WeTestBio

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

REF ISIN-525H	English

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

A rapid test for the qualitative detection of SARS-CoV-2 Nucleocapsid Protein, Influenza A and Influenza B nucleoproteins antigens present in nasal swab specimen.
For self-testing *in vitro* diagnostic use.

INTENDED USE
The SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab) is a single-use test kit intended to detect the SARS-CoV-2, Influenza A and Influenza B virus that causes COVID-19 and/or Influenza with self-collected nasal swab specimen. The test is intended for use in symptomatic individuals who are suspected of being infected with COVID-19 within the first 7 days of symptom onset and / or Influenza A+B within the first 4 days of symptom onset.
Results are for the detection of SARS-CoV-2 Nucleocapsid protein, Influenza A and Influenza B nucleoproteins antigens. An antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status.
Positive results are indicative of the presence of SARS-CoV-2 and/or Influenza A+B. Individuals who test positive should self-isolate and seek additional care from their healthcare provider. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 and/or Influenza A+B infection. Individuals who test negative and continue to experience COVID-like or flu-like symptoms should seek follow up care from their healthcare provider.
The SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab) obtain a preliminary result only, an aid diagnosis of COVID-19 and Influenza, the final confirmation should be based on clinical diagnostic results.

SUMMARY
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. It is a communicable disease easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus[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.

PRINCIPLE
The SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein, Influenza A and Influenza B nucleoproteins antigens in human swab specimen.

PRECAUTIONS
Please read all the information in this package insert before performing the test.
- For self-testing *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- **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.
- Store 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.
- This test kit is intended to be used as a preliminary test only and if unwell seek medical assistance.
- Follow the indicated time strictly.
- Use the test only once. Do not dismantle and touch the test window of the test cassette.
- The kit must not be frozen or used after the expiration date printed on the package.
- Test for children should be under the guidance of an adult.
- Wash hands thoroughly before and after handling.
- Please ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.
- Please performed the test immediately after collection the specimen.

STORAGE AND STABILITY
Store as packaged in the sealed pouch at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

MATERIALS
Materials Provided

	Kit size	1T/kit	5T/kit	10T/kit	20T/kit
Components	Test cassette	1	5	10	20
	Sterile swab	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 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab) will only indicate the presence of SARS-CoV-2 and/or Influenza A/Influenza B antigens in the specimen.
   If the test result is negative or non-reactive and clinical symptoms persist or being in a high risk setting or where there is an occupational risk or other requirement, it is because the very early infection virus may not be detected, It is recommended to test again with a new test 1-2 days later and if unwell seek medical assistance.
3. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. If unwell seek medical assistance.
4. A negative result for Influenza A or Influenza B obtained from this kit should be confirmed and if unwell seek medical assistance.
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. Failure to follow these procedures may alter test performance.
7. False negative results may occur if a specimen is improperly collected or handled.
8. False negative results may occur if inadequate levels of viruses are present in the specimen.
9. If testing is not performed within the first 7 days of symptom onset , it is possible for this test to give a negative result that is incorrect (a false negative).
10. Tests are less reliable in the later phase of infection and in asymptomatic individuals.
11. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
12. A negative result does not rule out infection with another type of respiratory virus.

PERFORMANCE CHARACTERISTICS
Clinical performance
The SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab) has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab). Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result.

SARS-CoV-2 Test:

SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test		RT-PCR		Total
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	248	3	251
	Negative	7	581	588
Total		255	584	839
Relative Sensitivity		97.25% (95%CI*: 94.44%~98.66%)		
Relative Specificity		99.49% (95%CI*: 98.50%~99.83%)		
Accuracy		98.81% (95%CI*: 97.82%~99.35%)		

Influenza A+B Test:

SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test		RT-PCR		Total
		Positive	Negative	
Influenza A Antigen	Positive	68	2	70
	Negative	3	485	488
Total		71	487	558
Relative Sensitivity		95.77% (95%CI：88.14%~99.12%)		
Relative Specificity		99.59% (95%CI：98.52%~99.95%)		
Accuracy		99.10% (95%CI: 97.92%~99.71%)		

SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test		RT-PCR		Total
		Positive	Negative	
Influenza B Antigen	Positive	48	3	51
	Negative	3	504	507
Total		51	507	558
Relative Sensitivity		94.12% (95%CI：83.76%~98.77%)		
Relative Specificity		99.41% (95%CI：98.28%~99.88%)		
Accuracy		98.92% (95%CI: 97.67%~99.60%)		

Lay-user Study
A lay-user study was performed by lay person to evaluate the use of the SARS-CoV-2 and Influenza A+B 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 550 lay-users participated in the study, the sensitivity of SARS-CoV-2 test is 96.00%, the Specificity is 100%; the sensitivity of Influenza A test is 92.98%, the Specificity is 98.99%, the sensitivity of Influenza B test is 92.06%, the Specificity is 98.36%. 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		Detection Level
SARS-CoV-2	BetaCoV/Wuhan/IPBCAMS-WH-01/2019	78 $TCID_{50}$/ml
Influenza A	A/Sydney/5/2021(H1N1)	50 $TCID_{50}$/mL
	A/South Australia/69/2019(H3N2)	50 $TCID_{50}$/mL
Influenza B	B/Austria/1359417/2021(Victoria)	50 $TCID_{50}$/mL
	B/Darwin/58/2019(Yamagata)	100 $TCID_{50}$/mL

VARIANTS
The SARS-CoV-2 variant Delta (Indian B.1.617.2) and Omicron (B.1.1.529, BA.2, BA.4, BA.5)could be detected out by the SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test at specific concentrations.

Specificity Testing with Various Viral Strains
The SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test was tested with the following viral strains. No discernible line at either of the test-line regions was observed at these concentrations listed:

SARS-CoV-2 Test:
Adenovirus type 3, Adenovirus type 7, Human coronavirus OC43, Human coronavirus 229E, Human coronavirus NL63, Human coronavirus HKU1, MERS COV Florida, Influenza A H1N1, Influenza A H3N2, Influenza B, Human Rhinovirus 2, Human Rhinovirus 14, Human Rhinovirus 16, Measles, Mumps, Parainfluenza virus 2, Parainfluenza virus 3, Respiratory syncytial virus.

Influenza A+B Test:
Adenovirus type 3, Adenovirus type 7, Human coronavirus OC43, Human coronavirus 229E, Human coronavirus NL63, Human coronavirus HKU1, MERS COV Florida, Human Rhinovirus 2, Human Rhinovirus 14, Human Rhinovirus 16, Measles, Mumps, Parainfluenza virus 2, Parainfluenza virus 3, Respiratory syncytial virus.

Cross-reactivity
The following organisms were negative when tested with the SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab):
Arcanobacterium, Candida albicans, Corynebacterium, Escherichia coli, Moraxella catarrhalis, *Neisseria lactamica, Neisseria subflava, Pseudomonas aeruginosa, Staphylococcus aureus subspaureus, Staphylococcus epidermidis, Streptococcus pneumonia, Streptococcus pyogenes, Streptococcus salivarius, Streptococcus sp group F.*

Cross-reactivity Continued
Our Test Results indicated there is 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. This is because SARS-CoV has high homology to the SARS-CoV-2.

Interfering Substances
Test results will not be interfered by following substances at certain concentrations:
Whole Blood, Mucin, Budesonide Nasal Spray, Dexamethasone, Flunisolide, Mupirocin, Oxymetazoline, Phenylephrine, Rebetol, Relenza, Tamiflu, Tobramycin.

EXTRA INFORMATIONS
1. How does the SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test work?
The test is for the qualitative detection of SARS-CoV-2 and/or Influenza A/Influenza B antigens in self-collected swab specimens. A positive result indicates SARS-CoV-2 and/or Influenza A/Influenza B antigens present in the specimen.
2. When should the test be used?
SARS-CoV-2 and/or Influenza A/Influenza B antigen can be detected in acute respiratory tract infection, it is recommended to run the test when you are suspected of being infected with COVID-19 and/or Influenza A/Influenza B.
3. Can the result be incorrect?
The results are accurate as far as the instructions are carefully respected.
Nevertheless, the result can be incorrect if inadequate sampling volume or the SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test gets wet before test performing, or if the number of extraction buffer drops are less than 3 or more than 4.
Besides, due to immunological principles involved, there exist the chances of false results in rare cases. If unwell seek medical assistance.
4. How to interpret the test 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. The test should be considered as positive whatever the color intensity of the test line is.
5. What do I have to do if the result is negative?
A negative result means that you are negative or that the viral load is too low to be recognized by the test. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19 and/or Influenza and/or This means you could possibly still have COVID-19 and/or Influenza 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 vrius cannot be precisely detected in all phases of an infection.
Even with a negative test result, distance and hygiene rules must be observed.
6. What do I have to do if the result is positive?
A positive result means the presence of SARS-CoV-2 /Influenza A//Influenza B antigens. A positive results means it is very likely you have COVID-19 and/or Influenza. 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 healthdirect helpline on 1800 022 222.
If you develop symptoms such as severe shortness of breath or chest pain, call triple zero (000) immediately.
7. 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.

BIBLIOGRAPHY

1. Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia (Trial Version 7). National Health Commission & National Administration of Traditional Chinese Medicine.2020.
2. Williams, KM, Jackson MA, Hamilton M. (2002) Rapid Diagnostic Testing for URIs in Children; Impact on Physician Decision Making and Cost. Infec. Med. 19(3): 109-111.

IVD	For *in vitro* diagnostic use only	Σ	Tests per kit
	Do not reuse		Use by
	Consult Instructions For Use		Manufacturer
REF	Catalog #	2°C~30°C	Store between 2-30°C
	Do not use if package is damaged	LOT	Lot Number

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.

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

Distributor: **We Test Bio** Level 26, 1 Bligh Street, Sydney NSW 2000
www.wetestbio.com.au Email: support@wetestbio.com.au

Number: 14602620000
Revision date: 2025-03-05

WeTestBio

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 if it 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.

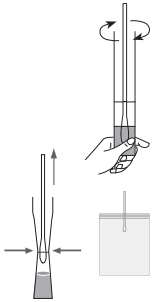
Withdraw the swab.

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

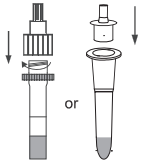


2E. Hold the Tube firmly with one hand.

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.



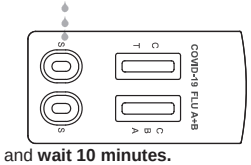
3. PERFORM THE TEST

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 both** 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:* Two colored lines appear in the COVID-19 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.

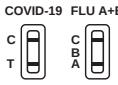
One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A).

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.

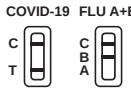
One colored line should be in the control region (C) and two colored line should be in the Influenza A region (A) and Influenza B region (B).



POSITIVE SARS-CoV-2 and Influenza A:* Two colored lines appear in the COVID-19 window; and two colored lines appear in the FLU A+B window.

COVID-19 window: One colored line should be in the control region (C) and another colored line should be in the Test region (T).

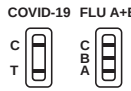
FLU A+B window: One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A).



POSITIVE SARS-CoV-2 and Influenza B:* Two colored lines appear in the COVID-19 window; and two colored lines appear in the FLU A+B window.

COVID-19 window: One colored line should be in the control region (C) and another colored line should be in the Test region (T).

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).



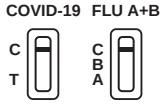
POSITIVE SARS-CoV-2 and Influenza A+B:* Two colored lines appear in the COVID-19 window; Three colored lines appear in the FLU A+B window.

COVID-19 window: One colored line should be in the control region (C) and another colored line should be in the Test region (T).

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).

***NOTE:** The intensity of the color in the test line region (T/B/A) will vary based on the amount of SARS-CoV-2 and/or Influenza A+B antigen present in the sample. So any shade of color in the test region (T/B/A) should be considered positive.
A positive results means it is very likely you have COVID-19 and/or Influenza A/Influenza B, but the positive samples should be confirmed to reflect this.
POSITIVE SARS-CoV-2: 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 healthdirect helpline on 1800 022 222.
If you develop symptoms such as severe shortness of breath or chest pain, call triple zero (000) immediately.
POSITIVE Influenza A and/or Influenza B: Individuals with a positive result or who are unwell are must consult a medical practitioner for follow-up clinical care.

NEGATIVE



NEGATIVE: One colored line appears in the control region (C).

No apparent colored line appears in the test line region (T/B/A).

You are unlikely to have COVID-19 and/or Influenza A/Influenza B. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19 and/or Influenza A/Influenza B. This means you could possibly still have COVID-19 and/or Influenza A/Influenza B 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 cannot be precisely detected in all phases of an infection. If symptoms persist advice to conduct repeat testing and consult a medical practitioner for follow-up clinical care.
Even with a negative test result, distance and hygiene rules must be observed.

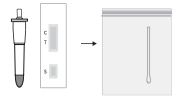
INVALID

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 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 (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.