diagnosticare

Influenza A+B Test Cassette (Swab/Nasal Aspirate) Package Insert

REF FI-FLU-502	English

A Fluorescence Immunoassay test kit for the diagnosis of Influenza A and Influenza B virus in nasopharyngeal swab, throat swab or nasal aspirate specimens with the use of Fluorescence Immunoassay Analyzer.
For professional in vitro diagnostic use only.

【INTENDED USE】

The Influenza A+B Test Cassette (Swab/Nasal Aspirate) is intended for *in vitro* detection of influenza A and B antigens in nasopharyngeal swab, throat swab or nasal aspirate specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.

【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 Test cassette (Swab/Nasal Aspirate) qualitatively detects the presence of Influenza A and/or Influenza B antigen in nasopharyngeal swab or throat swab or nasal aspirate specimens, providing results within 15 minutes. The test uses antibodies specific for Influenza A and Influenza B to selectively detect Influenza A and Influenza B antigen in nasopharyngeal swab, throat swab or nasal aspirate specimens.

【PRINCIPLE】

The Influenza A+B Test Cassette (Swab/Nasal Aspirate) detects Influenza A and Influenza B nucleoproteins based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains Influenza A and Influenza B nucleoproteins, it attaches to the fluorescent microspheres-conjugated anti- Influenza A and/or Influenza B antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of Influenza A and/or Influenza B in the sample correlates with the fluorescence signal intensity captured on the T line, which can be scanned by Fluorescence Immunoassay Analyzer. The testing result of Influenza A and Influenza B will display on the Fluorescence Immunoassay Analyzer screen.

【REAGENTS】

The test cassette contains anti-Influenza A and B conjugated fluorophores and anti-Influenza A and B coated on the membrane.

【PRECAUTIONS】

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The Influenza A+B Test Cassette should only be used with the Analyzer by approved medical professionals.

【STORAGE AND STABILITY】

1. The kit should be stored at 4-30 °C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze.**
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

【SPECIMEN COLLECTION AND PREPARATION】

Preparation
Before performing the test, please make sure that all components are brought to room temperature (15-30 °C). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
Sample Handling
• Nasopharyngeal swab sample
1. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.
2. Swab over the surface of the posterior nasopharynx 5-10 times.
• Throat swab sample
Insert a sterilized swab into pharynx and collect mucoepidermis mainly wiping flare region of post-pharyngeal wall and palatine tonsil several times, and be careful not to make saliva attach to the swab.
• 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 sterilized swab into the collected nasal aspirate sample and make the specimen cling to the swab.

【MATERIALS】

Materials Provided

•Test Cassettes	• Extraction Reagent	• Extraction Tubes
• Sterile Swabs	• Package Insert	• Workstation
• Extraction Tube Tips	• ID card	

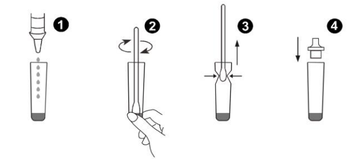
Materials Required But Not Provided

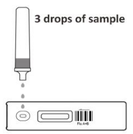
• Timer	• Fluorescence Immunoassay Analyzer

【DIRECTIONS FOR USE】

Refer to Fluorescence Immunoassay Analyzer Operation Manual for the complete instructions on use of the analyzer. The test should be conducted in room temperature.
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.
1. Turn on the Analyzer power. Then according to the need, select "standard test" or "Quick test" mode.
2. Take out the ID card and insert it into the Analyzer ID Card Slot.
3. Remove the test cassette 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.
4. Place the Extraction Tube in the workstation. Hold the extraction reagent bottle upside down vertically. Squeeze the bottle and let the solution drop into the extraction tube freely without touching the edge of the tube. Add **10 drops of extraction reagent (Approx. 400 µL)** to the Extraction Tube.
5. Place the swab specimen in the Extraction Tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.
6. 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.
7. Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface.
8. Add **three drops of the solution (approx. 120 µL)** to the sample well and then start the timer. (Follow the illustration as below)
9. There are two test modes for Fluorescence Immunoassay Analyzer, Standard Test mode and Quick Test mode. Please refer to the user manual of Fluorescence Immunoassay Analyzer for details.

"Quick test" mode: After **15 minutes** of adding sample, Insert the test cassette into the Analyzer, click "**QUICK TEST**", fill the test information and click "**NEW TEST**" immediately. The Analyzer will automatically give the test result after a few seconds.
"Standard test" mode: Insert the test cassette into the Analyzer immediately after adding specimen, click "**STANDARD TEST**", fill the test information and click **"NEW TEST"** at the same time, The Analyzer will automatically countdown **15 minutes**. After the countdown, the Analyzer will give the result at once.





【INTERPRETATION OF RESULTS】

Results read by Fluorescence Immunoassay Analyzer.
The result of tests for Influenza A+B is calculated by Fluorescence Immunoassay Analyzer and display the result on the screen. For additional information, please refer to the user manual of Fluorescence Immunoassay Analyzer.
NOTE: The test result of each specimen is given as Pos (+) or Neg (-) with a Value. This value is calculated by dividing the signal obtained with sample by cut-off value (S/C Ratio).
- Test results of Value ≥ 1.00 are considered positive for Influenza A and/or B.
- Test results of Value < 1.00 are considered negative for Influenza A and/or B.

【QUALITY CONTROL】

Each Influenza A+B Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test cassette was inserted and read properly by Fluorescence Immunoassay Analyzer. An invalid result from the internal control causes an error message on Fluorescence Immunoassay Analyzer indicating that the test should be repeated. An invalid result from the internal control causes an "N/A" message on Fluorescence Immunoassay Analyzer. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【LIMITATIONS】

1. The Influenza A+B Test Cassette (Swab/Nasal Aspirate) is for professional *in vitro* diagnostic use only. The test should be used for the qualitative detection of Influenza A and/or B virus in nasopharyngeal swab, throat swab or nasal aspirate specimens.
2. The Influenza A+B Test Cassette (Swab/Nasal Aspirate) 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. The test result of Value is not a quantitative value or the rate of influenza A/B virus concentration. This is only a qualitative 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.
9. The results of Influenza A+B Tests are based on measuring the levels of Influenza A+B in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

【PERFORMANCE CHARACTERISTICS】

Sensitivity, Specificity and Accuracy
The Influenza A+B Test Cassette (Swab/Nasal Aspirate) has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for The Influenza A+B Test Cassette (Swab/Nasal Aspirate). Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result.

● Nasopharyngeal Swab Specimen

		Type A			Type B		
		RT-PCR		Total	RT-PCR		Total
		Positive	Negative		Positive	Negative	
Influenza A+B	Positive	110	2	112	89	2	91
	Negative	2	189	191	2	187	189
Total		112	191	303	91	189	280
Sensitivity Agreement		98.2%			97.8%		
Specificity Agreement		99.0%			98.9%		
Overall Accuracy		98.7%			98.6%		

● Throat Swab Specimen

		Type A			Type B		
		RT-PCR		Total	RT-PCR		Total
		Positive	Negative		Positive	Negative	
Influenza A+B	Positive	65	1	66	75	1	76
	Negative	2	135	137	4	199	203
Total		67	136	203	79	200	279
Sensitivity Agreement		97.0%			94.9%		
Specificity Agreement		99.3%			99.5%		
Overall Accuracy		98.5%			98.2%		

● Nasal Aspirate Specimen

		Type A			Type B		
		RT-PCR		Total	RT-PCR		Total
		Positive	Negative		Positive	Negative	
Influenza A+B	Positive	49	2	51	89	1	90
	Negative	0	245	245	2	165	167
Total		49	247	296	91	166	257
Sensitivity Agreement		100.0%			97.8%		
Specificity Agreement		99.2%			99.4%		
Overall Accuracy		99.3%			98.8%		

Reactivity with Human Influenza Strain
The Influenza A+B Test Cassette (Swab/Nasal Aspirate) was tested with the following human influenza strains and the result is positive:

Influenza A Virus	*Influenza B Virus*
A/NWS/33 10(H1N1)	B/R5
A/Hong Kong/8/68(H3N2)	B/Russia/69
A/Port Chalmers/1/73(H3N2)	B/Lee/40
A/WS/33(H1N1)	B/Hong Kong/5/72
A/New Jersey/8/76(HswN1)	
A/Mal/302/54(H1N1)	
A/chicken/Yuyao/2/2006 (H5N1)	
A/swine/Hubei/251/2001 (H9N2)	
A/Duck/Hubei/216/1983(H7N8)	
A/Duck/Hubei/137/1982(H10N4)	
A/Anhui/1/2013 (H7N9)	

Specificity Testing with Various Viral Strains

Description	Test Level
Human adenovirus C	5.62 x 10^5 $TCID_{50}$/ml
Human adenovirus B	1.58 x 10^4 $TCID_{50}$/ml
Adenovirus type 10	3.16 x 10^3 $TCID_{50}$/ml
Adenovirus type 18	1.58 x 10^4 $TCID_{50}$/ml
Human coronavirus OC43	2.45 x 10^6 LD_{50}/ml
Coxsackievirus A9	2.65 x 10^4 LD_{50}/ml 1.58 x 10^5 $TCID_{50}$/ml
Coxsackievirus B5	1.58 x 10^7 $TCID_{50}$/ml
Human herpesvirus 5	1.58 x 10^4 $TCID_{50}$/ml
Echovirus 2	3.16 x 10^5 $TCID_{50}$/ml
Echovirus 3	1 x 10^4 $TCID_{50}$/ml
Echovirus 6	3.16 x 10^6 $TCID_{50}$/ml
Herpes simplex virus 1	1.58 x 10^6 $TCID_{50}$/ml
Human herpesvirus 2	2.81 x 10^5 $TCID_{50}$/ml
Human Rhinovirus 2	2.81 x 10^4 $TCID_{50}$/ml
Human Rhinovirus 14	1.58 x 10^6 $TCID_{50}$/ml
Human Rhinovirus 16	8.89 x 10^6 $TCID_{50}$/ml
Measles	1.58 x 10^4 $TCID_{50}$/ml
Mumps	1.58 x 10^4 $TCID_{50}$/ml
Sendai virus	8.89 x 10^7 $TCID_{50}$/ml
Parainfluenza virus 2	1.58 x 10^7 $TCID_{50}$/ml
Parainfluenza virus 3	1.58 x 10^8 $TCID_{50}$/ml
Respiratory syncytial virus	8.89 x 10^4 $TCID_{50}$/ml
Human respiratory syncytial virus	1.58 x 10^5 $TCID_{50}$/ml
Rubella	2.81 x 10^5 $TCID_{50}$/ml
Varicella-Zoster	1.58 x 10^3 $TCID_{50}$/ml

$TCID_{50}$ = Tissue Culture Infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated.
LD_{50} = Lethal Dose is the dilution of virus that under the conditions of the assay can be expected to kill 50% of the suckling mice inoculated.

Precision
Intra-Assay& Inter-Assay
Within-run and Between-run precision has been determined by using five specimens of Influenza standard control. Three different lots of the Influenza Test Cassette (Swab/Nasal Aspirate) 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.

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 Cassette (Swab/Nasal Aspirate):

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

【BIBLIOGRAPHY】

1. Williams, KM, Jackson MA, Hamilton M. (2002) Rapid Diagnostic Testing for URIs in Children; Impact on Physician Decision Making and Cost. Infec. 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 instructions for use or consult electronic instructions for use	Σ	Contains sufficient for <n> tests		Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		

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Statement: Information about manufacturer of sterile swab is placed on the packaging.
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