Influenza A+B Antigen Rapid Test Kit

Catalog Number: AU2032

For Research Use Only. Not for use in Diagnostic Procedures.

1. Intended Use

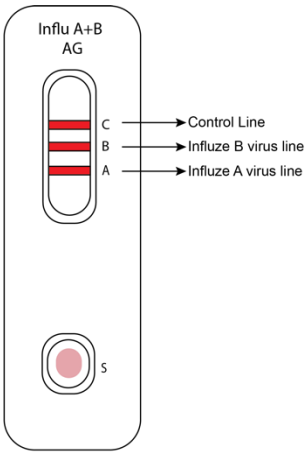
The Influenza A+B Antigen Rapid Test Kit is a rapid visual immunoassay for the qualitative, presumptive detection of influenza A and B viral antigens form throat swabs and nasopharyngeal swab specimens. The test is intended for use as an aid in the rapid detection of acute influenza type A and type B virus Antigen infection.

2. Introduction

Influenza is a highly contagious, acute, viral infection of the respiratory tract. The causative agents of the disease are immunologically diverse, single-strand RNA viruses known as influenza viruses. There are three types of influenza viruses: A, B, and C. Type A viruses are the most prevalent and are associated with most serious epidemics. Type B viruses produce a disease that is generally milder than that caused by type A. Type C viruses have never been associated with a large epidemic of human disease. Both type A and B viruses can circulate simultaneously, but usually one type is dominant during a given season. Influenza antigens may be detected in clinical specimens by immunoassay. The Influenza A+B Test is a lateral-flow immunoassay using highly sensitive monoclonal antibodies that are specific for influenza antigens. The test is specific to influenza types A and B antigens with no known cross-reactivity to normal flora or other known respiratory pathogens.

3. Principle

The Influenza A+B Rapid Test Device detects influenza A and B viral antigens through visual interpretation of color development on the strip. Anti-influenza A and B antibodies are immobilized on the test region A and B of the membrane respectively. During testing, the extracted specimen reacts with anti- influenza A and B antibodies conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient influenza A and B viral antigens in the specimen, colored band(s) will form at the according test region of the membrane.



The presence of a colored band in the A and/or B region indicates a positive result for the particular viral antigens, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

4. Kit Contents

Contents	Total Tests provided
Cassette Device	25 devices (each sealed foil pouch contains: 1 device, 1 desiccant)
Disposable Dropper	25 droppers
Sample Diluent	25 bottles
Collection Swabs	25 sterile single use specimen collection swabs
Instruction Manual	1 each

5. Storage and Stability

- The kit should be stored at 2~30°C, valid for 12months.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Care should be taken to protect components in this 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.

6. Precautions

- Read this IFU carefully before use.
- Do not spill solution into the reaction zone.
- Do not use test if pouch is damaged.
- Do not use test kit after expiration date.
- Do not mix Sample Diluent Solution and Transfer Tubes from different lots.

- Do not open the Test Cassette foil pouch until ready to perform the test.
- Do not spill solution into the reaction zone.
- For professional use only.
- Do not touch the reaction zone of the device to avoid contamination.
- Avoid cross-contamination of samples by using a new specimen collection container and specimen collection tube for each sample.
- All patient samples should be treated as if capable of transmitting disease. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Do not use more than the required amount of liquid.
- Bring all reagents to room temperature (15~30°C) before use.
- Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when testing.
- Evaluate the test result after 20 minutes and not beyond 30 minutes.
- Store and transport the test device always at 2~30°C.

7. Sample Collection and Storage

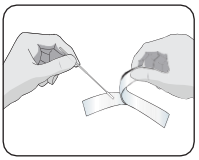
Prepare Materials

Open the package, take out the Influenza A+B Antigen test card in pouch, the Tube filled with the extraction buffer and the swab. When you are ready to proceed with the test, open the foil pouch of the Influenza A+B Antigen test card.

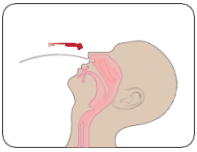
Note: Failure to swab properly may cause false negative results

Nasopharyngeal Swab Collection Method:

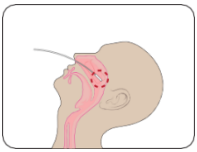
1. Remove the oropharyngeal swab from the pouch.



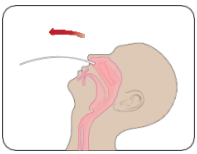
2. Tilt patient's head back 70 degrees. Gently and slowly insert the swab into one of patient's nostrils until it reaches the posterior nasopharynx; keep insert until resistance is equivalent to that from the ear to the nostril of the patient.



3. Slowly rotate 3-5 times the swab over the surface of the posterior nasopharynx.

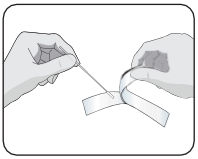


4. Leave swab in place for several seconds to absorb secretions. Slowly remove the swab from the nostril while rotating it.

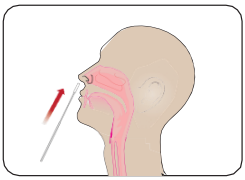


Anterior Nasal Swab Collection Method:

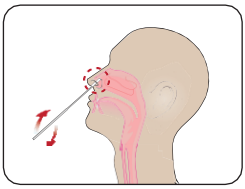
1. Remove the oropharyngeal swab from the pouch.



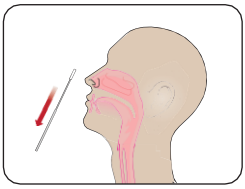
2. Insert the swab into one of patient's nostrils up to 1 inch from the edge of the nostril.



3. Slowly roll the swab 5 times over the surface of the nostril. Using the same swab repeat this collection process in the other nostril. Take approximately 15 seconds to collect the specimen.

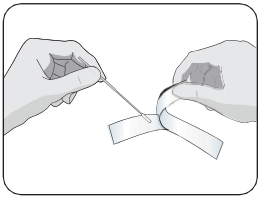


4. Slowly remove the swab from the nostril while rotating it.

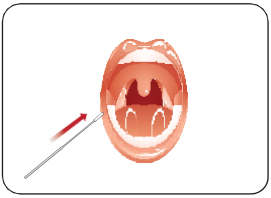


Oropharyngeal Swab Collection Method:

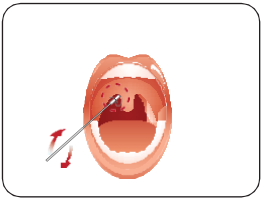
1. Remove the oropharyngeal swab from the pouch.



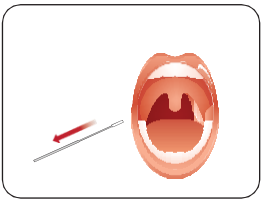
2. Tilt patient's head back 70 degrees



3. Insert swab into the oral cavity without touching the gums, teeth, and tongue (A tongue depressor may be used.) Swab the posterior pharyngeal wall using a rotatory motion.



4. Withdraw the swab from the oral cavity.



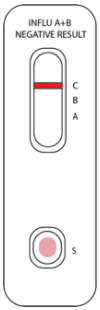
Sample Treatment:

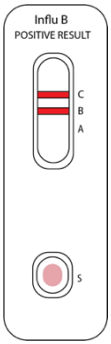
- Dip the swab after sample collection into the Sample Diluent solution tube, make the solution fully permeate the swab.
- Rotate and squeeze the swab 5 times, then pull out the swab, and take the remained liquid as the sample to be tested.

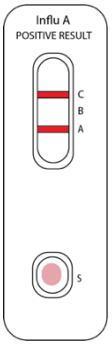
Assay Procedure:

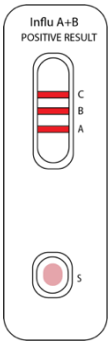
- Apply the treated Sample Diluent solution vertically into the sample well of the test cassette.
- The results are observed after 20 minutes and showed on clinical significance after 20 minutes.

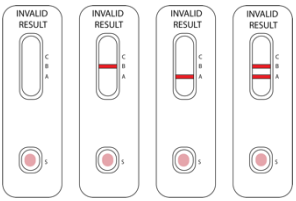
8. Interpretation of Results

Negative Results	
	If only the C band is present, the absence of any burgundy color in both test bands (A, B) indicates that no Influenza A or B are detected. The result is negative or non-reactive.

Influenza B Positive	
	In addition to the presence of C band, if only B band is developed, indicates for the presence of Influenza B virus; the result suggests Influenza B virus infection.

Influenza A Positive	
	In addition to the presence of C band, if only A band is developed, indicates for the presence of Influenza A virus; the result suggests Influenza A virus infection.

Influenza A/B Positive	
	In addition to the presence of C band, if B and A bands are developed, indicates for the presence of Influenza A virus and Influenza B virus; the result suggests Influenza A virus and Influenza B virus infection.

Invalid Result	
	**Control line (C) fails to appear.** Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test device. If the problem persists, discontinue using the test kit immediately and contact Attogene at 512-333-1330.

9. Note

The intensity of the color in test regions may vary depending on the concentration of antigen present in the sample. The antigen level cannot be determined by this qualitative test. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

10. Quality Control

Internal Control:

This test contains a built-in control feature, the (C) band. The (C) line develops after adding specimen and sample diluent. Otherwise, review the whole procedure and repeat test with a new device.

External Control:

External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performing of the assay, in particularly, under the following circumstances:

- New operator uses the kit, prior to performing testing of specimens.
- A new lot of test kit is used.
- A new shipment of kits is used.
- The temperature used during storage of the kit fall outside of 2°C -30°C.
- The temperature of the test area falls outside of 15°C -30°C.

11. Limitations of the Test

1. The Influenza A+B Antigen Rapid test kit (Nasal swab test) is for research use only. This test should be used for the detection of Influenza A+B antigens in human Nasal swab specimens.
2. The Influenza A+B Antigen Rapid test kit (Nasal swab test) will only indicate the presence to Influenza A+B antigens in the specimen and should not be used as the sole criteria for the detection of Influenza A+B.
3. If the symptom persists, while the result from Influenza A+B Antigen Rapid test kit is negative or

non-reactive result, it is recommended to re-sample few hours later.

4. A negative result does not at any time preclude the possibility of Influenza A+B infection.
5. The potential impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated in the test.
6. Due to inherent differences between methodologies, it is highly recommended that, prior to switching from one technology to the next, method correlation studies are undertaken to qualify technology differences. One hundred percent agreement between the results should not be expected due to differences between technologies.
7. Performance has only been established with the specimen types listed in the Intended Use. Other specimen types have not been evaluated and should not be used with this assay.

12. Notice

1. Must strictly follow the instructions for operation and interpretation of the results.

2. The product is qualitatively tested, and the result cannot be used as a quantitative basis.
should be tested using reagents within the validity period.

3. The reagent and swab if for one-time use and cannot be reused.

4. Because the sample titer is different, the red lines of the test line will show different shades of color, all of which indicate positive results. The depth of the test line color cannot be used as the basis for determining the antigen in the sample.

5. The samples stored at low temperature should be balanced to room temperature and fully mixed before testing.

6. Samples and waste must be treated as a potential source of infection and the desiccant in the foil bag is not edible.

Contact Us

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AU2032_V5