Influenza A+B Rapid Test
Swab/Nasal Secretion
Package Insert

REF IFLU-C82	English

Rapid test for the qualitative detection of influenza A and B viruses in throat and nasal swabs as well as nasal secretion specimens.
For professional in vitro diagnostic use only.

INTENDED USE
The Influenza A+B test is a chromatographic immunoassay-based rapid test for the qualitative detection of influenza A and B antigens in nasal and throat swabs. It serves as a diagnostic aid in the detection of and differentiation between an influenza A and B infection.

SUMMARY
Influenza (also known as the "flu") is an extremely infectious, acute viral infection of the respiratory tract. It is a disease that is transmitted by live viruses in airborne droplets. Influenza outbreaks occur annually, typically in the autumn and winter months. Type A viruses are generally more widespread than Type B viruses and cause the more serious influenza outbreaks.
The gold standard of laboratory diagnosis is a 14-day cell culture with a variety of cell lines that support the growth of influenza viruses. The cell cultures are only of limited use in everyday clinical practice, as the results are achieved too late to initiate medical treatment. The reverse transcriptase polymerase chain reaction (RT-PCR) is a newer, more sensitive method than the culture, with an improved detection rate of 2-23% compared to the culture method. However, RT-PCR is expensive, complex and can only be performed in specialised labs.
The RightSign Influenza A+B rapid test qualitatively detects influenza A and/or B antigens in nasal and throat swabs as well as nasal secretions and provides results within 15 minutes. For this purpose, influenza A and B-specific antibodies are used to detect influenza A or B antigens in the sample.

PRINCIPLE
This rapid influenza test cassette is an immunoassay-based membrane test for the qualitative detection of influenza A/B nucleoproteins in throat and nasal swabs and nasal secretions. For this purpose, two test lines (A and B) were coated with A and B specific antibodies. During the test, the sample migrates across the membrane and any antigens present in the specimen react with the particles coated with antibodies against influenza and one or two red test lines (A and B) appear. The coloured test line(s) indicate(s) a positive result. A control line (C) serves as an integrated procedural control and appears if the test has been performed correctly.

REAGENTS
The test cassette contains anti-influenza A and B particles and a membrane coated with antibodies against influenza A and B.

PRECAUTIONS
1.Pleastic use only. Do not use after the expiration date.prior to testing.

2. Leave the test cassette in the sealed pouch until testing.
3. Handle all specimens as if they contained infectious agents.
4. The used materials should be discarded according to local regulations regarding infectious agents.

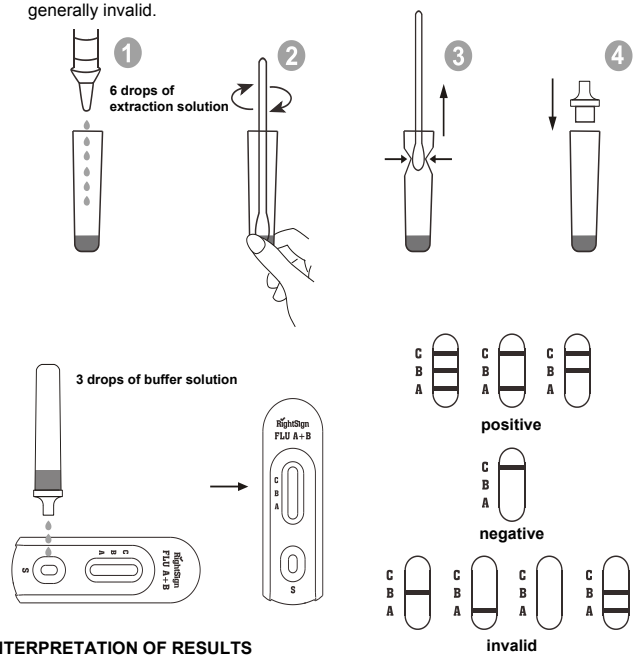
STORAGE AND STABILITY
The test in the sealed pouch can either be refrigerated or stored at room temperature (2-30°C). The test is stable through the expiration date printed on the sealed pouch and must remain in the sealed pouch until use. Do not use the test/ test materials after the expiration date and do not freeze them!

SPECIMEN COLLECTION AND PREPARATION
Nasal swab: Carefully insert the swab in the nose and gently wipe against the nasal mucus to collect the specimen.
Throat swab: Carefully insert the swab in the throat and collect the specimen by gently wiping the swab against the pharyngeal wall, the palatal tonsil and any inflamed, red areas. Avoid contact between the swab and saliva.
Nasal secretion: Connect a suction catheter to a suction unit or pump, insert the catheter through a nostril and suck out some nasal secretion. Dip a sterile swab into the secretion and ensure that a sufficient amount of secretion adheres to the swab.

MATERIALS
Provided materials
Test cassettes, extraction reagent, extraction tubes, sterile swabs, dropper caps, workstation, influenza A+/B- control, influenza A-/B+ control

Materials required but not provided
Timer
Suction accessories

TEST PERFORMANCE
Allow the test materials to reach room temperature (15-30°C) prior to testing.
1. Remove the test cassette from the sealed pouch and perform the test within one hour. The best results are achieved if the test is used immediately after opening the package.
2. Place an extraction tube on the workstation. Hold the bottle with the extraction solution vertically and upside down over the tube. Squeeze the bottle to add 6 drops (approx. 400 µl) to the tube without touching the rim.
3. Put the swab into the extraction tube and twist it for approx. 10 seconds while regularly pushing it against the tube wall to leave as many antigens in the solution as possible.
4. Squeeze the extraction tube a little when removing the swab to retain as much solution as possible. Dispose of the swab according to local regulations.
5. Place the dropper cap onto the tube and place the test cassette on a clean, level surface.
6. Add 3 drops (approx. 120µl) to the specimen well and start the timer. Read the results after 15 minutes. Test results read after more than 20 minutes are generally invalid.



INTERPRETATION OF RESULTS
(Please refer to the illustration above)
Influenza A Positive: 2 coloured lines appear. The 1st line appears in the control line region (C) and the 2nd line appears in the test line region (A). This means that influenza A antigens have been detected in the specimen.
Influenza B Positive: 2 coloured lines appear. The 1st line appears in the control line region (C) and the 2nd line appears in the test line region (B). This means that influenza B antigens have been detected in the specimen.
Influenza A and B Positive: 3 coloured lines appear. The 1st line appears in the control line region (C) and the 2nd line appears in the test line region (A) and the 3rd line appears in the test line region (B). This means that influenza A and B antigens have been detected in the specimen.
NOTE: The colour intensity varies depending on the antigen concentration present in the specimen. Therefore, any shade of colour in the test line region should be considered positive.
Negative: 1 coloured line appears. The only line appears in the control line region (C) while no lines appear in the test line regions (A + B).
Invalid: No coloured line appears. In most cases this is due to insufficient specimen application or incorrect procedural techniques. Review the procedure and repeat the test with a new cassette. If the problem persists, discontinue using the test immediately and contact your local distributor.

QUALITY CONTROL
Internal Quality Control
This test is equipped with an internal procedural control. A coloured line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen application and adequate membrane wicking.

External Quality Control
It is recommended to perform a positive and negative control for every 20th test or whenever your lab requires it. External positive and negative controls are supplied with this test. Alternatively, other influenza A and B controls may be used for verification. The use of other control solutions is not recommended as some standard control solutions may contain interfering preservatives.

PERFORMING AN EXTERNAL QUALITY CONTROL
1. Add 6 drops of extraction solution to an extraction tube.
2. Place either the influenza A+/B- swab or the A-/B+ swab in the extraction tube,
3. Twist the swab for approx. 10 seconds and repeatedly press it against the tube wall to transfer as many antigens to the solution as possible.
4. Slightly squeeze the extraction tube when removing the swab to retain as much solution as possible.
5. Place a dropper cap on the tube and place a test cassette on a clean and level surface.
6. Add 3 drops (approx. 120µl) to the specimen well and set the timer. Read the results after 15 minutes. Test results read after 20 minutes are generally invalid.

Should the obtained results not match the expected results, do not use the test kit. Perform a new quality control or contact your distributor.

LIMITATIONS
1. The RightSigh Influenza A+B rapid test is only intended for in vitro diagnostic use. It should only be used for detecting influenza A and B viruses in nasal and throat swabs and nasal secretion specimens. It delivers no quantitative results and should not be used to estimate changes in the virus concentration.
2. The test detects the presence of viable and non-viable influenza A and B viruses in the specimen.
3. As with all diagnostic tests, the results must be interpreted together with other clinical information available to the medical professional.
4. In case of clinical symptoms, a negative test result should be confirmed with help of a cell culture. A negative test result can occur e.g. if the virus concentration is below the detection limit.
5. Large quantities of blood or mucus in the specimen can lead to false positive results.
6. The accuracy of the test depends on the specimen quality. Incorrect specimen collection and storage may lead to false-negative results.
7. Frequent use of over-the-counter and prescription nose sprays can lead to invalid or false test results.
8. An influenza A and/or B positive test does not exclude the co-infection with another pathogen. Therefore, the possibility of bacterial co-infection should be considered.

EXPECTED VALUES
The results of the RightSign Influenza A+B rapid test were tested with an RT-PCR test. The accuracy of the methods was >99%.

PERFORMANCE CHARACTERISTICS
The Influenza A+B rapid test was evaluated with sample material obtained from patients. An RT-PCR test was used as a reference method. The specimens were considered positive if the RT-PCR test gave a positive result and negative if the RT-PCR gave a negative result.

●Nasal Swab

		Type A			Type B		
		RT-PCR		Total	RT-PCR		Total
		Positive	Negative		Positive	Negative	
Influenza A+B Rapid Test	Positive	100	2	102	85	2	87
	Negative	1	180	181	2	200	202
Total		101	182	283	87	202	289
Relative Sensitivity		99.0%			97.7%		
Relative Specificity		98.9%			99.0%		
Accuracy		98.9%			98.6%		

●Throat Swab

		Type A			Type B		
		RT-PCR		Total	RT-PCR		Total
		Positive	Negative		Positive	Negative	
Influenza Rapid Test	Positive	58	1	59	65	1	66
	Negative	3	150	153	4	162	166
Total		61	151	212	69	163	232
Relative Sensitivity		95.1%			94.2%		
Relative Specificity		99.3%			99.4%		
Accuracy		98.1%			97.8%		

●Nasal Secretion

		Type A			Type B		
		RT-PCR		Total	RT-PCR		Total
		Positive	Negative		Positive	Negative	
Influenza Rapid Test	Positive	46	2	48	94	1	95
	Negative	0	241	241	2	158	160
Total		46	243	289	96	159	255
Relative Sensitivity		100%			97.9%		
Relative Specificity		99.2%			99.4%		
Accuracy		99.3%			98.8%		

Reactivity with human influenza strains

The Influenza A+B rapid test was tested with the following human influenza strains, resulting in the appearance of distinctly coloured lines.

Influenza A Virus	*Influenza B Virus*
A/NWS/33 10(H1N1)	Bright
A/Hong Kong/8/68(H3N2)	B/R5
A/Port Chalmers/1/73(H3N2)	B/Russia/69
A/WS/33(H1N1)	B/Lee/40
A/New Jersey/8/76(HswN1)	B/Hong Kong/5/72
A/Mal/302/54(H1N1)	

Specificity Examination with different Viral Strains

Name	**Tested Concentration**
Human adenovirus C	5.62×10^5 TCID50/ml
Human adenovirus B	1.58×10^4 TCID50/ml
Adenovirus type 10	3.16×10^3 TCID50/ml
Adenovirus type 18	1.58×10^4 TCID50/ml
Human coronavirus OC43	2.45×10^6 LD50/ml
Coxsackievirus A9	2.65×10^4 LD50/ml 1.58×10^5 TCID50/ml
Coxsackievirus B5	1.58×10^7 TCID50/ml
Human herpes virus 5	1.58×10^4 TCID50/ml
Echovirus 2	3.16×10^5 TCID50/ml
Echovirus 3	1×10^4 TCID50/ml
Echovirus 6	3.16×10^5 TCID50/ml
Herpes simplex Virus 1	1.58×10^6 TCID50/ml
Human herpes virus 2	2.81×10^5 TCID50/ml
Human rhinovirus 2	2.81×10^4 TCID50/ml
Human rhinovirus 14	1.58×10^6 TCID50/ml
Human rhinovirus 16	8.89×10^6 TCID50/ml
Measles virus	1.58×10^4 TCID50/ml
Mumps	1.58×10^4 TCID50/ml
Sendai virus	8.89×10^7 TCID50/ml
Parainfluenza virus 2	1.58×10^7 TCID50/ml
Parainfluenza virus 3	1.58×10^8 TCID50/ml
Respiratory syncytial virus	8.89×10^4 TCID50/ml
Human respiratory syncytial virus	1.58×10^5 TCID50/ml
Rubella	2.81×10^5 TCID50/ml
Varicella zoster	1.58×10^3 TCID50/ml

TCID50: (Tissue Culture Infectious Dose) virus concentration at which 50% of the vaccinated cells are infected.

LD50: (Lethal Dose) virus concentration at which 50% of the mice will be killed.

RELIABILITY

Inter- and Intra-Array

The reliability of the tests in one batch and between batches was tested with 5 influenza standard control solutions. For this purpose, RightSign cassettes from 3 different batches were tested with negative, weakly positive A, weakly positive B, extremely positive A and extremely positive B specimens. Over three days, 10 tests were performed each and the specimens were correctly identified in >99% of the cases.

Cross-Reactivity

The cassette has been tested with the following organisms at a concentration of 1x108org/ml. None of the organisms had an impact on the correct test result.

Arcanobacterium	*Pseudomonas aeruginosa*
Candida albicans	*Staphylococcus aureus subsp aureus*
Corynebacterium	*Staphylococcus epidermidis*
Enterococcus faecalis	*Staphylococcus saprophylicus*
Enterococcus faecium	*Streptococcus agalactiae*
Escherichia coli	*Streptococcus bovis*
Haemophilus	*Streptococcus dysgalatiae*
Moraxella catarrhalis	*Streptococcus oralis (prior: Streptococcus)*
Neisseria gonorrhoeae	*Streptococcus pneumoniae*
Neisseria lactamica	*Streptococcus pygenes*
Neisseria subflava	*Streptococcus salivarius*
Proteus 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 HealthOrganisation, July 2005.

Index of Symbols

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorised Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Storage between 2-30°C	LOT	Lot Number	REF	Catalogue #
	Do not use if the package is damaged				

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

EC REP
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