

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

Package Insert

REF IN-502 English

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

INTENDED USE

The Influenza A+B Rapid Test Cassette (Swab/Nasal Aspirate) is a rapid chromatographic immunoassay for the qualitative 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 swab 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 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 Rapid Test Cassette (Swab/Nasal Aspirate) is a qualitative, lateral flow immunoassay for the detection of Influenza A and Influenza B nucleoproteins in nasopharyngeal swab, throat swab or nasal aspirate specimens. In this test, antibodies 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 antibodies to Influenza A and/or Influenza B that are coated onto particles. The mixture migrates up the membrane to react with the antibodies 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 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.

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until ready to use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- 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.

SPECIMEN COLLECTION AND PREPARATION

- Nasopharyngeal swab sample
- Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.
 - Swab over the surface of the posterior nasopharynx 5-10 times.
 - Throat swab sample
- Insert a sterilized swab into pharynx and collect mucopidermis 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.

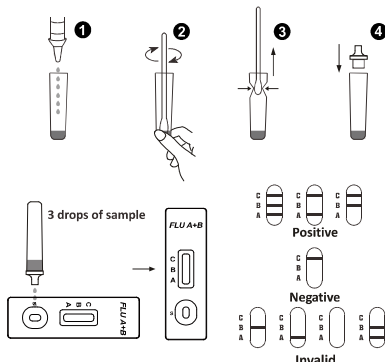
MATERIALS

- Materials provided**
- Test Cassettes
 - Sterile Swabs
 - Extraction Tube Tips
 - Extraction Reagent
 - Package Insert
 - Extraction Tubes
 - Workstation
- Materials required but not provided**
- Timer
 - Aspiration Device

DIRECTIONS FOR USE

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

- 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.
- 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. 400µl) to the Extraction Tube. See illustration 1.
- 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.
- 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.
- Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface. See illustration 4.
- Add **three drops of the solution** (approx. 120µl) to the sample well and then start the timer.
- Wait for the colored line(s) to appear. Read the result at **15 minutes**. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE Influenza A: * **Two 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 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 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 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

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. Control standards are not supplied with this kit; however, it is recommended that a positive control and a negative control be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- 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 nasopharyngeal 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.
- 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.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- 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 nasopharyngeal swab is not adequate or is below the detectable level of the test.
- Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result.
- The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
- 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.
- 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.

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. 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 | |
| Flu A+B | 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 Specimen

| | Type A | | | Type B | | |
|-----------------------------|----------------|------------|------------|-----------|------------|------------|
| | RT-PCR | | Total | RT-PCR | | Total |
| | Positive | Negative | | Positive | Negative | |
| Flu A+B | 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 Aspirate Specimen

| | Type A | | | Type B | | |
|-----------------------------|----------------|------------|------------|-----------|------------|------------|
| | RT-PCR | | Total | RT-PCR | | Total |
| | Positive | Negative | | Positive | Negative | |
| Flu A+B | 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 Strain

The Influenza A+B Rapid Test Cassette (Swab/Nasal Aspirate) was tested with the following human influenza strains and a discernible line at appropriate test-line regions was observed:

| 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 ⁶ TCID ₅₀ /ml |
| Adenovirus type 10 | 3.16 x 10 ⁷ TCID ₅₀ /ml |
| Adenovirus type 18 | 1.58 x 10 ⁸ 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 ³ 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 |

TCID₅₀ = 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.

LD₅₀ = 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 Rapid 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 1.0x10⁶org/ml and all found to be negative when tested with the Influenza A+B Rapid Test Cassette (Swab/Nasal Aspirate):

| | |
|------------------------------|---|
| <i>Arcanobacterium</i> | <i>Pseudomonas aeruginosa</i> |
| <i>Candida albicans</i> | <i>Staphylococcus aureus subsp. aureus</i> |
| <i>Corynebacterium</i> | <i>Staphylococcus epidermidis</i> |
| <i>Enterococcus faecalis</i> | <i>Staphylococcus saprophyticus</i> |
| <i>Enterococcus faecium</i> | <i>Streptococcus agalactiae</i> |
| <i>Escherichia coli</i> | <i>Streptococcus bovis</i> |
| <i>Haemophilus</i> | <i>Streptococcus dysgalactiae / subsp. dysgalactiae</i> |
| <i>Moraxella catarrhalis</i> | <i>Streptococcus oralis formerly Streptococcus</i> |
| <i>Neisseria gonorrhoeae</i> | <i>Streptococcus pneumoniae</i> |
| <i>Neisseria lactamica</i> | <i>Streptococcus pyogenes</i> |
| <i>Neisseria subflava</i> | <i>Streptococcus salivarius</i> |
| <i>Proteus vulgaris</i> | <i>Streptococcus sp group F. type 2</i> |

BIBLIOGRAPHY

- 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.
- 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.
- 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 |  | Contains sufficient for <n> tests |  | Temperature limit |
|  | In vitro diagnostic medical device |  | Batch code |  | Catalogue number |
|  | 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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