TOYO®

*in vitro* diagnostic test

# INSTRUCTION FOR USE
# INFLUENZA A /B Test

For Influenza A and Influenza B Antigens
Detection in nasal swab, nasopharyngeal swab, throat swab or nasal aspirate specimen

Only for professional *in vitro* diagnostic use

**Product Code: TIAB01**
Influenza A/B Test detects Influenza A antigen and Influenza B antigen

## BACKGROUND INFORMATION

Influenza is an epidemic that occurs in autumn and winter. Symptoms of influenza are not specific and may include sudden cough, fever, weakness and myalgia.
Some symptoms, especially cough, may last 2-3 weeks. The gold standard for laboratory diagnosis is a 14-day cell culture with one of several cell lines that can support the growth of influenza virus.
Unfortunately, this technique has limited clinical benefit, because the results have been obtained too late in the clinical phase for effective patient intervention.
Reference standards for laboratory confirmation of influenza virus infection in respiratory samples are reverse transcription polymerase chain reaction (RT-PCR). This method is expensive, complex and must be done in a private laboratory. Influenza A and B rapid testing qualitatively detects the presence of influenza and / or B antigens in nasal swabs, nasopharyngeal svabs, throat swabs or nasal aspirate samples in a short time.

## INTENDED USE

Influenza A/B Test is a rapid chromatographic immunoassay for the qualitative detection of influenza A and B antigens in nasopharyngeal swab, throat swab or nasal aspirate specimens.

## REAGENTS

This test included anti-influenza A and anti-influenza B antibody coated particles and anti-influenza A and anti-influenza B antibodies immobilized on the membrane.

## METHOD

Influenza A/B Test is a lateral flow chromatographic immunoassay. The test consists of antibodies against influenza A and influenza B and is coated separately in the test line regions of the test cassette. When the sample contains influenza A and / or B antigens, the sample migrates along the membrane and forms one or two colored lines in the test region. If the sample does not contain influenza A and B antigens and the test is performed properly, a colored line appears in the control region.

## PRECAUTIONS AND LIMITATIONS

1. For professional and *in vitro* diagnostic use only.
2. Do not use test kit beyond expiry date. The test device is single use. Do not reuse.
3. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
4. Wear disposable gloves while performing the test.
5. Use a new test tube and dropper tips for each sample.
6. The test device and swabs should be discarded in a proper biohazard container after testing.
7. Excess blood or mucus on the swab sample may interfere with test performance and may yield a false positive result. Avoid touching the tongue, cheeks and teeth and any bleeding areas of the mouth with the swab when collecting samples.
8. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
9. The use of over-the-counter and prescription nasal sprays at high concentrations can interfere with results, leading to either invalid or incorrect test results.
10. A negative result must be confirmed by culture. A negative result may be obtained if the concentration of the Influenza A and/or B virus present in the nasopharyngeal swab is not adequate or is below the detectable level of the test.
11. All patient samples should be handled as taking capable of transmitting disease into consideration. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
12. This test will indicate only the presence or absence of influenza A and/or B antigens in the sample, and should not be used as the only basis for the diagnosis of influenza A and B infection.

As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.

## STORAGE

Test device should be kept away from direct sunlight, moisture, heat and radiation sources. Store at 4 - 30°C (39 - 86°F). Do not freeze.
The test in the original packaging retains stable until expiry date at storage conditions. The test device should be used in maximum one hour after the foil is opened.

**Kit components:** Test cassettes, steril swabs, extraction test tubes and extraction tube tips, extraction reagent, work station, influenza A and B positive control swab, influenza A and B negative control swab and instructions for use.
**Additional materials required but not provided:** Aspiration device (for nasal aspirate) and timer.
**Additional materials recommended but not provided:** Micropipettes to deliver mentioned amount of sample in the test procedure.

## SAMPLE COLLECTION AND PREPARATION

The test can be performed using nasal swab, nasopharyngeal swab, throat swab, nasal aspirate.

**For Nasal Swab:** Gather mucoepidermic specimens by carefully inserting a sterile swab into the nasal cavity and rotating it several times.

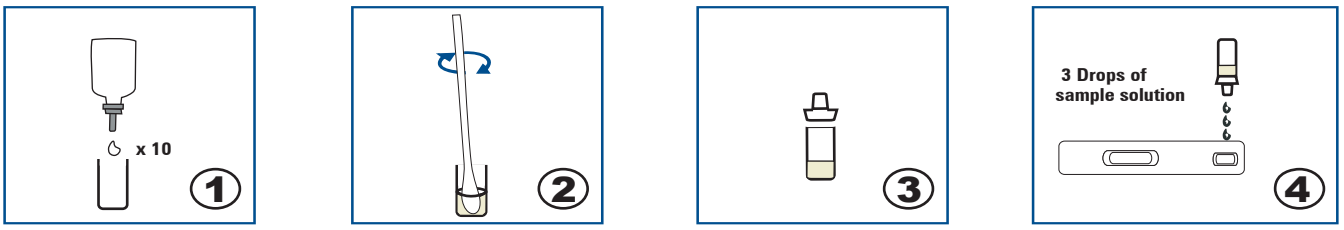
**For Nasopharyngeal Swab:** Carefully insert sterile swab in the nostril. The swab should reach depth from the nostrils to the outer ear opening and should be sampled.

**For Throat Swab:** Place a sterile swab into the pharynx area. Collect the mucoepoiermis by wiping the flare area several times in the pharyngeal wall and the palatine tonsils and be careful not to make saliva attach to the swab.

**For Nasal Aspirate:** Connect an aspiration catheter to an aspiration trap that is attached to an aspiration device, insert the catheter to nasal cavity from a nostril, start the aspiration device and then collect nasal aspirate sample. Dip a sterile swab into the collected nasal aspirate sample and make the specimen cling to the swab.

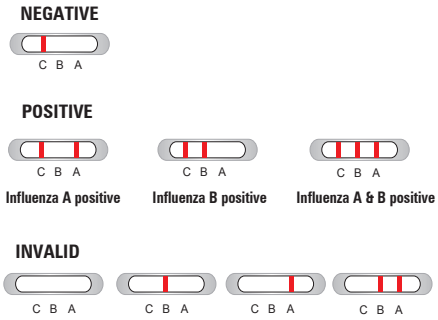
## TEST PROCEDURE

Bring the tests, reagents and samples to room temperature.
1. Place the test tube to the work station.
2. Hold extraction reagent bottle vertically and add 10 full drops (~ 400 µl) to the test tube (Figure 1)
3. Immediately dip the swab sample in the test tube.
4. Stir the swab sample in the tube for about 10 seconds while squeezing the test tube inside to release antigen from the swab specimen (Figure 2).
5. Press the swab on the walls of the tube and try to leave as much liquid as in the tube while taking the swab out off the tube.
6. Place the extraction tube tip tightly on top of the test tube (Figure 3).
7. Take the test device out of its pouch. Place the test on a flat surface.
8. Drop 3 drops of extracted sample solution (120 µl) to the sample well of the cassette (Figure 4).
9. Depending on the Influenza A/B antigen concentration in the sample, the test can react even in 5 minutes. Results should be read at 15 minutes as shown below.
Results forming after 20 minutes should be regarded as invalid.




## INTERPRETATION OF RESULTS

**Negative :** Only one colored line is visible in "C" area, indicating that influenza A and B antigens does not exist.
**Influenza A positive:** Two colored lines are visible in "C" and "A" areas, indicating that influenza A antigens exists. The appearance of a line in the "A" area is interpreted as "positive" for influenza A.
**Influenza B positive:** Two colored lines are visible in "C" and "B" areas, indicating that influenza B antigens exists. The appearance of a line in the "B" area is interpreted as "positive" for influenza B.
**Influenza A & B positive:** Three colored lines are visible in "C" , "A" and "B" areas, indicating that influenza A and B antigens exists. The sample is "positive" for influenza A and influenza B.
**Note:** Depending on the concentration of the virus antigens in the sample, the lines in the "A" or "B" test areas may have different colors. Even a faint line in the "A" and "B" areas should be interpreted as "positive".
**Invalid :** No colored line is visible or only one colored line is visible in "A" and/or "B" area; test should be repeated using a new test device.




## EXTERNAL QUALITY CONTROL

External quality control procedure is made with influenza A / B positive and negative swabs provided in the kit as described below;
1. Put 10 drops (~ 400 µl) reagent to the test tube from the extraction reagent bottle.
2. Remove from positive or negative swap from packaging.
3. Transfer the swab to the test tube and mix the solution in the tube for 10 seconds using the swab.
4. Remove the swab by pressing on the sides of the test tube and leaving as much solution as possible in the tube.
5. Continue the procedure with step 6 of the Test Procedure.
If the controls do not give the expected result, do not use the test results. Repeat the test or contact your authorized distributor.

## QUALITY CONTROL

Tests have built in procedural quality control features. When the test is complete, the user will see a colored line in the "C" area of the test on negative samples and a colored line in the "A" or/and "B" and "C" area on positive samples. The appearance of the control "C" line is considered as an internal procedural control. This line indicates that sufficient volume of sample was added as well as valid test result. It is recommended that a negative control and a positive control be used to verify proper test performance as an external control. Users should follow appropriate federal, state and local guidelines concerning the external quality controls.

## PERFORMANCE EVALUATION

The Influenza A/B Test has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the Influenza A/B Test.

**Tablo A: Nasal Swab Samples**

| Method | | Type A | | | Type B | | |
|---|---|---|---|---|---|---|---|
| | | RT-PCR | | Total | RT-PCR | | Total |
| | | Positive | Negative | | Positive | Negative | |
| Influenza A/B Test | Positive | 110 | 2 | 112 | 80 | 2 | 82 |
| | Negative | 1 | 150 | 151 | 2 | 250 | 252 |
| Total | | 111 | 152 | 263 | 82 | 252 | 334 |
| **Sensitivity** | | **99,10 %** | | | **97,56 %** | | |
| **Specificity** | | **98,68 %** | | | **99,21 %** | | |

**Tablo B: Throat Swab Samples**

| Method | | Type A | | | Type B | | |
|---|---|---|---|---|---|---|---|
| | | RT-PCR | | Total | RT-PCR | | Total |
| | | Positive | Negative | | Positive | Negative | |
| Influenza A/B Test | Positive | 65 | 1 | 66 | 68 | 1 | 69 |
| | Negative | 3 | 170 | 173 | 4 | 154 | 158 |
| Total | | 68 | 171 | 239 | 72 | 155 | 227 |
| **Sensitivity** | | **95,59 %** | | | **94,44 %** | | |
| **Specificity** | | **99,42 %** | | | **99,35 %** | | |

**Tablo C: Nasal Aspirate Samples**

| Method | | Type A | | | Type B | | |
|---|---|---|---|---|---|---|---|
| | | RT-PCR | | Total | RT-PCR | | Total |
| | | Positive | Negative | | Positive | Negative | |
| Influenza A/B Test | Positive | 102 | 2 | 104 | 88 | 1 | 89 |
| | Negative | 1 | 240 | 241 | 2 | 190 | 192 |
| Total | | 103 | 242 | 345 | 90 | 191 | 281 |
| **Sensitivity** | | **99,03 %** | | | **97,78 %** | | |
| **Specificity** | | **99,17 %** | | | **99,48 %** | | |

### Specificity Testing with Various Viral Strains

Human adenovirus C
Human adenovirus B
Adenovirus type 10
Adenovirus type 18
Human coronavirus OC43
Coxsackievirus A9
Coxsackievirus B5
Human herpesvirus 5
Echovirus 2
Echovirus 3
Echovirus 6
Herpes simplex virus 1
Human herpesvirus 2
Human Rhinovirus 2
Human Rhinovirus 14
Human Rhinovirus 16
Measles
Mumps
Sendai virus
Parainfluenza virus 2
Parainfluenza virus 3
Respiratory syncytial virus
Human respiratory syncytial virus
Rubella
Varicella-Zoster

**CROSS REACTIVITY:** The following organisms were tested at 1.0x10$^8$ org/ml and all found to be negative when tested with the Influenza A/ B Test:

*Arcanobacterium*
*Candida albicans*
*Corynebacterium*
*Enterococcus faecalis*
*Enterococcus faecium*
*Escherichia coli*
*Haemophilus*
*Moraxella catarrhalis*
*Neisseria gonorrhoeae*
*Neisseria lactamica*
*Nesseria subllava*
*Proleus vulgaris*
*Pseudomonas aeruginosa*
*Staphylococcus aureus subspaureus*
*Staphylococcus epidermidis*
*Staphylococcus saprophylicus*
*Streptococcus agalactiae*
*Streptococcus bovis*
*Streptococcus dysgalatiae / subsp.dysgalatiae*
*Streptococcus oralis formerly Streptococcus*
*Streptococcus pneumoniae*
*Streptococcus pygenes*
*Streptococcus salivarius*
*Streptococcus sp group F.type 2*

## REFERENCES


1. Gill, P. W., and A. M. Murphy. 1991. The diagnosis of influenza. Aust. Fam. Physician 20:1664–1665
2. Pachucki, C. T. 1992. The diagnosis of influenza. Semin. Respir. Infect. 7:46–53
3. Betts, R. F. 1995. Influenza virus, p. 1546–1567. In G. L. Mandell, R. G. Douglas, Jr. and J. E. Bennett (ed.), Principle and practice of infectious diseases, 4th ed. Churchill Livingstone, Inc., New York, N.Y.
4. McIntosh, K. 1996. Diagnostic virology, p. 401–430. In B. N. Fields, D. M. Knipe, and P. M. Howley (ed.), Fields virology, 3rd ed. Lippincott-Raven, Philadelphia, Pa.
5. Centers for Disease Control and Prevention, Rapid Influenza Diagnostic Tests.



TÜRKLAB
let us diagnose
**TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.**
ITOB 10031 Sokak No: 15 Tekeli Menderes Izmir / TURKEY
**T:** +90 232 **376 80 81** • **F:** +90 232 **376 80 40** • **www.turklab.com.tr** • **info@turklab.com.tr**


CE
Manufacturer
Consult instruction for use
Attention, see instruction for use
IVD In vitro diagnostic medical device
For single use only
Number of test
REF Catalog number
Storage temperature
LOT Lot number
Expiry date