Wondfo One Step Influenza A&B Test

INTENDED USE

Wondfo One Step Influenza A&B Test is intended for use by healthcare professionals and as qualitative screening *in vitro* diagnostic test for detection of influenza type A (including the subtype H1N1) and B nucleoprotein antigens extracted from the nasal swab specimen. These devices are used to aid in the differential diagnosis of influenza type A and B infection. This test is not automated and does not require any additional instrument.

For *in vitro* diagnostic use only. For professional use only.

SUMMARY

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. Only influenza A viruses are further classified by subtype on the basis of the two main surface glycoproteins hemagglutinin (HA) and neuraminidase (NA). Influenza A subtypes and B viruses are further classified by strains.
Humans can be infected with influenza types A, B, and C viruses. Subtypes of influenza A that are currently circulating among people worldwide include H1N1, H1N2, and H3N2 viruses. Influenza B viruses can cause morbidity and mortality among humans, but in general are associated with less severe epidemics than influenza A viruses. Although influenza type B viruses can cause human epidemics, they have not caused pandemics. Influenza type C viruses cause mild illness in humans and do not cause epidemics or pandemics.

PRINCIPLE

Wondfo One Step Influenza A&B Test is a rapid immunochromatographic test for the visual detection of influenza type A and B antigens (nucleoprotein) extracted from the nasal swab specimen. The test adopts double antibody sandwich method.
When the extracted specimen is added into the test device, the specimen is absorbed into the device by capillary action, mixes with antibody-dye conjugate, and flows across the pre-coated membrane, in which influenza type A and B monoclonal antibodies are coated respectively.

When the influenza type A antigen levels are at or above the target cutoff (the detection limit of the test), type A antigen in the specimen binds to the specific antibody-dye conjugate and are captured by influenza type A monoclonal antibody immobilized in the relative site of Test Region "2" of the device. This produces a colored test band in the Test Region "2". When the influenza type A antigen levels are zero or below the target cut off, there is not a visible colored band in the Test Region "2" of the device. This indicates a negative result for influenza type A.

When the influenza type B antigen levels are at or above the target cutoff (the detection limit of the test), type B antigen in the specimen binds to the specific antibody-dye conjugate and are captured by influenza type B monoclonal antibody immobilized in the relative site of Test Region "1" of the device. This produces a colored test band in the Test Region "1". When the influenza type B antigen levels are zero or below the target cut off, there is not a visible colored band in the Test Region "1" of the device. This indicates a negative result for influenza type B.

To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly.

PRECAUTIONS

1. This kit is for *in vitro* diagnostic use only.
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. Each test device cannot be used more than once.
7. The extraction tube and nasal swab are single use items – do not use with multiple specimens.
8. All specimens should be treated as potentially infectious diseases Protection glove should be worn when handling the specimen. Wash hands thoroughly afterwards.
9. Avoid splashing or aerosol formation.
10. Keep out of the reach of children.
11. The test result should be interpreted by the clinician along with clinical findings and other laboratory test results.
12. The desiccant is for storage purpose only, and is not used in the test procedure.
13. **DISPOSAL OF THE DIAGNOSTIC:** All specimens and used device, swab and extraction tube have infectious risks. The disposal process must follow the local infectious disposal law or laboratory rule.
14. If you have questions or suggestions during the use of this reagent, please contact the local distributor to solve problems timely.

MATERIAL

Materials Provided

REF	Sealed pouches*	Extraction tube	Sterile swab**	Extraction buffer (6 mL/bottle)	IFU
W059P0010	20	20	20	2	1
W059P0011	25	25	25	2	1
W059P0012	40	40	40	4	1
W71-C	25	25	25	2	1

*Each sealed pouch contains 1 Test Cassette and 1 Desiccant pouch.
** CE information of sterile swab: CE 0197 MDD 93/42/EEC

Materials Required but Not Provided

Timer

STORAGE AND STABILITY

1. Store at 4~30 ºC in the sealed pouch up to the expiration date.
2. The test cassette should be used within 1 hour after taking out from the foil envelope.
3. Keep away from sunlight, moisture and heat.
4. DO NOT FREEZE.
5. Kit contents are stable until the expiration date printed on the outer box.
6. The manufacturing date is printed on the outer box.

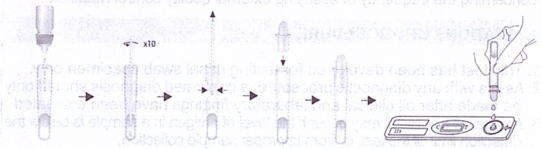
SPECIMEN COLLECTION AND PREPARATION

1. Take out the sterile swab provided. Tilt the head of the patient backwards to the angle of 70° and gently insert the sterile swab into the nostril which shows the most secretion.
2. Very gently rotate and push the swab until resistance is met at level of the turbinate. Gently rotate the swab against the nasal wall for a few times.
3. Patient samples perform best if tested immediately after collection. If immediate testing is not possible, the swab should be placed in a dry, sterile plastic tube (not provided) and stored at 2~4ºC for up to 8 hours.

TEST PROCEDURE

Allow the test cassette, specimen, and extraction buffer to equilibrate to 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.
2. Hold the extraction buffer bottle upside down vertically, then add 400µL of extraction buffer to the extraction tube.
3. Place the specimen swab in the tube and swirl the swab for 10 times while pressing the swab head against the inside of the tube to release the specimen in the swab.
4. 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. Cap the tube and mix contents by gently swirling. **The extraction specimen must be tested immediately.**
5. Remove the test cassette from its sealed foil pouch by tearing at the notch. Dispense 80µL (about 3~4 drops) of extraction specimen from the extraction tube into the sample well 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.**



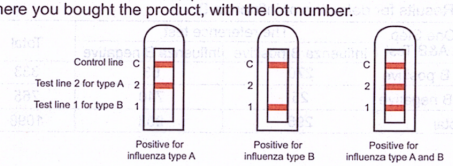
INTERPRETATION OF RESULTS

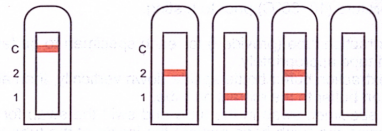
Positive (+)
A colored band is visible in the control region and one or two bands in the appropriate test region. It indicates a positive result for the influenza type A / B of that specific test zone.

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 type 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 in the control region. No colored band appears in the appropriate test region. It indicates that the concentration of the influenza type A/B antigen of that specific test zone 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. Another test should be run to re-evaluate the specimen. 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.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing nasal swab specimen only.
2. As it is with any diagnostic procedure, a confirmed diagnosis should only be made after all clinical and laboratory findings have been evaluated.
3. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test, or from improper sample collection.
4. Negative test results are not intended to rule-out other non-influenza viral infections.
5. Positive test results do not rule out co-infections with other pathogens and does not identify specific influenza A virus subtypes.

PERFORMANCE CHARACTERISTICS

A. Sensitivity and Specificity

A comparison study of Wondfo One Step Influenza A&B Test and another commercial influenza test (Colloidal gold method) was carried out in several medical institutions. Nasal swab samples were collected from adult and child patients exhibiting influenza-like symptoms. One swab was used to perform the Wondfo One Step Influenza A&B Test and one swab was used for another commercial influenza test analysis.

Compare the sensitivity and specificity between the two tests. The results for detection of influenza A are summarized in Table 1 and the results for detection of influenza B are summarized in Table 2.

Table 1: Results for detection of influenza A

Wondfo One Step Influenza A&B Test	The reference test		Total
	Influenza A positive	Influenza A negative	
Influenza A positive	282	38	320
Influenza A negative	29	744	773
Total	311	782	1093

(1) Sensitivity of Wondfo One Step Influenza A&B Test for influenza A: 282/311×100%＝90.7%
(2) Specificity of Wondfo One Step Influenza A&B Test for influenza A: 744/782×100%＝95.1%

Table 2: Results for detection of influenza B

Wondfo One Step Influenza A&B Test	The reference test		Total
	Influenza B positive	Influenza B negative	
Influenza B positive	270	63	333
Influenza B negative	25	740	765
Total	295	803	1098

(1) Sensitivity of Wondfo One Step Influenza A&B Test for influenza B: 270/295×100%＝91.5%
(2) Specificity of Wondfo One Step Influenza A&B Test for influenza B: 740/803×100%＝92.2%

B. Limit of Detection

Influenza type A (H1N1): 1:600
Influenza type A (Seasonal H1N1): 1:300
Influenza type A (Seasonal H3N2): 1:600
Influenza type B (Victoria): 1:300
Influenza type B (Yamagata): 1:600

C. Cross-Reactivity

1. The test for the influenza A has no cross-reactivity with influenza B virus, and test for the influenza B test has no cross-reactivity with influenza A virus.
2. No cross-reacted with the following microorganisms:

Bacteria	Viruses
Bordetella pertussis	Adenovirus (type 3/7)
Mycoplasma pneumoniae	Enterovirus 71
Chlamydia pneumoniae	Mumps virus
Haemophilus influenzae	Respiratory syncytial virus (type A/B)
Legionella pneumophila	Rhinovirus (type A/B)
Mycobacterium tuberculosis	Herpes simplex virus (type 1/2)
Candida albicans	Human coronavirus (229E, OC43, NL63, HKU1)
Diphtheria bacillus	Coronavirus (SARS-CoV, MERS-CoV, SARS-CoV-2)
Staphylococcus aureus	

D. Interference

1. The test result of One Step Influenza A&B Test was not interfered by human blood, nasal secretion and saliva.
2. The test result of One Step Influenza A&B Test was not interfered by drugs of the following concentration: 4 g/L antipyretic analgesics (acetaminophen and aspirin), 1 mg/mL decongestant (oxymetazoline hydrochloride and naphazoline hydrochloride), 60 mg/mL antitussive (dextromethorphan), 100 mg/mL antihistamine (chlorpheniramine and diphenhydramine), 1 mg/mL intranasal corticosteroids (beclomethasone and budesonide), or 400 mg/mL antivirotic (zanamivir and oseltamivir)

E. Hook Effect

Within the concentration range of influenza A virus and influenza B virus positive samples, the test results showed no hook effect.

F. Precision

1. Within run precision was determined by testing positive and negative specimens in a same lot of test devices. The negative agreement rate and the positive agreement rate were 100%.
2. Between run precision was determined by testing different specimens including positive and negative in 3 different lots of test devices. The negative agreement rate and the positive agreement rate were 100%.

BIBLIOGRAPHY

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INDEX OF SYMBOLS

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		

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