RightSign®

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

REF IFLU-C82	English

A rapid test for the qualitative detection of Influenza A and Influenza B virus in nasal swab, throat swab or nasal aspirate *specimens.*
For professional in vitro diagnostic use only.

【INTENDED USE】

The Influenza A+B Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of influenza A and B antigens in nasal swab or 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 Rapid Test cassette (Swab/Nasal Aspirate) qualitatively detects the presence of Influenza A and/or Influenza B antigen in nasal swab or throat swab or nasal aspirate specimens, providing results within 8 minutes. The test uses antibodies specific for Influenza A and Influenza B to selectively detect Influenza A and Influenza B antigen in nasal swab, throat swab or nasal aspirate specimens.

【PRINCIPLE】

The Influenza A+B Rapid Test Cassette (Swab/Nasal Aspirate) is a qualitative, lateral flow immunoassay for the detection of Influenza A and Influenza B nucleoproteins in nasal swab, throat swab or nasal aspirate 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 cassette. 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 cassette 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 infection agent.
4. The used test should be discarded according to the local regulations.
5. Avoid using bloody samples.
6. Wear gloves when handling the samples, avoid touching the reagent membrane and sample well.

【STORAGE AND STABILITY】

Store as packaged at room temperature or refrigerated (2-30℃). 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.

【SPECIMEN COLLECTION AND PREPARATION】

● Nasal swab sample

Insert a sterilized swab into a nasal cavity securely from a nostril and collect muco-epidermis wiping turbinate several times.

● Pharyngeal swab sample

Insert a sterilized swab into pharynx and collect muco-epidermis mainly wiping flare region of post-pharyngeal wall and palatine tonsil several times, and be careful not to make saliva attach to the swab.

● Nasopharyngeal 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	Dropper tips
Sterile Swabs	Package Insert	Workstation	

Influenza A+/B- Control Swab (Non-viable Flu A,0.02%NaN_3)
Influenza A-/B+ Control Swab (Non-viable Flu B,0.02%NaN_3)

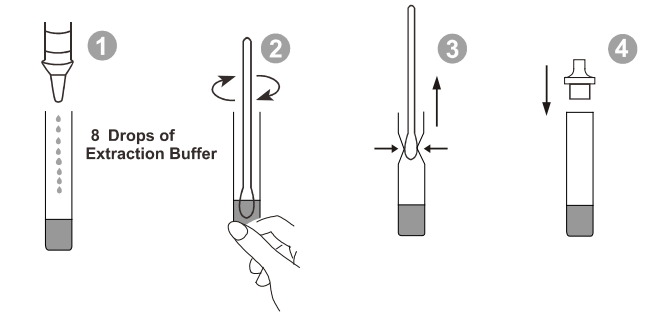
Materials required but not provided

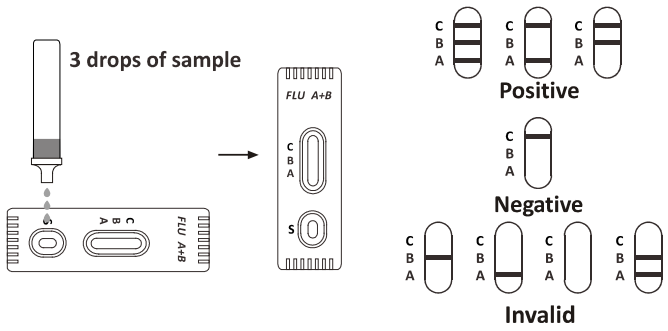
Timer Aspiration Device

【DIRECTIONS FOR USE】

Allow the test, specimen, extraction buffer to equilibrate to room temperature (15-30℃) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. 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 8 drops of solution (Approx. 300μL) to the Extraction Tube. See illustration 1.
3. 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. See illustration 2.
4. 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. See illustration 3.
5. Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface. See illustration 4
6. Add 3 drops of the solution (approx.80μL) to the sample well and then start the timer. Read the result at 8 minutes. Do not interpret the result after 15 minutes.





【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE Influenza A:* Two distinct colored lines appear. One purple colored line should be in the control region (C) and one red colored line should be in the Influenza A region (A). A positive result in the Influenza A region indicates that Influenza A antigen was detected in the sample.

POSITIVE Influenza B:* Two distinct colored lines appear. One purple colored line should be in the control region (C) and one blue colored line should be in the Influenza B region (B). A positive result in the Influenza B region indicates that Influenza B antigen was detected in the sample.

POSITIVE Influenza A and Influenza B:* Three distinct colored lines appear. One purple colored line should be in the control region (C) and one red colored line should be in the Influenza A region (A) and one blue colored line should be in the Influenza B region (B). A positive result in the Influenza A region and Influenza B region indicates that Influenza A antigen and Influenza B antigen were detected in the sample.

***NOTE**: The intensity of the color in the test line regions (A or B) will vary based on the amount of Flu A or B antigen present in the sample. So any shade of color in the test regions (A or B) should be considered positive.

NEGATIVE: One purple colored line appears in the control region (C). No apparent colored line appears in the test line regions (A or B).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

INTERNAL QUALITY CONTROL: A procedural control is included in the test. A purple colored line appearing in the control region (C) is the internal procedural control. It confirms adequate membrane wicking.

EXTERNAL QUALITY CONTROL: It is recommended that positive external controls be run every kit, and as deemed necessary by your internal laboratory procedures. External positive controls are supplied in the kit. Alternatively, other type A and type B Influenza reference strains may be used as external controls. Some commercial controls may contain interfering preservatives; therefore, other commercial controls are not recommended.

PROCEDURE FOR EXTERNAL QUALITY CONTROL TESTING:

1. Add 8 drops of solution (Approx. 300μL) to the Extraction Tube. See illustration 1.
2. Add the Influenza A+/B- or A-/B+ control swab into the extraction tube.
3. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab. See illustration 2.
4. 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. See illustration 3.
5. Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface. See illustration 4
6. Add 3 drops of the solution (approx. 80μL) to the sample well and then start the timer. Read the result at 8 minutes. Do not interpret the result after 15 minutes.

If the controls do not yield the expected results do not use the test results. Repeat the test or contact your distributor.

【LIMITATIONS】

1. The Influenza A+B Rapid Test Cassette (Swab/Nasal Aspirate) is for professional in vitro diagnostic use only. The test should be used for the detection of Influenza A and/or B virus in nasal swab, throat swab or nasal aspirate 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 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. 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 nasal 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.
9. Performance of the test has not been established for monitoring antiviral treatment of influenza.

【PERFORMANCE CHARACTERISTICS】

Sensitivity, Specificity and Accuracy

The Influenza A+B Rapid 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 Rapid Test Cassette (Swab/Nasal Aspirate). Specimens were considered positive if RT-PCR indicated a positive result.

	Type A			Type B		
	RT-PCR		Total	RT-PCR		Total
	Positive	Negative		Positive	Negative	

Flu A+B Rapid Test Cassette	Positive	68	14	82	49	7	56
	Negative	10	242	252	4	274	278
Total		78	256	334	53	281	334
Relative Sensitivity		87.2%			92.5%		
Relative Specificity		94.5%			97.5%		
Accuracy		92.8%			96.7%		

Reactivity with Human Influenza Strain

Influenza A strains

Subtype of H1N1: Mal/302/54, New Jersey/8/76, NWS/33, WS/33; H3N2: Aichi/2/68, Hong Kong/8/68, Port Chalmers/1/73 all are positive.

Influenza B strains

Russia/69, Hong Kong/5/72, Lee/40, Brigit, R5 , Wisconsin/1/2010, Florida/78/2015 all are positive.

Specificity Testing with Various Viral Strains

Virus other than influenza

No cross reaction with following pathogens:

Adenovirus, Coxsackie virus, Cytomegalovirus, Parainfluenza Virus Type1,2,3,4a, Enterovirus, Mumps virus, Respiratory syncytial virus, Rhinovirus.

Bacteria

No cross reaction with following bacteria:

Bordetella pertussis, Haemophilusparainfluenzae, Staphylococcus aureus, Streptococcus agalactiae, Neisseria meningitides, Streptococcus sp. group A, B, C.

Interfering Substances

No Interfering with following material:

Mucosolvan Ambroxol Hydrochloride Oral Solution,Nin Jiom Pei Pa Kao cough syrup,Flixonase Fluticasone propionate nasal spray ,Dextromethorphan Hydrobromide Oral Solution,Hyland's 4 Kids Cold Cough Liquid Safe Natural Relief,Durham's Canker-Rid,Listerine mouthwashScope mouthwash

【BIBLIOGRAPHY】

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3. WHO recommendations on the use of rapid testing for influenza diagnosis, World Health Organisation, July 2005.
4. Norihiko KUBO, Hideyuki IKEMATSU, Shigeki NABESHIMA: Evaluation of an Immunochromatography TestKit for Rapid Diagnosis of Influenz, Kansenshogaku Zasshi, 2003,77:1007～1014.
5. Michimaru HARA, Shinichi TAKAO, Shinji FUKUDA, Yukie SHIMAZU, Masaru KUWAYAMA and Kazuo MIYAZAKI: Comparison of Four Rapid Diagnostic Kits Using Immunochromatography to Detect Influenza B Viruses, Kansenshogaku Zasshi, 2005,79:803～811.

Index of Symbols

	Consult Instruction for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	**REF**	Catalog #
	Do not use if package is damaged				

Manufacturer
BiotesT
Hangzhou Biotest Biotech Co., Ltd.
17#, Futai Road, Zhongtai Street,
Yuhang District, Hangzhou, P. R. China

CE

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

Number: RP5306600
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