Dry
LOT Batch Number	EC REP Authorized Representative	Keep away from Sunlight
Manufacturer	Do not reuse	REF Catalog #
30°C 4°C Store between 4~30°C		

Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Luogang District,
510663, Guangzhou, P.R.China
Tel: (+86)400-830-8768
E-mail: sales@wondfo.com.cn
Website: en.wondfo.com.cn

CE 0123 EC REP
Qarad BV
Cipalstraat 3
2440 Geel
Belgium

Rev.A1 Rel.: 2022/03/09

Wondfo 万孚	物料编码：13014591	项目名称：流感A&B分泌物卡1T说明书(210*285mm)70g双胶英文V02		
	尺寸(长*宽*高)：210*285mm	颜色：K20 C100M40	材质：70g双胶	工艺：
	折页方式：长边风琴3折4页+短边对折	修改内容：□文字 □颜色 □尺寸 □工艺 □材质 □其他 □无		修改内容截图
	改稿前编码：	申请人：赵慧婷	设计师：朱雅静	设计时间：2022.03.10

稿件确认签名：