

size: 297x210mm



Influenza A+B Rapid Test Package Insert

REF Flu-602

Sample: Nasopharyngeal swab/Oropharyngeal swab

Version: A

Effective Date: 2023.08.23

For professional in vitro diagnostic use only

INTENDED USE

The Influenza A+B Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of influenza A and B antigens in nasopharyngeal swab/oropharyngeal swab specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.

PACKAGE SPECIFICATIONS

1 test/ kit, 25 tests/ kit

SUMMARY

Influenza (commonly known as 'flu') is a highly contagious, acute viral infection of the respiratory tract. It is a communicable disease easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus.¹ Influenza outbreaks occur each year during the fall and winter months. Type A viruses are typically more prevalent than type B viruses and are associated with most serious influenza epidemics, while type B infections are usually milder. The gold standard of laboratory diagnosis is 14-day cell culture with one of a variety of cell lines that can support the growth of influenza virus.² Cell culture has limited clinical utility, as results are obtained too late in the clinical course for effective patient intervention. Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) is a newer method that is generally more sensitive than culture with improved detection rates over culture of 2-23%.³ However, RT-PCR is expensive, complex and must be performed in specialized laboratories.

The Influenza A+B Rapid Test qualitatively detects the presence of Influenza A and/or Influenza B antigen in nasopharyngeal swab/oropharyngeal swab specimens, providing results within 10 minutes. The test uses antibodies specific for Influenza A and Influenza B to selectively detect Influenza A and Influenza B antigen in nasopharyngeal swab/oropharyngeal swab specimens.

PRINCIPLE

The Influenza A+B Rapid Test is a qualitative, lateral flow immunoassay for the detection of Influenza A and Influenza B nucleoproteins in nasopharyngeal swab/oropharyngeal swab specimens. In this test, antibody specific to the Influenza A and Influenza B nucleoproteins is separately coated on the test line regions of the test kit. During testing, the extracted specimen reacts with the antibody to Influenza A and/or Influenza B that are coated onto particles. The mixture migrates up the membrane to react with the antibody to Influenza A and/or Influenza B on the membrane and generate one or two colored lines in the test regions. The presence of this colored line in either or both of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

REAGENTS

The test kit contains anti-Influenza A and B particles and anti- Influenza A and B coated on the membrane.

PRECAUTIONS

- Please read all the information in this package insert before performing the test.
1. For professional in vitro diagnostic use only. Do not use after the expiration date.
 2. The test should remain in the sealed pouch until ready to use.
 3. All specimens should be considered potentially hazardous and handled in the same manner as an infections agent.
 4. The used test should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use.

DO NOT FREEZE.

Do not use beyond the expiration date.

SAMPLE COLLECTION

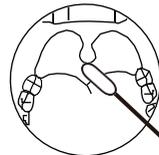
1. Nasopharyngeal swab collection method:

- 1) Tip the patient's head back and collect sample from the nostril that has more mucus (head should be inclined from vertical for proper specimen collection).
- 2) Insert the swab through the nostril entry and then slowly move along the bottom of the nasal cavity (move gently to avoid traumatic bleeding).
- 3) When the tip of the swab reaches the posterior wall of the nasopharyngeal cavity, gently rotate it several times (Collect as much secretion as possible).
- 4) To prevent reflex coughing, stop for one minute.
- 5) Slowly remove the swab.
- 6) Test the sample as soon as possible.



2. Oropharyngeal swab collection method:

- 1) Tip the patient's head slightly.
- 2) Instruct the patient to open mouth as wide as possible to reveal the pharyngeal tonsils on either side.
- 3) Wipe the base of patient's tongue with swab.
- 4) Slightly rub the pharyngeal tonsils back and forth on both sides of the collected position at least 3 times.
- 5) Rub the posterior pharyngeal wall up and down at least 3 times.
- 6) Test the sample as soon as possible.



Sample treatment:

1. Place the swab sample in the tube, dip the swab in the solution and rotate it 10 times, then leaving the swab in the treatment tube. Wait for 1 minute of reaction.
2. Remove the swab while squeezing the swab head against the inside of the extraction tube as you remove it to expel as much liquid as possible from the swab.

MATERIALS

Materials provided		
Test Cards	Sterile Swabs	Package Insert
Extraction Buffer with Integrated Extraction Tube, 0.5mL/tube		
Tube Holder (the tube holder of 1 test is on the color box)		

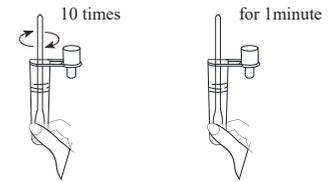
NOTE: Materials required but not provided: **Timer.**

DIRECTIONS FOR USE

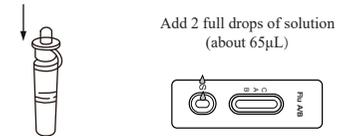
Allow the test kit, reagents, and/or controls to reach room temperature (15°C~30°C) before testing.

1. Remove the test kit from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.

2. Place the swab sample in the tube, dip the swab in the solution and rotate it 10 times, then leaving the swab in the treatment tube. Wait for 1 minute of reaction.



3. Remove the swab while squeezing the swab head against the inside of the extraction tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.
4. Fit the dropper tip on top of the extraction test tube. Place the test device on a clean and level surface. Add 2 drops (about 65µL) of solution to the specimen well (S) and then start the timer.



5. Wait for the colored line(s) to appear. Read the result at 10 minutes. Do not interpret the result after 30 minutes.
- NOTE:** Very low concentrations of Flu A and/or Flu B antigen might result in a weak line appearing in the test line regions (A and B) after an extended period of time, therefore, do not read results after 30 minutes.

INTERPRETATION OF RESULTS

POSITIVE RESULT:



Influenza A Positive: *A colored band appears in the control band region (C) and another colored band appears in the A line region.



Influenza B Positive: *A colored band appears in the control band region (C) and another colored band appears in the B band region.



Influenza A+B Positive: *A colored band appears in the control line region (C) and two other colored bands appear in A line region and B line region respectively.

NEGATIVE RESULT:



One colored band appears in the control band region (C). No band appears in the test band region (A/B).

INVALID RESULT:



Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.



QUALITY CONTROL

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

LIMITATIONS

1. The Influenza A+B Rapid Test is for professional in vitro diagnostic use only. The test should be used for the detection of Influenza A and/or B virus in nasopharyngeal swab/oropharyngeal swab specimens. Neither the quantitative value nor the rate of increase in Influenza A and/or B virus concentration can be determined by this qualitative test.
2. The Influenza A+B Rapid Test will only indicate the presence of Influenza A and/or B virus in the specimen from both viable and non-viable Influenza A and B strains.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. A negative result obtained from this kit should be confirmed by culture. A negative result may be obtained if the concentration of the Influenza A and/or B virus present in the swab is not adequate or is below the detectable level of the test.
5. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result.
6. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
7. 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.
8. A positive result for influenza A and/or B does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.

EXPECTED VALUES

The Influenza A+B Rapid Test has been compared with leading commercial RT-PCR tests. The correlation between these two systems is no less than 97%.

PERFORMANCE CHARACTERISTICS

Sensitivity, Specificity and Accuracy

The Influenza A+B Rapid Test has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the Influenza A+B Rapid Test. Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result. The sensitivity, specificity, total coincidence rate when compared with reference kits of the candidate kits were calculated. The data is provided in the Table below:

Influenza A+B Rapid Test		Type A			Type B		
		RT-PCR		Total	RT-PCR		Total
Influenza A+B Rapid Test	Positive	100	2	102	85	2	87
	Negative	1	180	181	2	200	202
Total Results		101	182	283	87	202	289
Relative Sensitivity		99.0% (95%CI*: 94.6%-99.8%)			97.7%(95%CI*:92.0%-99.4%)		
Relative Specificity		98.9% (95%CI*: 96.1%-99.7%)			99.0%(95%CI*:96.5%-99.7%)		
Accuracy		98.9% (95%CI*: 96.9%-99.6%)			98.6%(95%CI*:96.5%-99.5%)		

*Confidence Intervals

Specificity Testing with Various Viral Strains

The Influenza A+B Rapid Test was tested with the following viral strains. No discernible line at either of the test-line regions was observed at these concentrations listed:

Description	Cross reaction
Human adenovirus 3	N/A
Human adenovirus 7	N/A
Human coronavirus OC43	N/A
Parainfluenza virus 1	N/A
Parainfluenza virus 2	N/A
Parainfluenza virus 3	N/A
Measles	N/A
Mumps	N/A
Human respiratory syncytial virus	N/A
Human Rhinovirus 1A	N/A
Human herpesvirus 5	N/A
Herpes simplex virus 1	N/A
Human herpesvirus 2	N/A
Rubella	N/A
Varicella-Zoster	N/A

Precision Intra-Assay & Inter-Assay

Within-run and Between-run precision has been determined by using seven specimens of Influenza A/B standard control. Three different lots of the Influenza A+B Rapid Test have been tested using negative, Influenza A weak, Influenza B Weak, Influenza A Strong and Influenza B Strong. Ten replicates of each level were tested each day for 3 consecutive days. The specimens were correctly identified >99% of the time.

Interfering Substances

The test results do not be interfered with the substance at the following concentration:

Interfering substance	Conc.
Whole Blood	4%
Ibuprofen	1mg/mL
tetracycline	3ug/mL
Mucin	0.5%
Erythromycin	3ug/mL
Tobramycin	5%
menthol	15%
Afrin	15%
Compound Benzoin Gel	1.5mg/mL
Cromolyn glycate	15%
chloramphenicol	3ug/mL
Mupirocin	10mg/mL
Oseltamivir	5mg/mL
Naphazoline Hydrochloride Nasal Drops	15%
Fluticasone propionate spray	15%
Deoxyepinephrine hydrochloride	15%

BIBLIOGRAPH

1. Williams, KM, Jackson MA, Hamilton M. (2002) Rapid Diagnostic Testing for URIs in Children; Impact on Physician Decision Making and Cost. *Infect. Med.* 19(3): 109-111.
2. 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.
3. WHO recommendations on the use of rapid testing for influenza diagnosis, World Health Organisation, July 2005.

Index of Symbols

	Consult instruction for use		Tests per kit		Caution
	For in vitro diagnostic use only		Use by date		Do not reuse
	Store between 2-30 C		Lot Number		Catalogue number
	Manufacturer		Keep dry		Keep away from sunlight
	Do not use if package is damaged		Date of manufacture		Authorized Representative



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Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany



Swab information

Accessory	Manufacturer	EC Representative	CE-Mark
Swab A	Hangzhou Yiguoren Biotechnology Co., Ltd Room 402, Building 2, No.2628, Yuhangtang Road, Cangqian Street, Yuhang District, Hangzhou City, Zhejiang, People's Republic of China	Zoustech S.L. Pasco de la Castellana, 141 28049 Madrid	
Swab B	Jiangsu Changfeng Medical Industry Co., Ltd. Tougiao Town, Guangling District, Yangzhou, 225109 Jiangsu, P.R. China	Llins Service & Consulting GmbH Obere Seegasse 34/2, 69124 Heidelberg, Germany	
Swab C	Jiangsu Rongye Technology Co., Ltd. Tougiao Town, Yangzhou City, 225109, Jiangsu, P.R. China	Riomavix S.L. Calle de Almansa 55, 1D, Madrid 28039 Spain	