Berightest™

COVID-19/FLU A+B/RSV/Adenovirus Antigen Rapid Test (Nasal Swab) Package Insert For Self-testing

REF IRT-N545H	English

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

INTENDED USE

The COVID-19/FLU A+B/RSV/Adenovirus Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2, Influenza A, Influenza B, RSV and Adenovirus antigens in self-collected nasal swab specimens as an aid in the diagnosis of SARS-CoV-2, Influenza A/Influenza B, RSV and Adenovirus 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, RSV and Adenovirus 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]

Human Adenoviruses comprise an important group of etiologic agents that are responsible for various diseases in adults and children, such as respiratory, ocular, gastroenteric, and urinary infections. In immunocompromised and organ-transplanted individuals, these agents can cause generalized infections.[4]

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, Adenovirus antibody coated particle and contains SARS-CoV-2 antibody, Influenza A antibody, Influenza B antibody, RSV antibody, Adenovirus 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 COVID-19/FLU A+B/RSV/Adenovirus Antigen 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. TheCOVID-19/FLU A+B/RSV/Adenovirus Antigen Rapid Test will only indicate the presence of SARS-CoV-2, Influenza A/Influenza B, RSV and Adenovirus 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, RSV or Adenovirus 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 COVID-19/FLU A+B/RSV/Adenovirus Antigen 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.
10. A false negative result may be obtained if testing is not performed within the first 7 days of symptom onset for SARS-CoV-2, and 4 days post symptom onset for FLU A & B, RSV, and Adenovirus.
11. The tests are less reliable in the later phase of infection and in asymptomatic individuals.
12. A positive result cannot necessarily determine whether a person is infectious.

PERFORMANCE CHARACTERISTICS

Accuracy

The COVID-19/FLU A+B/RSV/Adenovirus Antigen 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.

COVID-19 Test:

COVID-19/FLU A+B/RSV/Adenovirus Antigen Rapid Test		RT-PCR		Total
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	105	3	108
	Negative	2	398	400
Total		107	401	508
Relative Sensitivity		98.13% (95%CI*: 93.41%~99.77%)		
Relative Specificity		99.25% (95%CI*: 97.83%~99.85%)		
Accuracy		99.02% (95%CI*: 97.72%~99.68%)		

Influenza A+B Test:

COVID-19/FLU A+B/RSV/Adenovirus Antigen Rapid Test		RT-PCR		Total
		Positive	Negative	
Influenza A Antigen	Positive	71	4	75
	Negative	2	431	433
Total		73	435	508
Relative Sensitivity		97.26% (95%CI*: 90.45%~99.67%)		
Relative Specificity		99.08% (95%CI*: 97.66%~99.75%)		
Accuracy		98.82% (95%CI*: 97.45%~99.57%)		

COVID-19/FLU A+B/RSV/Adenovirus Antigen Rapid Test		RT-PCR		Total
		Positive	Negative	
Influenza B Antigen	Positive	56	5	61
	Negative	2	445	447
Total		58	450	508
Relative Sensitivity		96.55% (95%CI*: 88.09%~99.58%)		
Relative Specificity		98.89% (95%CI*: 97.43%~99.64%)		
Accuracy		98.62% (95%CI*: 97.18%~99.44%)		

RSV Test:

COVID-19/FLU A+B/RSV/Adenovirus Antigen Rapid Test		RT-PCR		Total
		Positive	Negative	
RSV Antigen	Positive	64	2	66
	Negative	1	441	442
Total		65	443	508
Relative Sensitivity		98.46% (95CI*: 91.72%~99.96%)		
Relative Specificity		99.55% (95CI*: 98.38%~99.95%)		
Accuracy		99.41% (95CI*: 98.28%~99.88%)		

Adenovirus Test:

COVID-19/FLU A+B/RSV/Adenovirus Antigen Rapid Test		RT-PCR		Total
		Positive	Negative	
Adenovirus Antigen	Positive	50	7	57
	Negative	3	448	451
Total		53	455	508
Relative Sensitivity		94.34% (95CI*: 84.34%~98.82%)		
Relative Specificity		98.46% (95CI*: 96.86%~99.38%)		
Accuracy		98.03% (95CI*: 96.41%~99.05%)		

Lay-user Study

A lay-user study was performed by lay person to evaluate the use of the COVID-19/FLU A+B/RSV/Adenovirus Antigen 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 284 lay-users participated in the study, the sensitivity of SARS-CoV-2 test is100.0%, the Specificity is 99.60%; the sensitivity of Influenza A test is 96.88%, the Specificity is 99.21%, the sensitivity of Influenza B test is 96.88%, the Specificity is 99.60%, the sensitivity of RSV test is 97.06%, the Specificity is 99.60%, the sensitivity of Adenovirus test is 96.77%, the Specificity is 99.21%. 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	$2.5X10^3$ $TCID_{50}$/mL
B WV/14617/85	RSV type B	$1.0X10^3TCID_{50}$/mL
GB	Adenovirus type 3	$1.0X10^3TCID_{50}$/mL
Gomen	Adenovirus type 7	$5.0X10^3TCID_{50}$/mL

Variants

These following strains could be detected out by the COVID-19/FLU A+B/RSV/Adenovirus Antigen Combo Rapid Test:

SARS-CoV-2:

Virus Strains	Virus Strains	Virus Strains
Delta variants (B.1.617.2)	Omicron variants (B.1.1.529)	Delta variants (AY Sub-lineages)
Delta variants (B.1.617.3)	Omicron variants (BA.2)	/

Influenza A+B:

Virus Strains	Virus Strains	Virus Strains
A/Brisbane/02/2018(H1N1)	A/Brisbane/192/2017(H3N2)	B/Victoria/2110/19(Victoria)
A/Victoria/2570/2019(H1N1)	A/Perth/9/2019(H3N2)	B/Brisbane/35/2018(Victoria)
A/Sydney/175/2022(H1N1)	A/Darwin/9/2021(H3N2)	B/Victoria/705/2018(Victoria)
A/Darwin/122/2018(H1N1)	A/Victoria/6/2022(H3N2)	B/South Australia/67/2018(Yamagata)
A/Darwin/6/2018(H1N1)	A/Sydney/1020/2018(H3N2)	B/Victoria/706/2018(Yamagata)

RSV:

Virus Strains	Virus Strains
Long(RSV A)	Fukushima/RSVB/OR-379/2021(BA 9)
18537(RSV B)	hRSV/B/China/SH100201028A10/2010(BA 10)

Adenovirus:

Virus Strains	Virus Strains	Virus Strains
Adenoid 71(Adenovirus type 1)	Clinical Virus Isolate(Adenovirus type 11)	RI-67(Adenovirus type 4)
Adenoid 6(Adenovirus type 2)	Clinical Virus Isolate(Adenovirus type 14)	7A(Adenovirus type 7)
Clinical Virus Isolate(Adenovirus type 3)	Clinical Virus Isolate(Adenovirus type 55)	Tonsil 99(Adenovirus type 6)
Clinical Virus Isolate(Adenovirus type 5)	/	/

Cross-Reactivity

The COVID-19/FLU A+B/RSV/Adenovirus Antigen Rapid Test was evaluated with the following bacterial isolates. None of them gave a positive result.

Chlamydophila pneumoniae	*Staphylococcus aureus subsp. aureus*	*Corynebacterium*	*Haemophilus influenzae*
Mycoplasma pneumoniae	*Streptococcus pneumoniae*	*Escherichia coli*	*Bordetella pertussis*
Moraxella catarrhalis	*Streptococcus pyogenes*	*Neisseria lactamica*	*Legionella pneumophila*
Staphylococcus epidermidis	*Streptococcus salivarius*	*Neisseria subflava*	*Candida albicans*
Arcanobacterium	*Streptococcus sp Group F*	*Pseudomonas aeruginosa*	*Klebsiella Pneumoniae*

The COVID-19/FLU A+B/RSV/Adenovirus Antigen Rapid Test was evaluated with the following viral strains. None of them gave a positive result.

Human coronavirus OC43	Mumps virus	Human Rhinovirus 1A	Human Metapneumovirus
Human coronavirus 229E	Parainfluenza virus 1	Human Rhinovirus 2	Human Enterovirus 71
Human coronavirus NL63	Parainfluenza virus 2	Human Rhinovirus 14	Human herpesvirus 1
Human coronavirus HKU1	Parainfluenza virus 3	Human Rhinovirus 16	Epstein-Barr virus
MERS COV Florida	Parainfluenza virus 4	Measles virus	Varicella-Zoster Virus

There was the cross reactivity between SARS-CoV-1 and SARS-CoV-2 at the concentration equal to or more than 1ng/mL in detection of SARS-CoV-1 recombinant nucleocapsid protein.

Interfering Substances

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

Whole Blood	Albuterol	Doxylamine Succinate	Rebetol
Mucin	4-Acetamidophenol	Ephedrine	Relenza
Sinus Buster Nasal Spray	Acetylsalicylic Acid	Flunisolide	Rimatadine
Budesonide Nasal Spray	Chlorpheniramine	Guaiacol glyceryl ether	Tamiflu
Zicamn Extreme Congestion Relief	Dexamethasone	Mupirocin	Tobryamycin
Afrin Nasal Congestion Relief Pump Mist	Dextromethorphan	Oxymetazoline	Triamcinolone
Amazon Basic Care Nasal Four Nasal Spray	Diphenhydramine	Phenylephrine	/

QUESTIONS & ANSWERS

1. How does the COVID-19/FLU A+B/RSV/Adenovirus Antigen Rapid Test work?
The test can qualitatively detect SARS-CoV-2, Influenza A, Influenza B, RSV and Adenovirus antigens in self-collected nasal swab specimens through the specific antibodies it contains. A positive result indicates SARS-CoV-2, Influenza A, Influenza B, RSV and/or Adenovirus antigens present in the specimen.

2. When should the test be used?
SARS-CoV-2, Influenza A, Influenza B, RSV and Adenovirus 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 COVID-19/FLU A+B/RSV/Adenovirus Antigen 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/Adenovirus cannot be precisely detected in all phases of an infection.

6. If the test result is Influenza, RSV or Adenovirus positive, what should I do?
Individuals with a positive result for Influenza, RSV or Adenovirus who are unwell are advised to consult a medical practitioner for follow-up clinical care.

7. If the test result is COVID-19 positive, what should I do?
If you have a COVID-19 POSITIVE result, staying at home protects the people in your community and you should not visit high-risk settings like hospitals and aged and disability care settings.
If you feel unwell or need COVID-19 advice for someone in your care, talk with your health provider, or speak to a nurse by calling the health direct helpline on 1800 022 222.
If you develop symptoms such as severe shortness of breath or chest pain, call triple zero (000) immediately. Tell the call handler and the paramedics on arrival if you have COVID-19.

8. Information of how to contact locally available support services.
For CUSTOMER SUPPORT HELPLINE: Call (03) 5986 5465 9am-7pm (AEST), 7 days per week
For information on the correct use of this test and for interpretation of the test results.

9. Information on how to contact the TGA to report poor performance or usability issues in the self-test environment
Report an issue via the Users Medical Device Incident Report, email iris@health.gov.au or call 1800 809 361.

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

Number: 14603114300
Revision Date: 2026-02-04

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.

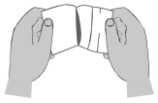
1B. Ensure kit is at room temperature for at least 30 minutes prior to use.
Open the box carefully as it will be used in a later step (1D).
Do not open individual components until instructed.
Note: A timing device (clock, timer, phone etc.) is required, but not provided.

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.



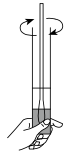
Keep fingers away from the swab end.
Touch the stick end only.

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.

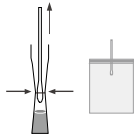
2C. Using the same swab, repeat step 2B, in your other nostril.
Withdraw the swab.

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.

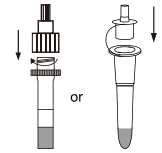


2E. Hold the tube firmly with one hand.
Remove the swab while squeezing the swab head against the inside of the extraction tube.
Place the swab in a plastic bag.



2F. Close the cap of the extraction tube

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

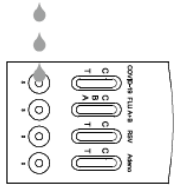


3. PERFORM THE TEST

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.**

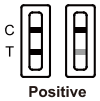
Do not touch the test device during this period.

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.

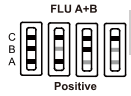
POSITIVE



POSITIVE COVID-19/RSV/Adenovirus:* Two colored lines appear in the COVID-19/RSV/Adenovirus 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/Adenovirus and/or RSV antigen present in the specimen. So any shade of color in the test region (T/B/A) should be considered positive.

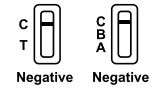
If you have a Covid-19 POSITIVE result, staying at home protects the people in your community and you should not visit high-risk settings like hospitals and aged and disability care settings.

If you feel unwell or need COVID-19 advice for someone in your care, talk with your health provider, or speak to a nurse by calling the health direct helpline on 1800 022 222.

If you develop symptoms such as severe shortness of breath or chest pain, call triple zero (000) immediately. Tell the call handler and the paramedics on arrival if you have COVID-19.

Individuals with a positive result for Influenza, RSV or ADV who are unwell are advised to consult a medical practitioner for follow-up clinical care.

NEGATIVE



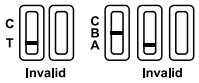
NEGATIVE: One colored line appears in the control region (C).
No colored line appears in the test line region (T/B/A).

You are unlikely to have COVID-19, Influenza A/Influenza B/Adenovirus 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/Adenovirus 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 /Adenovirus 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/Adenovirus guidelines/requirements.

INVALID

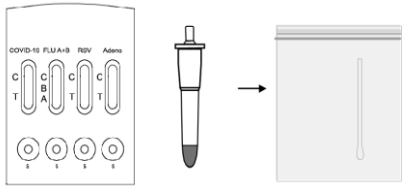


INVALID: Control line fails to appear.

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/RSV/Adenovirus 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.



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:
Compliance Management Solutions Pty Ltd
3/85 Curzon Street
North Melbourne VIC 3051
Australia.

For Customer Support Helpline: Call (03) 5986 5465 9am-7pm (AEST), 7 days per week for information on the correct use of this test and for interpretation of the test results.