SARS-COV-2 Antigen/Influenza A+B Antigen Rapid Test Kit (Nasal Swab Test)

IVD

Instruction for Use

Read this instruction carefully before use

A rapid test for the qualitative detection of SARS-COV-2 antigen, Influenza A/B in nasal swab specimens.For professional medical institutions use only,Not for self testing.

PRODUCT NAME

SARS-COV-2 Antigen/Influenza A+B Antigen Rapid Test Kit (Nasal Swab Test)

SPECIFICATION

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

INTENDED USE

SARS-COV-2 Antigen/Influenza A+B Antigen Rapid Test Kit (Nasal Swab Test) is a rapid visual immunoassay for the qualitative, presumptive detection of influenza A and B viral antigens and SARS-CoV-2 Antigen form Nasal swabs and nasopharyngeal swab specimens. The test is intended for use as an aid in the rapid differential diagnosis of acute influenza type A and type B virus and SARS-CoV-2 infection.

INTRODUCTION

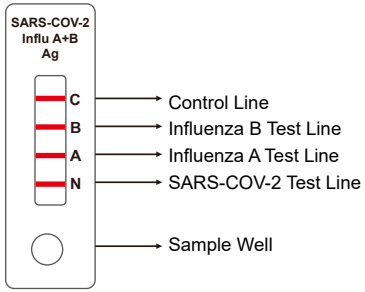
Influenza is a highly contagious, acute, viral infection of the respiratory tract. The causative agents of the disease are immunologically diverse, single-strand RNA viruses known as influenza viruses. There are three types of influenza viruses: A, B, and C. Type A viruses are the most prevalent and 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 novel coronaviruses belong to the βgenus. COVID-19 is an acuterespiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

SARS-COV-2 Antigen/Influenza A+B Antigen Rapid Test Kit (Nasal Swab Test) is a lateral-flow immunoassay using highly sensitive monoclonal antibodies that are specific for influenza types A and B and SARS-CoV-2 antigens. The test is specific to influenza types A and B and SARS-CoV-2 antigens with no known cross- reactivity to normal flora or other known respiratory pathogens.

PRINCIPLE

SARS-COV-2 Antigen/Influenza A+B Antigen Rapid Test Kit (Nasal Swab Test) detects influenza A and B viral antigens and SARS-CoV-2 Antigen through visual interpretation of color development on the strip. Anti-influenza A and B antibodies , Anti-SARS-CoV-2 antibodies and Goat anti-Rabbit IgG Antibodies are immobilized on the test region A, B, N and C of the membrane respectively. During testing, the extracted specimen reacts with anti-influenza A, B, SARS-CoV-2 antibodies and rabbit IgG 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 or SARS-CoV-2 antigen 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 and/or N 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.

MAIN COMPONENTS

Materials Provided

Components	25 tests/kit	5 tests/kit	1 tests/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 test cassettes:

Mouse anti-SARS-COV-2 NP antibody, Mouse anti-Influenza A antibody, Mouse anti-Influenza B antibody, Goat anti-rabbit IgG polyclonal antibody, Rabbit IgG, Colloidal gold conjugate, Other test device support; one desiccant

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.

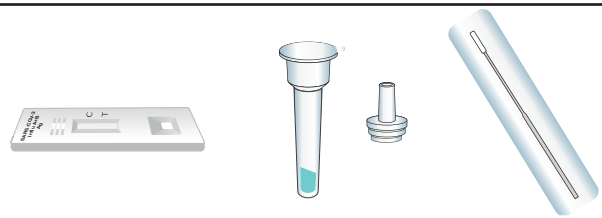
STORAGE AND STABILITY

- 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

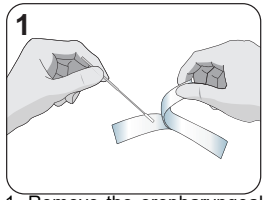
Open the package,take out the SARS-COV-2 Antigen/Influenza A+B Antigen test card in pouch, the Tube filled with the extraction buffer and the swab. When you are ready to proceed with the test,open the foil pouch of the SARS-COV-2 Antigen/Influenza A+B Antigen test card.



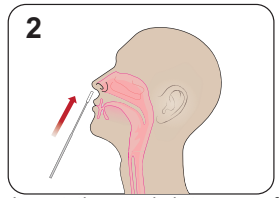
1 SARS-COV-2 Antigen/ Influenza A+B Antigen Test Kit | 1 Sample Diluent Solution With Dropper | 1 Swab

2.Collect Sample

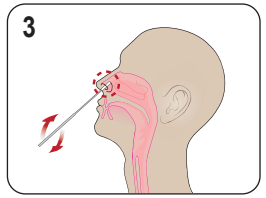
2.1 Anterior Nasal Swab collection:



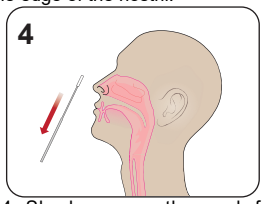
1. Remove the oropharyngeal swab from the pouch.



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



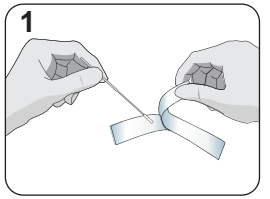
3. Slowly roll the swab 5 times over the surface of the nostril. Using the same swab repeat this collection process in the other nostril. Take approximately 15 seconds to collect the specimen.



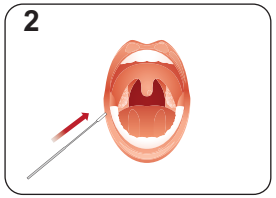
4. Slowly remove the swab from the nostril while rotating it.

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

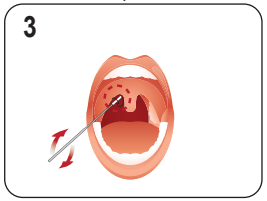
2.2 Oropharyngeal Specimen collection:



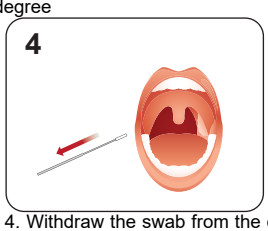
1. Remove the oropharyngeal swab from the pouch.



2. Tilt patient's head back 70 degree



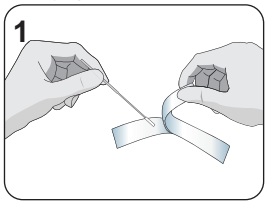
3. Insert swab into the oral cavity without touching the gums, teeth and tongue (A tongue depressor may be used.) Swab the posterior pharyngeal wall using a rotatory motion.



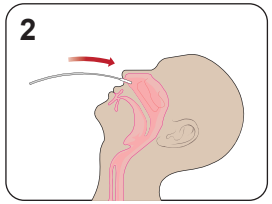
4. Withdraw the swab from the oral cavity.

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

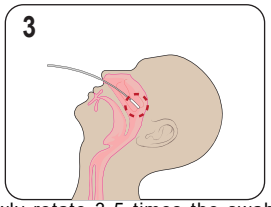
2.3 Nasopharyngeal Swab collection:



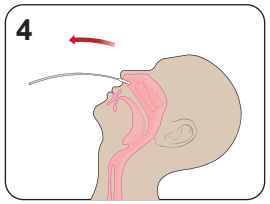
1. Remove the oropharyngeal swab from the pouch.



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.

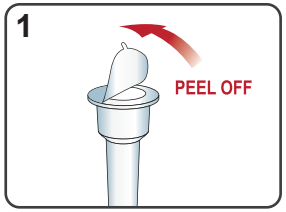
3.Process Sample

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.

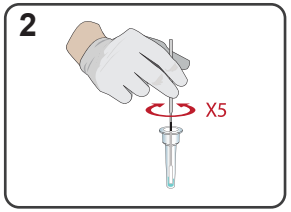
3.2 Use the cassette as soon as possible after opening the inner packing.

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

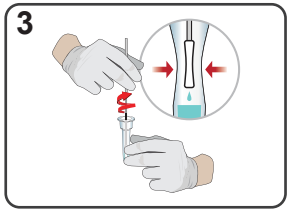
3.4 Apply 3 full drops of the sample diluent solution(90-100ul) vertically into the sample well of the test cassette.



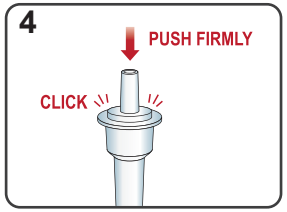
1. Peel off aluminum foil seal from the top of the extraction vial containing the extraction buffer.



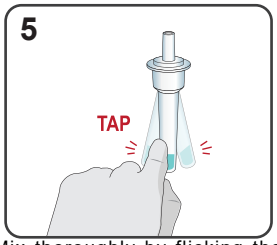
2. Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.



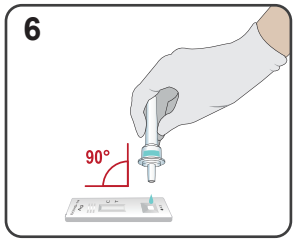
3. Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Properly discard the swab.



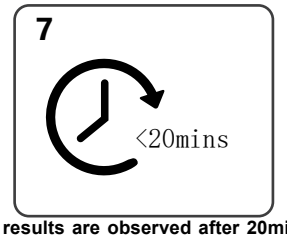
4. Close the vial by pushing the cap firmly onto the vial.



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.

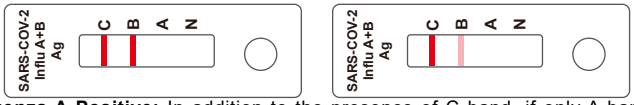
INTERPRETATION OF ASSAY RESULT

Negative Control

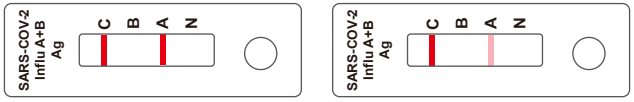
If only the C band is present, the absence of any burgundy color in the both test bands (A,B and N) indicates that no Influenza A ,B and SARS-COV-2 virus are detected.The result is negative or non-reactive.

Positive Control

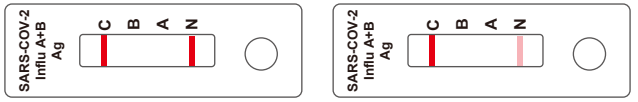
Influenza B Positive: In addition to the presence of C band, if only B band is developed, indicates for the presence of Influenza B virus; the result suggests Influenza B virus infection.



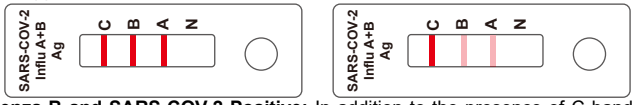
Influenza A Positive: In addition to the presence of C band, if only A band is developed, indicates for the presence of Influenza A virus; the result suggests Influenza A virus infection.



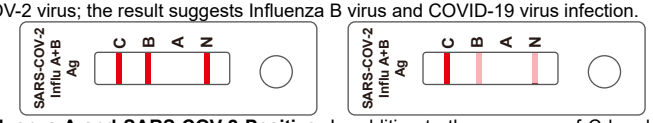
SARS-COV-2 Positive: In addition to the presence of C band, if only N band is developed, indicates for the presence of SARS-COV-2 virus; the result suggestsCOVID-19 infection.



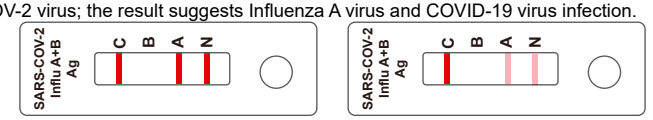
Influenza A/B Positive: In addition to the presence of C band, if B and A bands are developed, indicates for the presence of Influenza A virus and Influenza B virus; the result suggests Influenza A virus and Influenza B virus infection.



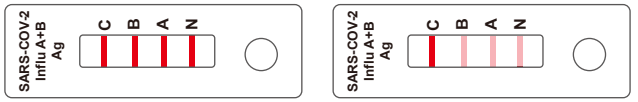
Influenza B and SARS-COV-2 Positive: In addition to the presence of C band, if B and N bands are developed, indicates for the presence of Influenza B virus and SARS-COV-2 virus; the result suggests Influenza B virus and COVID-19 virus infection.



Influenza A and SARS-COV-2 Positive: In addition to the presence of C band, if A and N bands are developed, indicates for the presence of Influenza A virus and SARS-COV-2 virus; the result suggests Influenza A virus and COVID-19 virus infection.



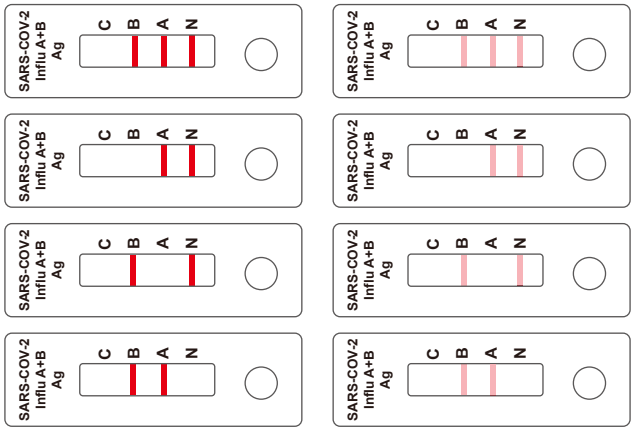
Influenza A+B and SARS-COV-2 Positive: In addition to the presence of C band, if B,A and N bands are developed, indicates for the presence of Influenza B virus,Influenza A virus and SARS-COV-2 virus; the result suggests Influenza B virus, Influenza A virus and COVID-19 virus infection.

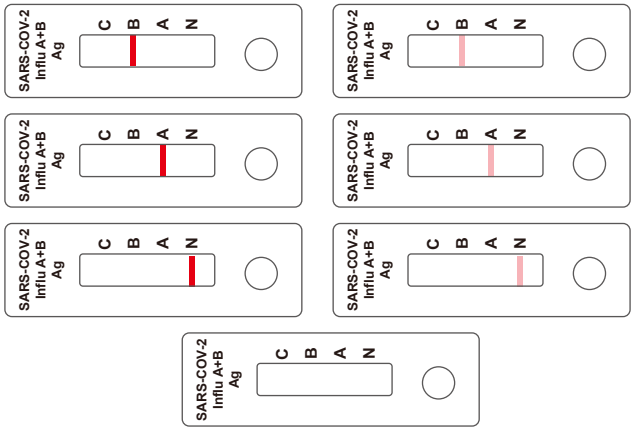


Samples with positive or reactive results should be confirmed with alternative testing method(s) such as ELISA or PCR and clinical findings before a diagnostic decision is made.

INVALID:

If no C band is developed, the assay is invalid regardless of any burgundy color in the test bands(B,A and N) as indicated below. Repeat the assay with a new device.





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 161 patient 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 SARS-COV-2 Antigen Test

A total of 393 patient samples from susceptible subjects were test by the PCR test. and 400 SARS-COV-2 negative samples. Comparison for all subjects is showed in the following table:

SARS-CoV-2 Antigen Test	RT-PCR		
BESTest	Positive	Negative	Total
Positive	392	1	393
Negative	0	400	400
Total	392	401	793
Relative Sensitivity: 99.75%; Relative Specificity:100%; Overall agreement: 99.876%			

1.4 Influenza A+B Antigen Test

A total of 100 patient samples from susceptible subjects were test by the PCR test (both Influenza A/B positive) and 400 influenza A/B negative samples. Comparison for all subjects is showed in the following table:

Influenza A+B Antigen Test	RT-PCR		
BESTest	Positive	Negative	Total
Positive	98	2	100
Negative	0	400	400
Total	98	402	500
Relative Sensitivity: 98%; Relative Specificity:100%; Overall agreement: 99.6%			

1.5 Influenza B Antigen and SARS-COV-2 Antigen Test

A total of 105 patient samples from susceptible subjects were test by the PCR test (both Influenza B and SARS-COV-2 Antigen positive) and 430 influenza B and SARS-COV-2 Antigen negative samples. Comparison for all subjects is showed in the following table:

Influenza B Antigen and SRAS-Cov-2 Antigen Test	RT-PCR		
BESTest	Positive	Negative	Total
Positive	103	2	105
Negative	1	429	430
Total	104	431	535
Relative Sensitivity: 98.09%; Relative Specificity:100%; Overall agreement: 99.6%			

1.6 Influenza A Antigen and SARS-COV-2 Antigen Test

A total of 95 patient samples from susceptible subjects were test by the PCR test (both Influenza A and SARS-COV-2 Antigen positive) and 410 influenza A and SARS-COV-2 Antigen negative samples. Comparison for all subjects is showed in the following table:

Influenza A Antigen and SRAS-Cov-2 Antigen Test	RT-PCR		
BESTest	Positive	Negative	Total
Positive	94	1	95
Negative	1	409	410
Total	95	410	505
Relative Sensitivity: 98.95%; Relative Specificity:99.76%; Overall agreement: 99.6%			

1.7 Influenza A/B Antigen and SARS-COV-2 Antigen Test

A total of 99 patient samples from susceptible subjects were test by the PCR test (both Influenza A, Influenza B and SARS-COV-2 Antigen positive) and 500 influenza A,Influenza B and SARS-COV-2 Antigen negative samples. Comparison for all subjects is showed in the following table:

Influenza A/B Antigen and SRAS-Cov-2 Antigen Test	RT-PCR		
BESTest	Positive	Negative	Total
Positive	97	2	99
Negative	2	498	500
Total	99	500	599
Relative Sensitivity: 97.98%; Relative Specificity:99.6%; Overall agreement: 99.33%			

2. Limit of Detection（LOD）

The limit of detection of the SARS-COV-2 Antigen/Influenza A+B Antigen Rapid test has been studied. The LOD of the test to the SARS-COV-2 virus(inactivated)is about $5*10^2 TCID_{50}$/ml.The LOD of the test to the Influenza A virus(inactivated) is about $1.51*10^3 TCID_{50}$/ml.The LOD of the test to the Influenza B virus(inactivated)is about $1.05*10^3$ $TCID_{50}$ /ml.

3. Cross-reactivity

The SARS-COV-2 Antigen/Influenza A+B Antigen Rapid test kit was evaluated with a total of 33 bacterial and viral isolates. Bacterial isolates were evaluated at a concentration between 107 and 109 org/mL. Viral isolates were evaluated at a concentration of at least 10^4–10^8 $TCID_{50}$/mL. Adenovirus 18 and Parainfluenza virus 3 were tested at 10^2 $TCID_{50}$/mL. None of the organisms or viruses listed below gave a positive result in the Influenza A+B/SARS-CoV-2 antigen Rapid Test Device.The cross-reactivity results showed in below sheet.

Bacterial Panel

Name	Result	Name	Result
Acinetobacter Calcoaceticus	Negative	Bacteroides Fragilis	Negative
Pseudomonas aeruginosa	Negative	Staphylococcus Aureus	Negative
Proteus Vulgaris	Negative	Staphylococcus SP.GP.B	Negative
Mycoplasma Orale	Negative		Negative
Neisseria Gonorrhoeae	Negative	Neisseria Meningitidis	Negative
Staphylococcus Pneumoniae	Negative	Staphylococcus Sanguis	Negative
Staphylococcus SP.GP.G	Negative	Mycobacterium Tuberculosis	Negative
	Negative		Negative

Virus Panel

Name	Result	Name	Result
Human Adenovirus B	Negative	Human Adenovirus C	Negative
Human Rhinovirus 16	Negative	Adenovirus type 10	Negative
Human Coronavirus 229E	Negative	Human Coronavirus NL63	Negative
Human Coxsackievirus A9	Negative	Parainfluenza Virus 2	Negative
Human Rhinovirus 2	Negative	Human Rhinovirus 14	Negative
Adenovirus type 18	Negative	Measles	Negative
MERS	Negative	Sendai Virus	Negative
Parainfluenza Virus 3	Negative	Human Coxsackievirus B5	Negative

4. 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 SARS-COV-2 Antigen/Influenza A+B Antigen Rapid test kit(Nasal swab test) is for in vitro diagnostic use only. This test should be used for the detection of SARS-CoV-2 antigens and Influenza A+B antigens in human Nasal swab specimens.

2.The SARS-COV-2 Antigen/Influenza A+B Antigen Rapid test kit(Nasal swab test) will only indicate the presence to SARS-CoV-2/Influenza A+B in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 and Influenza A+B infections.

3.If the symptom persists, while the result from SARS-COV-2 Antigen/Influenza A+B Antigen Rapid test kit(Nasal swab 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 SARS-CoV-2 and Influenza A+B 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
	Batch code		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		Tests per kit
	CE Mark		Biological Risks
	Authorized representative in the European Community		