

CorePharma 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.

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, fatique and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases

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 virus². 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

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 repeatedly abnormal results should follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, 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

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	Kit size	1T/kit	5T/kit	10T/kit	20T/kit
	Test cassette	1	5	10	20
Components	Sterile swab	1	5	10	20
	Extraction buffer	1	5	10	20
	Package insert	1	1	2	4
	Tube holder	On th	e 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 or follow the guidance
- from your local State or Territory Health Department for guidance on confirmation testing if necessary, 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. Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance
- A negative result for Influenza A or Influenza B obtained from this kit should be confirmed by following the guidance from your local State or Territory Health Department for guidance on confirmation testing if

- necessary, 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
- Failure to follow these procedures may after test performance.
- False negative results may occur if a specimen is improperly collected or handled
- False negative results may occur if inadequate levels of viruses are present in the specimen.
- 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		T-4-1
		Positive	Negative	Total
SARS-CoV-2 Antigen	Positive	248	3	251
	Negative	7	581	588
Total		255	584	839
Rela	Relative Sensitivity 97.25% (95%CI*: 94.44%~98.66%		98.66%)	
Rela	tive Specificity	99.49% (95%CI*: 98.50%~99.83%)		
Accuracy		98.81	% (95%CI*: 97.82%~9	99.35%)

Influenza A+R Test

SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test		RT-PCR		Total
		Positive	Negative	Iotai
Influenza A Antigen	Positive	68	2	70
	Negative	3	485	488
Total		71	487	558
Rela	tive Sensitivity	95.77% (95%CI: 88.14%~99.12%)		12%)
Relative Specificity 99.59% (95%CI: 98.52%~99.95%)		95%)		
Accuracy 99.10% (95%CI: 97.92%~99.71%		1%)		

SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test		RT-PCR		Total
		Positive	Negative	Total
Influenza B Antigen	Positive	48	3	51
	Negative	3	504	507
Total		51	507	558
Rela	tive Sensitivity	94.12% (95%CI: 83.76%~98.77%)		77%)
Rela	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. Mumos. 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

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

I. 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?

he 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. Such tests based on immunological principles must follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and 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, migration/traveling, attending events and etc. should follow your local COVID/Influenza guidelines/requirements.

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. Immediately go into self-isolation in accordance with the local guidelines and follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance 7. Information of how to contact locally available support services.

For advice on how to seek medical help or get tested for coronavirus (COVID-19) you can contact your state or territory health authority, Please see your local contact numbers below

BIBLIOGRAPHY

Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia (Trial Version 7). National Health Commission & National Administration of Traditional Chinese Medicine, 2020.

Commission a National Administration of i fragitional Crimese 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.

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.

LOCAL CONTACT DETAILS

TO LOCATE YOUR NEAREST COVID TESTING CENTRE AND LABORATORY PLEASE CONTACT STATE AND TERRITORY CONTACT NUMBERS Medical Device Incident Report

You can contact the Therapeutic Goods Administration (TGA) to report performance or usability issues via the online Users Medical Device Incident Report, emailing iris@tga.gov.au or calling 1800 809 361. 02 6207 7244

Australian Capital Territory Coronavirus Helpline (8am-8pm daily)

New South Wales Coronavirus Helpline (Service NSW 24/7)

Northern Territory Coronavirus National Hotline (National Helpline)

Queensland Coronavirus Helpline (134COVID)

South Australia Coronavirus Helpline (9am -5 pm Daily)

Tasmanian Public Health Hotline (Coronavirus)

Victoria Coronavirus Hotline (24/7)

Western Australia Coronavirus Hotline 13COVID (8am-6pm Mon-Fri For in vitro

Do not reuse

Consult Instructions For Use

Catalog #

Do not use if package is damaged

https:// 1800 5	/www.dhhs.vic.gov.au/ 595 206 /www.healthywa.wa.gov.au/
Σ	Tests per kit
2	Use by
	Manufacturer
re A we	Store between 2-30°C
LOT	Lot Number

https://health.act.gov.au/

https://health.nt.gov.au/

https://www.health.nsw.gov.au/

https://www.health.qld.gov.au/ 1800 253 787

https://www.health.tas.gov.au/

https://www.sahealth.sa.gov.au/

137 788

134 268

1800 020 080

1800 671 738

IVD

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REF

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

Distributed by: DPP Pharmaceuticals Pty Ltd

Level 5, 484 St Kilda Road, Melbourne 3004 www.corepharma.com.au

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



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.



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.

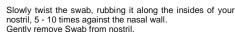
Remove the sterile swab from the pouch





2B. Swabbing both nostrils.

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





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

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.

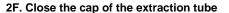
2D. Insert the Swab into the extraction Tube.

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.



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

3. PERFORM THE TEST

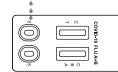
3A. Remove the test cassette from the sealed foil pouch and use it within one (1) hour.

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 and carefully follow your local COVID guidelines/requirements.

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

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

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).



COVID-19 FLU A+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).





COVID-19 FLU A+B 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).



COVID-19 FLU A+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: Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical

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

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, migration/traveling, attending events and etc. should follow your local COVID/Influenza quidelines/requirements.

INVALID COVID-19





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.





