Influenza A and B (FLU A&B) Test Kit
Instruction for Use

Artron

Format: Cassette

Specimen: Nasal Swab

Catalog Number: A03-41-422PNS1 / A03-41-422PNS5 / A03-41-422PNS25

Specimen: Nasopharyngeal Swab

Catalog Number: A03-41-422PNP1 / A03-41-422PNP5 / A03-41-422PNP25

* Please read the instructions carefully before use

INTENDED USE

Artron Influenza A and B (FLU A&B) Test Kit is a rapid and convenient immunochromatographic assay for the qualitative detection of Influenza Type A and B nucleoproteins antigens from nasal swab or nasopharyngeal swab obtained from patient with signs and symptoms of respiratory infection. The device is designed to aid in the rapid differential diagnosis of influenza A and B viral infection.

This assay provides only a preliminary result. The test is not intended to detect influenza C antigens. Negative results should be confirmed by viral culture; they do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.

SUMMARY AND PRINCIPLE OF THE ASSAY

Influenza is a highly contagious acute viral infection of the respiratory tract.It is a communicable disease easily transmitted from person to person through aerosol droplets excreted when sneezing and coughing. Common symptoms include high fever, chills, headache, cough, sore throat and malaise. The type A influenza virus is more prevalent and is the primary pathogen associated with serious epidemics. The type B virus causes a disease that is generally not as severe as that caused by the type A virus. Both type A and B viruses can circulate simultaneously, but usually one type is dominant during a given season.

Early differential diagnosis of influenza type A or type B can allow for proper treatment with appropriate antiviral therapy while reducing the incidence of inappropriate treatment with antibiotics. Early diagnosis and treatment is of particular value in a clinical setting where accurate diagnosis can assist the healthcare professional with management of influenza patients who are at risk for complications. Artron Flu A& B is a rapid immunoassay to be used as an aid for the differential diagnosis of influenza type A and type B.

Artron One-Step FLU A&B Antigen test is an antigen-capture immunochromatographic assay, detecting presence of Influenza A and B nucleoproteins antigen in nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash samples. This assay utilizes the chemical extraction of viral antigens followed by solid-phase immunoassay technology for the detection of extracted antigen influenza A and/or B. Monoclonal antibodies specifically against Influenza A and B antigen are conjugated with colloidal gold and deposited on the conjugate pad, and immobilized on the Test Zone on the nitrocellulose membrane. When a sample is added, thegold-antibody conjugate is rehydrated and the Influenza A and B antigen, if any in the sample, will interact with the gold conjugated antibodies. The antigen-antibody-gold complex will migrate towards the test window until the Test Zone (A and/or B) where they will be captured by immobilized antibodies, forming a visible pink line (Test band) indicative of positive results. If Influenza A and B antigen are absent in the sample, no pink line will appear in the Test Zone (T).

To serve as an internal process control, a control band was designed to indicate that the test is performed properly. By utilizing the different antigen/antibody reaction, this control line should always be seen after test is completed. Absence of a pink control line in the control region is an indication of an invalid result.

PACKAGE CONTENTS

- Pouch contents: Test Cassette and Desiccant,1 device for 1pc/pack, 5 devices for 5 pcs/pack, 25 devices for 25 pcs/pack.
- Extraction tubes sealed with sample extraction buffer (300μL/tube):1 tube for 1pc/pack, 5 tubes for 5pcs/pack, 25 tubes for 25 pcs/pack.
- Tube caps: 1 cap for 1pc/pack, 5 caps for 5 pcs/pack, 25 caps for 25 pcs/pack.
- Sterilized Nasopharyngeal Swab for Catalog A03-41-422PNP1 / A03-41-422PNP5 / A03-41-422PNP25, 1 swab for 1pc/pack, 5 swabs for 5 pcs/pack, 25 swabs for 25 pcs/pack;

Sterilized Nasal Swab for Catalog A03-41-422PNS1 / A03-41-422PNP5 / A03-41-422PNP25; 1 swab for 1pc/pack, 5 swabs for 5 pcs/pack, 25 swabs for 25 pcs/pack.

- 1 tube rack for 25pcs/pack
- Test Instructions

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clock or timer.
- Latex gloves

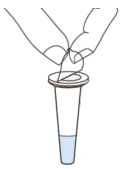
WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- Do not reuse.
- Do not use if the pouch seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.
- Wash hands thoroughly after finishing the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are being handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
- Keep out of children's reach.

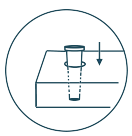
SPECIMEN COLLECTION AND PREPARATION

Note:
Before proceeding with sample collection and testing, please read the instruction carefully, and operate strictly in accordance with the instructions.
Freshly collected specimens should be processed immediately. Specimens in Artron sample extraction buffer are stable for up to 4 hours at 2-8°C or room temperature.

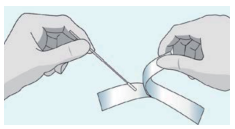
1.Tear off the aluminum foil seal from the extraction tube.



2.Before collecting the sample, place the sample extraction tube into the tube holder on the box(for 1pc/pack and 5 pcs/pack) or provided tube rack.

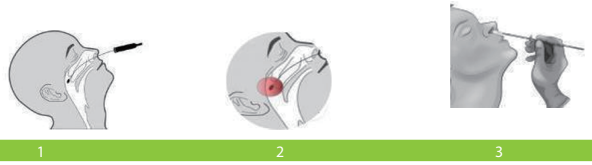


3. Remove a swab from the pouch.



4a. For Nasopharyngeal Swab Specimen collection

1. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.
2. Swab over the surface of the posterior nasopharynx.
3. Withdraw the sterile swab from the nasal cavity.



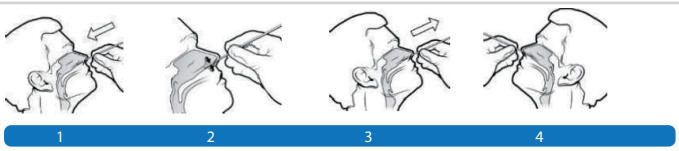
4b. For Nasopharyngeal Swab Specimen collection

1. Insert the entire absorbent tip of the swab into your nostril, but do not insert the swab more than 3/4 of an inch (1.5 cm) into your nose.

2. Slowly rotate the swab in a circular path against the inside of your nostril at least 5 times for a total of 15 seconds. Be sure to collect any nasal drainage that may be present on the swab.

3. Gently remove the swab.

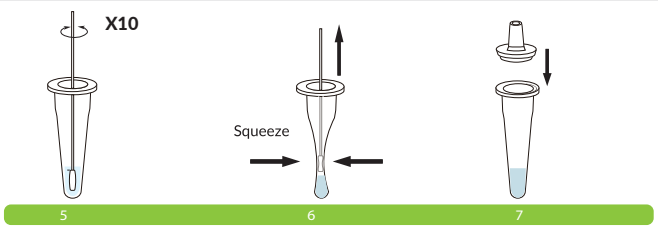
4. Using the same swab, repeat steps 1 to 3 in your other nostril.



5. Insert the swab in the extraction tube. Swirl the swab tip vigorously in the buffer fluid at least 10 times.

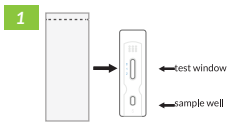
6. Remove the swab by rotating against the extraction tube while squeezing the sides of the tube to release the liquid from the swab. Properly discard the swab.

7. Close the extraction tube with the provided extraction tube cap and push firmly onto the tube.

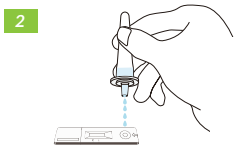


TEST PROCEDURES

1. Get the test cassette from the sealed pouch by tearing at the notch and place the cassette on a flat, dry surface



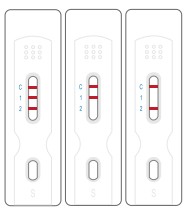
2. Hold the reagent tube vertically with the filter tip pointing downward. Add 4 drops (about 120 µl) of the specimen without air bubbles into the sample well.



3. Read and interpret the test result within 20-30 minutes. The test result should not be read and interpreted after 30 minutes. If a test shows a negative result at the 20 minutes, not to discard the device immediately as some positive results may develop later in the 20-30 min interval.

4. All used test components should be disposed of in Biohazard Container.

RESULT INTERPRETATION



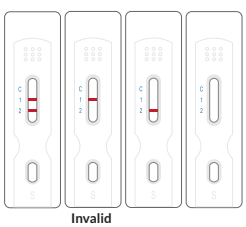
Positive

A clear pink control band (C) and a detectable test band (T1) or (T2) appears, indicating a positive result.

Band T1: Positive for Influenza A
Band T2: Positive for Influenza B

Negative

A pink colored band appears only at the control region (C), indicating a negative result



Invalid

No visible band appears at the control region. Repeat with a new test kit. If the test still fails, please contact the distributor with the lot number.

QUALITY CONTROL

Although the testing device contains an internal quality control (pink or purple colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND STABILITY

- Test device in the sealed pouch can be stored at 2-30°C up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture, and heat.
- Shelf life:18 months.

LIMITATIONS

- The contents of this kit are to be used for the qualitative detection of influenza A and B antigen from nasal swab, nasopharyngeal swab, nasal wash and nasal aspirate specimens.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
- Failure to follow the Test Procedure and Interpretations of Test Results may adversely affect test performance and/or invalidate the Test Result.
- Test Results must be evaluated in conjunction with other clinical data available to the physician.
- Negative test results do not rule-out possible other non-influenza viral infections.
- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not identify specific influenza A virus subtypes.
- Children tend to shed virus more abundantly and for longer periods of time than adults. Therefore, testing specimens from adults will often yield lower sensitivity than testing specimens from children.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low influenza activity when prevalence is moderate to low.
- Individuals who received nasally administered influenza A vaccine may have positive test results for up to 3 days after vaccination.
- Monoclonal antibodies may fail to detect, or detect with less sensitivity, influenza A viruses that have undergone minor amino acid changes in the target epitope region.
- If differentiation of specific influenza A subtypes and strains is needed, additional testing, in consultation with the State or Local public health department, is required.

PERFORMANCE CHARACTERISTICS

An evaluation study was carried out during flu season at multiple hospitals. Clinical specimens were recruited from patients with flu-like symptoms including fever, dry cough and myalgia. Nasal swab specimens from a total of 247 subjects were tested with RT-PCR for confirmation and then examined with Artron Influenza A&B Test (Flu A&B).

Influenza Type A	RT-PCR		
Artron Flu A&B Test	A(+)	A(-)	Total
Flu A Positive	91	8	99
Flu A and B Positive	2	0	2
Negative	15	131	146
Total	108	139	247

Diagnostic Sensitivity: (91+2)/108 = 86.1%
Diagnostic Specificity: 131/139 = 94.2%
Overall Accuracy: (93+131)/274 = 90.7%

Influenza Type B	RT-PCR		
Artron Flu A&B Test	B(+)	B(-)	Total
Flu B Positive	79	11	90
Flu A and B Positive	2	0	2
Negative	20	135	155
Total	101	146	247

Diagnostic Sensitivity: (79+2)/101 = 80.2%
Diagnostic Specificity: 135/146 = 92.5%
Overall Accuracy: (81+135)/247 = 87.4%

INDEX OF SYMBOLS

Do not reuse	Batch code
In vitro diagnostic medical device	Use by
Temperature limitation	Contains sufficient for < n > tests
Caution	Catalog number
Manufacturer	Consult instructions for use
Authorized representative in the European community	CE Mark

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