SARS-CoV-2/Influenza A+B /RSV Antigen Combo Rapid Test (Nasal Swab)
Package Insert
For Self-testing

REF ISIR-N535H | English

Before testing, scan the QR code to watch the "how to use" video.

【INTENDED USE】

The SARS-CoV-2/Influenza A+B/RSV Antigen Combo Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2, Influenza A, Influenza B and RSV antigens in self-collected nasal swab specimens as an aid in the diagnosis of SARS-CoV-2, Influenza A/Influenza B and RSV infection.

The test is intended for individuals who are suspected of being infected with SARS-CoV-2 within 7 days of symptom onset and/or Influenza A+B and RSV within the first 4 days of symptom onset.

For self-testing *in vitro* diagnostic use.

【HOW DOES IT WORK】

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory 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.[1]

Influenza (commonly known as 'flu') is a highly contagious, acute viral infection of the respiratory tract. Virus transmission occurs when a susceptible individual comes into contact with aerosols or respiratory fomites from an infected individual.[2] 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.

Respiratory Syncytial Virus (RSV), which causes infection of the lungs and breathing passages, is a major cause of respiratory illness in young children. In adults, it may only produce symptoms of a common cold, such as a stuffy or runny nose, sore throat, mild headache, cough, fever, and a general feeling of being ill. Most children with RSV infection, both those who were hospitalized and those who were treated as outpatients, had no coexisting medical conditions or characteristics that significantly identified them as being at greater risk for severe RSV disease, except for being under 2 years of age.[3]

When the specimen is added to the specimen well of the test, the extracted specimen reacts specifically with the virus antibodies coated onto the particles, forming a mixture. The mixture migrates up the membrane and reacts with the virus antibodies on the membrane, resulting in the generation of one or two colored lines in the test regions. The presence of the colored line(s) in the test regions indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that an appropriate volume of the specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains SARS-CoV-2 antibody coated particle, Influenza A antibody coated particle, Influenza B antibody coated particle, RSV antibody coated particle, and contains SARS-CoV-2 antibody, Influenza A antibody, Influenza B antibody, RSV antibody coated on the membrane.

【WARNINGS AND PRECAUTIONS】

Please read all the information in this package insert before performing the test.

1.This kit is for self-testing *in vitro* diagnostic use only.
2.Do not use it after the expiration date. Do not reuse it.
3.Do not eat, drink or smoke in the area where the specimens or kits are handled.
4.**Do not drink the buffer in the kit.** Carefully handle the buffer and avoid it contacting skin or eyes, rinse with plenty of running water immediately if contacting.
5.Store the kit in a dry place at 2-30 °C (36-86 °F), avoiding areas of excess moisture. If the foil packaging is damaged or has been opened, please do not use.
6.Use the test only once and follow the test procedures strictly. Do not dismantle the test cassette or touch the test window of the test cassette.
7.Keep the kit out of the reach of children. Test for children should be conducted by an adult.
8.Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
9.This test kit is intended to be used as a preliminary test only and repeated abnormal results should be discussed with doctor or medical professional.
10.The used test kit should be discarded according to local regulations.
11.Wash hands thoroughly before and after handling.
12.Please ensure that an appropriate amount of specimen is used for testing. Too much or too little specimen may lead to deviation of results.
13.Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority.
14.Components provided in the kit are approved for use in the SARS-CoV-2/Influenza A+B/RSV Antigen Combo Rapid Test. Do not use any other component from another commercial kit.

【STORAGE AND STABILITY】

1.Store the kit at 2-30 °C. **DO NOT FREEZE.**
2.Keep the kit away from sunlight, moisture and heat.
3.Do not use beyond the expiration date.
4.Open the pouch only shortly before the test.
5.Please use the test cassette within one hour after removing it from the foil pouch.

【KIT COMPONENTS】

Materials Provided

	Kit size	1T/kit	5T/kit	10T/kit	20T/kit
Components	Test cassette(s)	1	5	10	20
	Sterile swab(s)	1	5	10	20
	Extraction buffer	1	5	10	20
	Package insert	1	1	2	4
	Tube holder	On the box		1	1

Materials Required But Not Provided: Timer

【LIMITATIONS】

1. Performance was evaluated with nasal swab specimens only, using the procedures provided in this package insert.
2. The SARS-CoV-2/Influenza A+B/RSV Antigen Combo Rapid Test will only indicate the presence of SARS-CoV-2, Influenza A/Influenza B and RSV antigens in the specimen. Neither the quantitative value nor the rate of increase in the concentration of viruses can be determined by this qualitative test.
3. If the test result is negative and clinical symptoms persist, it is because the virus in very early infection stage may not be detected, and it is recommended to test again with a new kit or test with a molecular diagnostic device to rule out infection in these individuals.
4. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals. A negative result for Influenza A, Influenza B or RSV obtained from this kit should be confirmed by RT-PCR/culture.
5. Positive results of COVID-19 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors. 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.
6. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result.
7. 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.
8. A false negative result may be obtained if the concentration of the viruses present in the specimen is not adequate or below the detectable level of the test, or if you fail to follow these procedures such as improper specimen collection or testing.
9. The SARS-CoV-2/Influenza A+B/RSV Antigen Combo Rapid Test provides preliminary test results and they can't be used as the sole basis for treatment or other management decision. As with all diagnostic tests, a confirmed diagnosis should only be made after evaluating other clinical information available.

【PERFORMANCE CHARACTERISTICS】

Accuracy

The SARS-CoV-2/Influenza A+B/RSV Antigen Combo Rapid Test has been evaluated with clinical specimens obtained from patients. RT-PCR was used as the reference method. Study results are presented in the tables below.

SARS-CoV-2 Test:

SARS-CoV-2/Influenza A+B/RSV Antigen Combo Rapid Test		RT-PCR		Total
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	97	2	99
	Negative	3	422	425
Total		100	424	524
Relative Sensitivity		97.00% (95%CI*: 91.48%~99.38%)		
Relative Specificity		99.53% (95%CI*: 98.31%~99.94%)		
Accuracy		98.05% (95%CI*: 97.79%~99.69%)		

Influenza A+B Test:

SARS-CoV-2/Influenza A+B/RSV Antigen Combo Rapid Test		RT-PCR		Total
		Positive	Negative	
Influenza A Antigen	Positive	82	3	85
	Negative	3	436	439
Total		85	439	524
Relative Sensitivity		96.47% (95%CI*: 90.03%~99.27%)		
Relative Specificity		99.32% (95%CI*: 98.02%~99.86%)		
Accuracy		98.85% (95%CI*: 97.52%~99.58%)		

SARS-CoV-2/Influenza A+B/RSV Antigen Combo Rapid Test		RT-PCR		Total
		Positive	Negative	
Influenza B Antigen	Positive	69	3	72
	Negative	2	450	452
Total		71	453	524
Relative Sensitivity		97.18% (95%CI*: 90.19%~99.66%)		
Relative Specificity		99.34% (95%CI*: 98.08%~99.86%)		
Accuracy		99.05% (95%CI*: 97.79%~99.69%)		

RSV Test:

SARS-CoV-2/Influenza A+B/RSV Antigen Combo Rapid Test		RT-PCR		Total
		Positive	Negative	
RSV Antigen	Positive	59	1	60
	Negative	2	462	464
Total		61	463	524
Relative Sensitivity		96.72% (95%CI*:88.65%~99.60%)		
Relative Specificity		99.78% (95%CI*:98.80%~99.99%)		
Accuracy		99.43% (95%CI*:98.34%~99.88%)		

Lay-user Study

A lay-user study was performed by lay person to evaluate the use of the SARS-CoV-2/Influenza A+B/RSV Antigen Combo Rapid Test for Home and OTC Use by lay users in a simulated home use environment. In the lay-user self testing group, the study participants followed written instructions with illustrations for taking a nasal swab sample and performing the test themselves. The samples were collected and the tests performed under the observation of professionals, who did not intervene at any stage.

Total 250 lay-users participated in the study, the sensitivity of SARS-CoV-2 test is 97.22%, the Specificity is 99.53%; the sensitivity of Influenza A test is 97.06%, the Specificity is 99.07%, the sensitivity of Influenza B test is 96.88%, the Specificity is 99.54%, the sensitivity of RSV test is 96.97%, the Specificity is 99.08%. The results showed that the labeling provided with the test kit was comprehensive for its intended population; the ease of use was suitable for its intended population.

Detection Level Determination

Virus Strains	Subtype	Detection Level
BetaCoV/Wuhan/IPBCAMS-WH-01/2019	/	78 $TCID_{50}$/mL
A/Sydney/5/2021	H1N1	50 $TCID_{50}$/mL
A/South Australia/69/2019	H3N2	50 $TCID_{50}$/mL
B/Austria/1359417/2021	Victoria	50 $TCID_{50}$/mL
B/Darwin/58/2019	Yamagata	100 $TCID_{50}$/mL
A2	RSV type A	$2.5X10^{5}$ $TCID_{50}$/mL
B WV/14617/85	RSV type B	$1.0X10^{5}$ $TCID_{50}$/mL

Recombinant antigen	Detection Level
SARS-CoV-2	0.5 ng/mL
Influenza A	100 HA/mL
Influenza B	30 HA/mL
RSV	10 ng/mL

Cross-Reactivity

The SARS-CoV-2/Influenza A+B/RSV Antigen Combo Rapid Test was evaluated with the following bacterial isolates. None of them gave a positive result.

Chlamydia pneumoniae	*Staphylococcus epidermidis*
Arcanobacterium	*Streptococcus pneumoniae*
Candida albicans	*Streptococcus pygenes*
Corynebacterium	*Streptococcus salivarius*
Escherichia coli	*Streptococcus sp Group F*
Moraxella catarrhalis	*Haemophilus influenzae*
Neisseria lactamica	*Legionella pneumophila*
Neisseria subflava	*Bordetella pertussis*
Pseudomonas aeruginosa	*Mycoplasma pneumoniae*
Staphylococcus aureus	/

The SARS-CoV-2/Influenza A+B/RSV Antigen Combo Rapid Test was evaluated with the following viral strains. None of them gave a positive result.

Adenovirus type 2	Human Rhinovirus 14
Adenovirus type 3	Human Rhinovirus 16
Adenovirus type 5	Measles
Adenovirus type 7	Mumps
Human coronavirus OC43	Parainfluenza virus 1
Human coronavirus 229E	Parainfluenza virus 2
Human coronavirus NL63	Parainfluenza virus 3
Human coronavirus HKU1	Parainfluenza virus 4
MERS COV Florida	Human Metapneumovirus
Human Rhinovirus 2	Enterovirus 71

Interfering Substances

Test results will not be interfered by following substances at certain concentrations:

Whole Blood	Acetylsalicylic Acid	Ephedrine	Rebetol
Mucin	Chlorpheniramine	Flunisolide	Relenza
Sinus Buster Nasal Spray	Dexamethasone	Guaiacol glyceryl ether	Rimatadine
NeoSynephrine Cold & Sinus Extra Strength Spray	Dextromethorphan	Mupirocin	Tamiflu
Zicamn Extreme Congestion Relief	Diphenhydramine	Oxymetazoline	Tobryamycin
Albuterol	Doxylamine Succinate	Phenylephrine	Triamcinolone
4-Acetamidophenol	/	/	/

【QUESTIONS & ANSWERS】

1. How does the SARS-CoV-2/Influenza A+B/RSV Antigen Combo Rapid Test work?

The test can qualitatively detect SARS-CoV-2, Influenza A, Influenza B and RSV antigens in self-collected nasal swab specimens through the specific antibodies it contains. A positive result indicates SARS-CoV-2, Influenza A, Influenza B and/or RSV antigens present in the specimen.

2. When should the test be used?

SARS-CoV-2, Influenza A, Influenza B and RSV antigens can be detected in acute respiratory tract infection. You can do this test when you have the symptoms such as a stuffy or runny nose, sore throat, mild headache, cough, fever, and a general feeling of being ill.

3. Can the result be incorrect?

The results are accurate as far as the instructions are carefully followed. Nevertheless, the result can be incorrect due to inadequate specimen or that the SARS-CoV-2/Influenza A+B/RSV Antigen Combo Rapid Test gets wet before being used, or when the number of drops of extraction specimen applied is less than 3 or more than 4.

Besides, due to the immunological principle involved, there exist the chances of false results in rare cases. A consultation with the doctor is always recommended for such tests based on immunological principles.

4. How do I interpret the test results if the color and the intensity of the lines are different?

The color and intensity of the lines have no importance for result interpretation. The lines should only be homogeneous and clearly visible. It should be considered as positive whatever the color or intensity of the test line is.

5. My test result is negative. Does that mean I'm not infected?

A negative result means that you are not infected or that the viral load is too low to be recognized by the test.

In case of suspicion, repeat the test after 1-2 days, as the coronavirus/Influenza virus/RSV cannot be precisely detected in all phases of an infection.

6. If the test result is positive, what should I do?

A positive result indicates you probably have a SARS-CoV-2/Influenza A/Influenza B/RSV infection. Please see a doctor for medical aid.

7. Information of how to contact locally available support services.

For CUSTOMER SUPPORT HELPLINE: Call (02) 9959 2243, 9am-7pm (AEST)，7 days per week
For information on the correct use of this test and for interpretation of the test results.

【BIBLIOGRAPHY】

1. Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia (Trial Version 7). Chin Med J (Engl). 2020 May 5;133(9):1087-1095.
2. Kalil AC, Thomas PG. Influenza virus-related critical illness: pathophysiology and epidemiology. Crit Care. 2019 Jul 19;23(1):258.
3. Hall CB, Weinberg GA, Iwane MK, et al. The burden of respiratory syncytial virus infection in young children. N Engl J Med. 2009 Feb 5;360(6):588-598.

【INDEX OF SYMBOLS】

	Consult instructions for use or consult electronic instructions for use	Σ	Contains sufficient for <n> tests	30°C / 2°C	Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
	Manufacturer		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Caution		

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

Australian Sponsor:
ACESO DIAGNOSTICS PTY LTD
Level 25, 100 Mount Street,
North Sydney, NSW, 2060.

Statement: Information about manufacturer of sterile swab is placed on the packaging.

Number: 14602958400
Revision Date: 2025-04-18

Before testing, scan the QR code to watch the "how to use" video.

BEFORE STARTING

Wash your hands with soap and water for at least 20 seconds before and after test. If soap and water are not available, use hand sanitizer with at least 60% alcohol.

1. PREPARE FOR THE TEST

1A. Check the expiration date on the box.
Do not use if the kit has been damaged or has expired.

1B. Ensure kit is at room temperature for at least 30 minutes prior to use.
Open the box carefully as it will be used in a later step (1D).
Do not open individual components until instructed.
Note: A timing device (clock, timer, phone etc.) is required, but not provided.

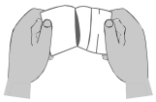
1C. Remove the cover of the tube with extraction buffer.

1D. Put the tube in the tube holder in the box.
Note: Being careful not to spill the tube contents.

2. NASAL SWAB SPECIMEN COLLECTION

2A. Open swab protective pouch.

Remove the sterile swab from the pouch.



! Keep fingers away from the swab end.
Touch the stick end only.

2B. Swabbing both nostrils.

Insert the soft end of the swab into your nostril until you feel resistance (Approx. 2cm up your nose).

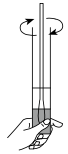
Slowly twist the swab, rubbing it along the insides of your nostril, 5-10 times against the nasal wall.
Gently remove Swab from nostril.

2C. Using the same swab, repeat step 2B, in your other nostril.
Withdraw the swab.

Note:
1 This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain.
2 When the nasal mucosa is damaged or bleeding, nasal swab collection is not recommended.
3 If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab as far into the nostril.
4 For very young children, you may need another person to steady the child's head while swabbing.

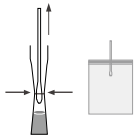
2D. Insert the swab into the extraction tube.

Ensure it is touching the bottom and stir the swab to mix well.
Press the swab head against the tube and rotate the swab for 10-15 seconds.



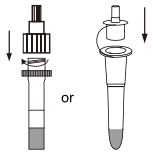
2E. Hold the tube firmly with one hand.

Remove the swab while squeezing the swab head against the inside of the extraction tube.
Place the swab in a plastic bag.



2F. Close the cap of the extraction tube

Return the tube to the Kit Box tube holder before proceeding to the next step.

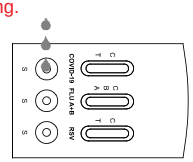


3. PERFORM THE TEST

3A. Remove the test cassette from the sealed foil pouch and use it within one (1) hour.
Note: Best results will be obtained if the test is performed immediately after opening the foil pouch.
Place the test cassette on a flat and level surface.

! Do not move the test cassette during test developing.

3B. Invert the specimen extraction tube and add **3 drops of extracted specimen to each** sample well (S) of the test cassette.



Start the timer. Secure tube cap back on extraction tube and **wait 10 minutes.**

! Do not touch the test device during this period.

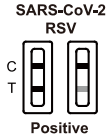
3C. Read the result at 10 minutes.

Keep test device flat on table.
Do not read the result earlier than 10 minutes or after 20 minutes.

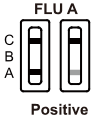
4. READING THE RESULTS

Please share your test result with your healthcare provider.

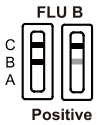
POSITIVE



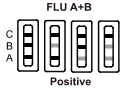
POSITIVE SARS-CoV-2/RSV:* Two colored lines appear in the COVID-19/RSV window.
One colored line should be in the control region (C) and another colored line should be in the Test region (T).



POSITIVE Influenza A:* Two colored lines appear in the FLU A+B window.
One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A).



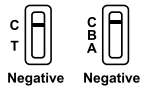
POSITIVE Influenza B:* Two colored lines appear in the FLU A+B window.
One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B).



POSITIVE Influenza A and Influenza B:* Three colored lines appear in the FLU A+B window.
One colored line should be in the control region (C) and two colored line should be in the Influenza A region (A) and Influenza B region (B) respectively.

***NOTE:** The intensity of the colored line in the test line region (T/B/A) varies based on the amount of SARS-CoV-2, Influenza A/Influenza B and/or RSV antigen present in the specimen. So any shade of color in the test region (T/B/A) should be considered positive.
A positive result means it is very likely you have COVID-19, Influenza A/Influenza B and/or RSV, but the positive specimens should be confirmed to reflect this. Immediately go into self-isolation in accordance with the local guidelines, immediately contact your general practitioner/doctor or the local health department and obtain guidance on confirmation testing if necessary in accordance with the instructions of your local authorities. Seek medical assistance if you feel unwell.

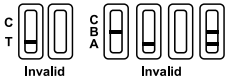
NEGATIVE



NEGATIVE: One colored line appears in the control region (C).
No colored line appears in the test line region (T/B/A).

You are unlikely to have COVID-19, Influenza A/Influenza B and/or RSV. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19, Influenza A/Influenza B and/or RSV. This means you could possibly still have COVID-19, Influenza A/Influenza B and/or RSV even though the test is negative.
In addition, you can repeat the test with a new test kit. In case of suspicion, repeat the test after 1-2 days, as the coronavirus/Influenza virus/Respiratory syncytial virus cannot be precisely detected in all phases of an infection.
Even with a negative test result, distance and hygiene rules must be observed. Migration/traveling, attending events and etc. should be done following your local COVID/Influenza/RSV guidelines/requirements.

INVALID

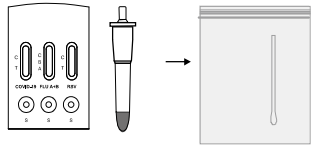


INVALID: Control line fails to appear.

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 or contact with a COVID-19 and/or Influenza test center. If an invalid result continues after repeating, advice to contact the sponsor.

5. DISPOSE THE TEST KIT

After the test is complete, place all the components in a plastic bag and tightly sealed, then dispose in household waste or rubbish bin.



For Customer Support Helpline: Call (02) 9959 2243 9am-7pm (AEST), 7 days per week for information on the correct use of this test and for interpretation of the test results.