CE IVD

Influenza A/B + RSV Antigen Rapid Test Kit (Nasal Swab Test)

Instruction for Use

Read this instruction carefully before use

A rapid test for the qualitative detection of Influenza A/B + RSV Antigen in oropharyngeal swab, nasopharyngeal swabs and Anterior nasal swab specimens. For professional medical institutions use only, Not for self testing.

PRODUCT NAME

Influenza A/B + RSV Antigen Rapid Test Kit (Nasal Swab Test)

SPECIFICATION

25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE

The Influenza A/B+RSV Antigen Rapid Test Kit (Nasal Swab Test)is a lateral flow chromatographic immunoassay for the qualitative detection of Influenza A/B and Respiratory Syncytial Virus in human oropharyngeal swab, nasopharyngeal swabs and Anterior nasal swab specimens. It is suitable for the auxiliary diagnosis of Influenza A/B and Respiratory Syncytial Virus infection.

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.

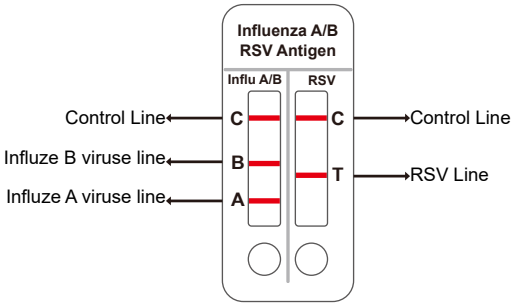
Respiratory Syncytial Virus(RSV) is the most common cause of bronchiolitis and pneumonia among infants and children under 1 year of age.Illness begins most frequently with fever,runny nose,cough and sometimes wheezing. Severe lower respiratory tract disease may occur at any age,especially among the elderly or among those with compromised cardiac, pulmonary or immune systems.RSV is spread from respiratory secretions through close contact with infected persons or contact with contaminated surfaced or objects.

PRINCIPLE

The Influenza A/B+RSV Antigen Rapid Test Kit is based on the principle of a qualitative immunochromatographic assay for the determination of Influenza A/B+RSV antigens in the Nasal Sawb specimen.

StripA consists of: 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.

Strip B consists of : 1) a burgundy colored conjugate pad containing recombinant antigen conjugated with colloid gold (monoclonal mouse anti Respiratory Syncytial Virus(RSV) antibody conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing test band (T bands) and a control band (C band). The T band is pre-coated with monoclonal mouse anti- Respiratory Syncytial Virus(RSV) antibody for the detection of Respiratory Syncytial Virus(RSV) glycoprotein F antigen, and the C band is pre-coated with goat anti rabbit IgG.



Strip A: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 hasbeen added and membrane wicking has occurred.

Strip B:When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. Respiratory Syncytial Virus(RSV) if present in the specimen will bind to the monoclonal mouse anti-Respiratory Syncytial Virus(RSV) antibody conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti-Respiratory Syncytial Virus(RSV) antibody, forming a burgundy colored T band, indicating a Respiratory Syncytial Virus(RSV) antigen positive test result. Absence of test band (T) suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the test bands. Otherwise, the test result is invalid, and the specimen must be retested with another device.

MAIN COMPONENTS

Materials Provided

Components	25 tests/kit	5 tests/kit	1 test/kit
Cassettes	25 cassettes with dependent sealed foil pouch	5 cassettes with dependent sealed foil pouch	1 cassette with dependent sealed foil pouch
Sample Diluent Solution With Dropper	25tubes (300ul/tube)	5tubes (300ul/tube)	300ul/tube
Cotton Swab	25 pcs	5 pcs	1 pcs
Package insert	1 pcs	1 pcs	1 pcs

Main ingredients of Sample Diluent Solution:

Neutral salt buffer

Reagents of different batch numbers cannot be used interchangeably.

MATERIALS REQUIRED BUT NOT PROVIDED

Timer for timing use

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.
- For in-vitro diagnostic 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.

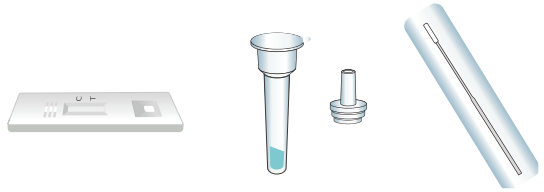
STORAGE AND STABILITY

- 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.
- Cares 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.

SPECIMEN COLLECTION AND HANDLING

1.Prepare Materials

Open the package,take out the Influenza A/B + RSV 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 + RSV Antigen test card.



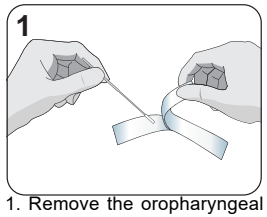
1 Influenza A/B + RSV Antigen Test card

1 Sample Diluent Solution With Dropper

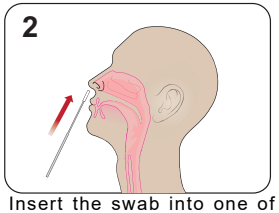
1 Swab

2.Collect Sample

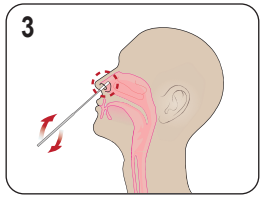
2.1 Anterior Nasal Swab collection:



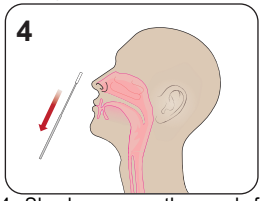
1. Remove the oropharyngeal swab from the pouch.



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



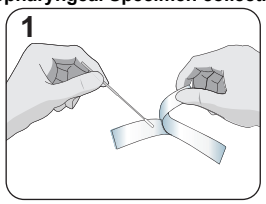
3. Slowly roll the swab 5 times over the surface of the nostril. Using the same swab repeat this collection process in the other nostril. Take approximately 15 seconds to collect the specimen.



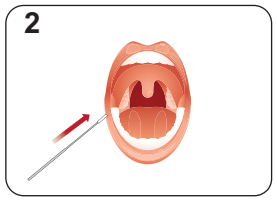
4. Slowly remove the swab from the nostril while rotating it.

Note: Failure to swab properly may cause false negative results.

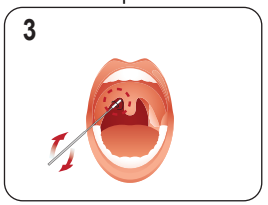
2.2 Oropharyngeal Specimen collection:



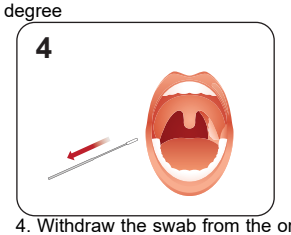
1. Remove the oropharyngeal swab from the pouch.



2. Tilt patient's head back 70 degree



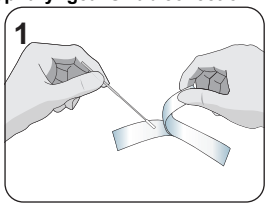
3. Insert swab into the oral cavity without touching the gums, teeth and tongue (A tongue depressor may be used.) Swab the posterior pharyngeal wall using a rotatory motion.



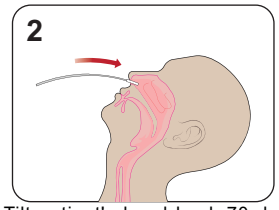
4. Withdraw the swab from the oral cavity.

Note: Failure to swab properly may cause false negative results.

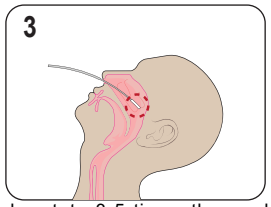
2.3 Nasopharyngeal Swab collection:



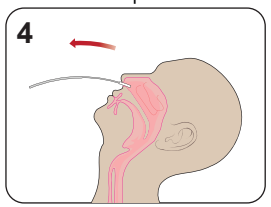
1. Remove the oropharyngeal swab from the pouch.



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.

Note: Failure to swab properly may cause false negative results.

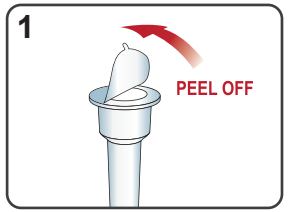
3.Process Sample

3.1 Instructions must be read entirely before test, Leave the reagent and sample at room temperature for 30min before use to rewarm to room temperature.

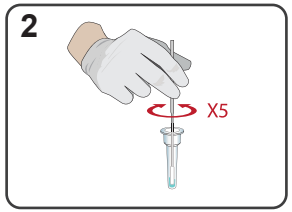
3.2 Use the cassette as soon as possible after opening the inner packing.

3.3 Open the aluminum foil bag at the tear hole, take out the test card and lay it flat.

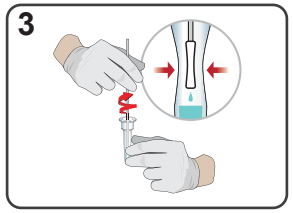
3.4 Apply 3 full drops of the sample diluent solution(90-100ul) vertically into the sample well of the test cassette.



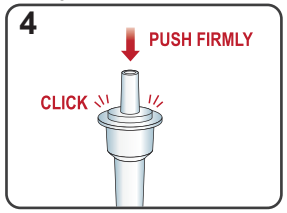
1. Peel off aluminum foil seal from the top of the extraction vial containing the extraction buffer.



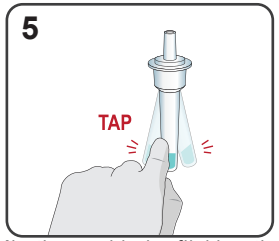
2. Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.



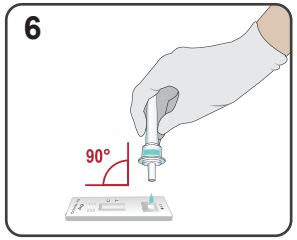
3. Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Properly discard the swab.



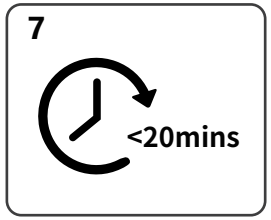
4. Close the vial by pushing the cap firmly onto the vial.



5. Mix thoroughly by flicking the bottom of the tube.



6. Invert the extraction vial and hold the sample vertically above the sample well. Squeeze the vial gently. Allow three (3) drops of sample to fall into the sample well.



7. Start the timer by clicking the "Start Timer" button, immediately after adding sample to the sample port. The result will be ready in 20 minutes.

The results are observed after 20minutes and showed on clinical significance after 20 minutes.

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: 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:

a. New operator uses the kit, prior to performing testing of specimens.

b.A new lot of test kit is used.

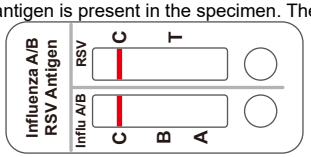
c.A new shipment of kits is used.

d.The temperature used during storage of the kit fall outside of 2°C -30°C.

e.The temperature of the test area falls outside of 15°C -30°C.

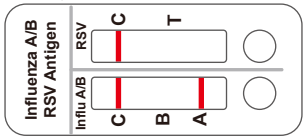
RESULT INTERPRETATION

NEGATIVE: If only the C band is developed, the test indicates that no detectable Influenza A/B and RSV antigen is present in the specimen. The result is non-reactive.

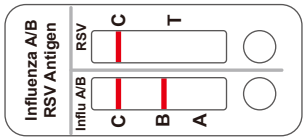


POSITIVE:

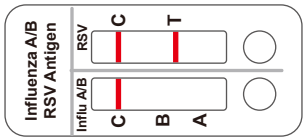
Influenza A Positive: If both C and Influenza A lines are developed, the test indicates the presence of Influenza A antigen in the specimen. The result is positive.



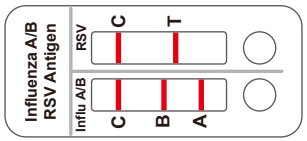
Influenza B Positive: If both C and Influenza B lines are developed, the test indicates the presence of Influenza B antigen in the specimen. The result is positive.



RSV antigen positive: If both C and RSV lines are developed, the test indicates the presence of RSV antigen in the specimen. The result is positive.



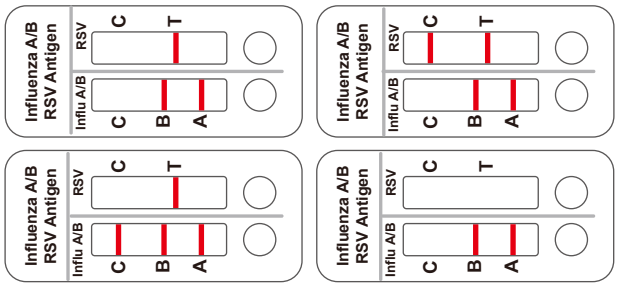
Influenza A/B and RSV antigen positive: If both C, Influenza A/B and RSV lines are developed, the test indicates the presence of Influenza A/B and RSV antigen in the specimen. The result is positive.

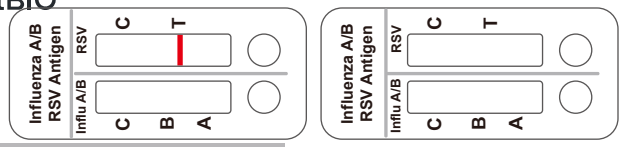


INVALID:

If no C line is developed, the assay is invalid regardless of any color development on the T line as indicated below. Repeat the assay with a new test device.

Excess fecal specimen can lead to invalid test results; if this is the cause, re- sample and re-test (see instructions for collection of specimen).





PERFORMANCE CHARACTERISTICS

1.Sensitivity, Specificity and Accuracy

1.1 Influenza B Antigen Test

A total of 150 patient samples from susceptible subjects were test by the PCR test. and 450 Influenza B negative samples. Comparison for all subjects is showed in the following table:

Influenza B Antigen Test	RT-PCR		
BESTest	Positive	Negative	Total
Positive	149	1	150
Negative	3	447	450
Total	153	447	600
Relative Sensitivity: 99.33%; Relative Specificity:99.33%; Overall agreement: 99.33%			

1.2 Influenza A Antigen Test

A total of 161patient samples from susceptible subjects were test by the PCR test. and 430 Influenza A negative samples. Comparison for all subjects is showed in the following table:

Influenza A Antigen Test	RT-PCR		
BESTest	Positive	Negative	Total
Positive	160	1	161
Negative	1	429	430
Total	161	430	591
Relative Sensitivity: 99.38%; Relative Specificity:99.77%; Overall agreement: 99.66%.			

1.3 RSV Antigen Test

A total of 438 patient samples from susceptible subjects were test by the PCR test. Comparison for all subjects is showed in the following table:

RSV Antigen Test	RT-PCR		
BESTest	Positive	Negative	Total
Positive	80	2	82
Negative	2	354	356
Total	82	356	438
CT value≤35:Relative Sensitivity: 97.56%; Relative Sp ecificity:99.44%; Overall agreement: 99.09%			

2. Cross-reactivity

The Influenza A/B +RSV antigen rapid test kit is associated with a panel of proteins of other human coronavirus recombinant antigen and other respiratory symptoms relative virus. The cross-reactivity results showed in below sheet.

Substance	Concentration	Rusult
MERS-CoV N-Protein	10^5 pfu/ml	Negative
HCoV-NL63 N-Protein	10^5 pfu/ml	Negative
HCoV-229E N-Protein	10^5 pfu/ml	Negative
HCoV-HKU1 N-Protein	1μg/mL	Negative
SARS-COV-2 Virus	$1X10^5TCID_{50}$ /mL	Negative
Parainfluenza-Virus	$1X10^5TCID_{50}$ /mL	Negative
Chlamydia pneumoniae	$1X10^5TCID_{50}$ /mL	Negative

3. Interfering Substances

This kit has no interference with HAMA, Human serum Albumin, Antinuclear antibody, Antimitochondrial antibody, Cholesterol, Bilirubin conjugated, Lipids, Hemoglobin, Bilirubin unconjugated, Rheumatoid factor, et al.

QUALITY CONTROL

1.Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
2.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.

TEST LIMITATIONS

1.The Influenza A/B +RSV Antigen Rapid Test Kit (Nasal Swab Test) is for in vitro diagnostic use only. This test should be used for the detection of Influenza A/B +RSV antigens in human Nasal Swab specimens.
2.The Influenza A/B +RSV Antigen Rapid Test Kit (Nasal Swab Test)will only indicate the presence to Influenza A/B +RSV in the specimen and should not be used as the sole criteria for the diagnosis of Influenza A/B +RSV infections.
3.If the symptom persists, while the result from Influenza A/B +RSV Antigen Rapid Test is negative or non-reactive result, it is recommended to re-sample the patient few hours later.
4.As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5.If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Influenza A/B +RSV infection.
6.The potential impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated in the test.
7.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.
8.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.

CAUTION

1.This product is used for in vitro diagnosis only.
2.Must strictly follow the instructions for operation and interpretation of the results.
3.The product is qualitatively tested, and the result cannot be used as a quantitative basis.should be tested using reagents within the validity period.
4.The cassetes, collectors,droppers,and tubes are for single person one-time use, cannot be reused.
5.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 antibody titer in the sample.
6.The samples stored at low temperature should be balanced to room temperature and fully mixed before testing.
7.Samples and waste must be treated as a potential source of infection and the desiccant in the foil bag is not edible.

SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
LOT	Batch code	IVD	In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don't use the product when the package is damaged		Keep dry
	Date of manufacture	Σ	Tests per kit
CE	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

BASIC INFORMATION

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