Rapid Response™

Influenza A+B Test Cassette
(Swab/Aspirate)
REF **FLUAB -19C20** **Product Insert**

A rapid test for the qualitative detection of Influenza A and Influenza B virus in nasopharyngeal swab/nasal swab, throat swab or nasal aspirate specimens.

For Laboratory *in vitro* diagnostic use only.

Intended Use

The Rapid Response™ Influenza A+B Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of influenza A and B antigens in nasopharyngeal swab/nasal swab, throat swab or nasal aspirate specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.

Introduction

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 Rapid Response™ Influenza A+B Test Cassette qualitatively detects the presence of Influenza A and/or Influenza B antigen in nasopharyngeal swab/nasal swab, throat swab or nasal aspirate specimens, providing results within 8 minutes and the test uses antibodies specific for Influenza A and Influenza B to selectively detect Influenza A and Influenza B antigen.

Principle

The Rapid Response™ Influenza A+B Test Cassette is a qualitative, lateral flow immunoassay for the detection of Influenza A and Influenza B nucleoproteins in nasopharyngeal swab/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 the test regions indicate 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 laboratory *in vitro* diagnostic use only.
2. Do not use after the expiration date.
3. The test should remain in the sealed pouch until ready to use.
4. All specimens should be considered potentially hazardous and handled in the same manner as an infection agent.
5. The used test should be discarded according to the local regulations.
6. Avoid using bloody samples.
7. 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°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.

Materials

Materials provided

- Test cassettes
- Extraction Buffer Tubes
- Workstation
- Sterile Swabs
- Package Insert
- Influenza A+/B- Control Swab (Non-viable Flu A)
- Influenza A-/B+ Control Swab (Non-viable Flu B)

Materials required but not provided

- Timer
- Aspiration Device

Specimen Collection

To collect Nasopharyngeal swab specimen

Insert swab through the nostril parallel to the palate (not upwards) .The distance should be equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx or until resistance is encountered. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave swab in place for several seconds to saturate tip with secretions. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab is saturated with fluid from the first collection. If a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

To collect Nasal swab specimen

Prior to collecting the nasal swab, the patient should be instructed to blow their nose. To collect a nasal swab sample, insert the entire absorbent tip of the nasal swab (usually ⅗ to 1 of an inch (1.5 to 2.5cm)) inside the nostril and firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall at least 5 times. Take approximately 15 seconds to collect the sample per nostril. Be sure to collect any nasal drainage that may be present on the swab. Sample both nostrils with the same swab before testing.

To collect Throat swab specimen

Insert swab into the throat areas. Rub swab over both throat pillars and avoid touching the tongue, teeth, and gums.

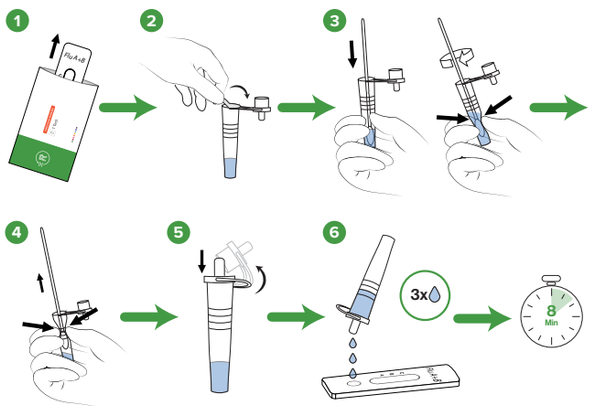
To collect Nasal aspirate

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.

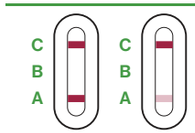
Test Procedure

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

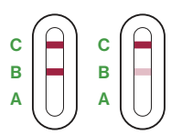
1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the assay is performed immediately after opening the foil pouch. See illustration 1.
2. Tear the aluminum foil off the top of the extraction buffer tube. See illustration 2.
3. Place the swab specimen inside the extraction buffer tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the extraction buffer tube to release the antigen in the swab. See illustration 3.
4. Remove the swab while squeezing the swab head against the inside of the extraction buffer 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 4.
5. Secure the nozzle dropper cap tightly onto the top of the extraction buffer tube. Place the test cassette on a clean and level surface. See illustration 5.
6. Invert the tube and transfer 3 drops of the sample solution (approx. 80µL) to the sample well and then start the timer. See illustration 6.
7. Read the result at 8 minutes. Do not interpret the result after 15 minutes.



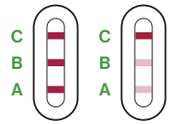
Results Interpretation



POSITIVE Influenza A:* Two distinct colored lines appear. One colored line should be in the control region (C) and another 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.

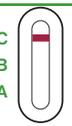


POSITIVE Influenza B:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B). A positive result in the Influenza B region indicates that Influenza B antigen was detected in the sample.

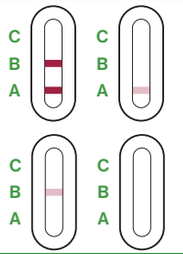


POSITIVE Influenza A and Influenza B:* Three distinct colored lines appear. One colored line should be in the control region (C) and two colored lines should be in the Influenza A region (A) and Influenza B region (B). A positive result in the Influenza A region and Influenza B region indicates that 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 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 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 are run for 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. Tear the aluminum foil off the top of the extraction buffer tube.
2. Place the Influenza A+/B- or A-/B+ control swab in the extraction buffer tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the extraction buffer tube to release the antigen in the swab.
3. Remove the swab while squeezing the swab head against the inside of the extraction buffer tube as you remove it to expel as much liquid as possible from the swab.
4. Secure the nozzle dropper cap tightly onto the top of the extraction buffer tube. Place the test cassette on a clean and flat surface. Do not move the test cassette during the test.
5. Invert the tube and transfer 3 drops of the sample 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.

Document Number: Insert Doc #
Effective Date: 2023-07-06

Limitations

1. The Rapid Response™ Influenza A+B Test Cassette is for laboratory *in vitro* diagnostic use only. The test should be used for the detection of Influenza A and/or B virus in nasopharyngeal swab/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 Rapid Response™ Influenza A+B Test Cassette 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 Rapid Response™ Influenza A+B Test Cassette has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for The Rapid Response™ Influenza A+B Test Cassette. Specimens were considered positive if RT-PCR indicated a positive result.

		Type A		
		RT-PCR		Total
		Positive	Negative	
Rapid Response™ Influenza A+B Test Cassette	Positive	68	14	82
	Negative	10	242	252
Total		78	256	334
Relative Sensitivity		87.2%		
Relative Specificity		94.5%		
Accuracy		92.8%		

		Type B		
		RT-PCR		Total
		Positive	Negative	
Rapid Response™ Influenza A+B Test Cassette	Positive	49	7	56
	Negative	4	274	278
Total		53	281	334
Relative Sensitivity		92.5%		
Relative Specificity		97.5%		
Accuracy		96.7%		

Reactivity with Human Influenza Strain

Influenza A strains

Subtype of H1N1: Mal/302/54, New Jersey/8/76, NWS/33, WS/33, Guangdong-Maonan/SWL1536/2019; H3N2: Aichi/2/68, Hong Kong/8/68, Port Chalmers/1/73, H7N9: Anhui/1/2013 all are positive.

Influenza B strains

Russia/69, Hong Kong/5/72, Lee/40, Brigit, R5, Wisconsin/1/2010, Florida/78/2015, Phuket/3073/2013, Washington/02/2019, Hong Kong/2671/2019 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, Streptococcus pneumoniae.

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.
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.

Glossary of Symbols

Consult instructions for use	Test per Kit	REF	Catalogue #
Store between 2˚C to 30˚C	Use by		Do Not Reuse
LOT Lot Number	IVD For *in vitro* diagnostic use only	EC REP	Authorized Representative

EC REP
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CE

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Document Number: Insert Doc #
Effective Date: 2023-07-06