Pure LIVING

SARS-CoV-2 Antigen Rapid Test (Nasal Swab) Package Insert For Self-testing

REF INCP-502H	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 antigens present in nasal swab specimen.
For self-testing in vitro diagnostic use.

INTENDED USE

The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is a lateral flow chromatographic immunoassay single-use test kit intended to qualitative detect the SARS-CoV-2 that causes COVID-19 with self-collected nasal swab specimen. The test is intended for use in symptomatic individuals meeting the case definition for COVID-19 within the first 7 days of symptom onset.
Results are for the detection of SARS-CoV-2 Nucleocapsid protein 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. Individuals who test positive should self-isolate and contact your State or Territory Coronavirus testing services to get a laboratory PCR test. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection. Individuals who test negative and continue to experience COVID-like symptoms should seek follow up care from their COVID testing centre.
The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) obtain a preliminary result only, an aid diagnosis of COVID-19, for the final confirmation should be based on clinical diagnostic results.
The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is intended to be used by laypersons as a self-test for home and workplace (in offices, for sporting events, airports, schools, etc.).

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].

PRINCIPLE

The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein 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 repeatedly abnormal results should be discussed with doctor or medical professional.
- 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.
- Keep out of the reach of children.
- Test for children and young people should be used with an adult.
- Small children under the age of 16 should be swabbed with the help of a second 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.

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/kits	5T/kits	10T/kits	20T/kits
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
	Biosafety bag	1	5	10	20

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 Antigen Rapid Test (Nasal Swab) will only indicate the presence of SARS-CoV-2 antigens in the specimen.
3. 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 contact the nearest Covid test centre using the rules of your local authority.
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.
5. Positive results of COVID-19 may be due to infection with non- SARS-CoV-2 coronavirus strains or other interference factors.
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. The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is less reliable in the later phase of infection, it is recommended to use the test within the first 7 days of symptom onset.
10. Tests are less reliable in asymptomatic individuals.
11. A negative result does not rule out infection with another type of respiratory virus.
12. A positive result cannot necessarily determine whether a person is infectious.
13. 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).
14. The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is a presumptive test only and the need for confirmatory testing of positive results by a laboratory PCR test and for follow-up clinical care.
15. A negative result means that you are negative or that the viral load is too low to be recognized by the test. If you experience symptoms such as headaches, migraines, fever, loss of sense of smell and taste, you must seek immediate further testing by PCR.

PERFORMANCE CHARACTERISTICS

Clinical performance

A clinical evaluation was conducted comparing the results obtained using the SARS-CoV-2 Antigen Rapid Test with RT-PCR test result. The clinical trial included 1074 nasal swab specimens. The results demonstrated > 99.9% specificity and 93.6% sensitivity with an overall accuracy of 98.1%.

	PCR confirmed sample number	Correct identified	Rate
Positive sample	311	291	93.6% (Sensitivity)
Negative sample	763	763	> 99.9% (Specificity)
Total	1074	1054	98.1% (Total Accuracy)

93.6% Sensitivity: In total 311 PCR confirmed positive samples: 291 PCR confirmed positive samples were correctly detected by SARS-CoV-2 Antigen Rapid Test. There are 20 false negative cases.
> 99.9% Specificity: In total 763 PCR confirmed negative samples: 763 PCR confirmed negative samples were correctly detected by SARS-CoV-2 Antigen Rapid Test. There are no false positive cases.
98.1% Accuracy: In total 1074 PCR confirmed samples: 1054 PCR confirmed samples were correctly detected by SARS-CoV-2 Antigen Rapid Test.

Lay-user Study

A lay-user study was performed by lay person at 3 sites including Germany, Italy and Slovenia to evaluate use of the SARS-CoV-2 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 319 lay-users participated in the study, the reading of the results of the lay-users was only in 1 case discrepant with the observation of professionals. 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.

Specificity Testing with Various Viral Strains

The SARS-CoV-2 Antigen Rapid Test was tested with the following viral strains. No discernible line at either of the test-line regions was observed at specific concentrations:
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, Enterovirus Type 68 (2007 Isolate), Haemophilus influenzae type b, Nasal Wash (0.90%).

VARIANTS

The SARS-CoV-2 variant Alpha (UK B.1.1.7), Delta (Indian B.1.617.2), Gamma (B.1.1.28), VUI-21ARP-03 (Indian B.1.617.3) and Beta (South Africa B.1.351) could be detected out by the SARS-CoV-2 Antigen Rapid Test at specific concentrations.

LIMITATION OF DETECTION

The SARS-CoV-2 Antigen Rapid Test can detect out SARS-CoV-2 heat-inactivated virus strain as low as $1X10^2$ $TCID_{50}$/mL.

CROSS-REACTIVITY

Test results will not be affected by other respiratory viruses and commonly encountered microbial flora and low pathogenic coronaviruses listed in table below at certain concentrations.
Arcanobacterium, Pseudomonas aeruginosa, Candida albicans Staphylococcus aureus subspaureus, Corynebacterium, Staphylococcus epidermidis, Escherichia coli, Streptococcus pneumoniae, Moraxella catarrhalis, Streptococcus pygenes, Neisseria lactamica, Streptococcus salivarius, Neisseria subflava, Streptococcus sp group F, Chlamydia pneumoniae Legionella pneumophila Philadelphia Bordetella Pertussis A639,Mycoplasma Pneumoniae M129.

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

The interfering substances below were spiked with negative, SARS-CoV-2 Antigen weak positive. No substances showed any interference with the SARS-CoV-2 Antigen Rapid Test (Nasal Swab):
Whole Blood, Mucin, Budesonide Nasal Spray, Dexamethasone, Flunisolide, Mupirocin, Oxymetazoline, Phenylephrine, Rebetol, Relenza, Tamiflu, Tobramycin, HAMA and Biotin.

EXTRA INFORMATIONS

1. How does the SARS-CoV-2 Antigen Rapid Test work?
The test is for the qualitative detection of SARS-CoV-2 antigens in self-collected swab specimens. A positive result indicates SARS-CoV-2 antigens present in the specimen.
2. When should the test be used?
SARS-CoV-2 antigen can be detected in acute respiratory tract infection, it is recommended to run the test in symptomatic individuals meeting the case definition for COVID-19 (•Acute onset of fever, cough; or •Acute onset of ANY THREE OR MORE of the following signs or symptoms: Fever, cough, general weakness/fatigue, headache, myalgia, sore throat, coryza, dyspnoea, anorexia/nausea/vomiting, diarrhoea, altered mental status.), and to test asymptomatic individuals limited to contacts of confirmed COVID-19 cases or probable cases and to at-risk health workers.
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 Antigen 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. A consultation with the doctor is always recommended for such tests based on immunological principles.
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. This means you could possibly still have COVID-19 even though the test is negative.
If you experience symptoms such as headaches, migraines, fever, loss of sense of smell and taste, contact the nearest Covid test centre using the rules of your local authority. 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 cannot be precisely detected in all phases of an infection. Distance and hygiene rules must still be observed.
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 antigens. A positive results means it is very likely you have COVID-19. 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.
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@tga.gov.au or call 1800 809 361).

BIBLIOGRAPHY

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

INDEX OF SYMBOLS

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

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

Distributor:
Australia & New Zealand Health Products Pty Ltd
Level 8/ 167-169, Queen Street, Melbourne VIC 3000
Email: info@anzhpl.com.au
Telephone: +61 3 9640 0566
Website: anzhpl.com.au | pureliving.net.au

Number: 14602414900
Revision date: 2024-08-21

SARS-CoV-2 Antigen Rapid Test (Nasal Swab) Instruction Guide

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. Make sure they are dry before starting.

PREPARE FOR THE TEST

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

Ensure kit is at room temperature for at least 30 minutes prior to use.

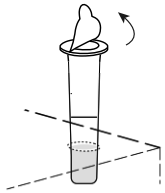
Open the box carefully as it will be used in a later step .

Do not open individual components until instructed.

Note: A timing device (clock, timer, phone etc.) is required, but not provided.

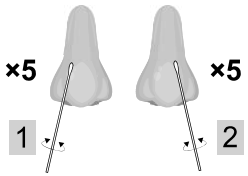
1. SPECIMEN COLLECTION

Remove the cover of the tube with Extraction buffer and place the tube in the tube holder.



Nasal swab specimen Collection

1. Remove the sterile swab from the pouch.
2. Insert the swab into your nostril until you feel slight resistance (Approx. 2cm up your nose). Slowly twist the swab, rubbing it along the insides of your nostril for 5-10 times against the nasal wall.
   Note:
   This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain.
   When the nasal mucosa is damaged or bleeding, nasal swab collection is not recommended.
   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. For very young children, you may need another person to steady the child's head while swabbing.
3. Gently remove the swab.
4. Using the same swab, repeat step 2 in your other nostril.
5. Withdraw the swab.

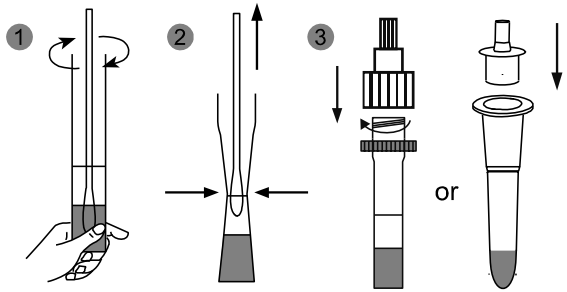


2. SPECIMEN PREPARATION

1. Place the swab into the Extraction tube, ensure it is touching the bottom and stir the swab to mix well. Press the swab head against to the tube and rotate the swab for **10-15 seconds**.

2. Remove the swab while squeezing the swab head against the inside of the Extraction tube.
   Place the swab in a biosafety bag.

3. Close the cap or fit the tube tip onto the tube.



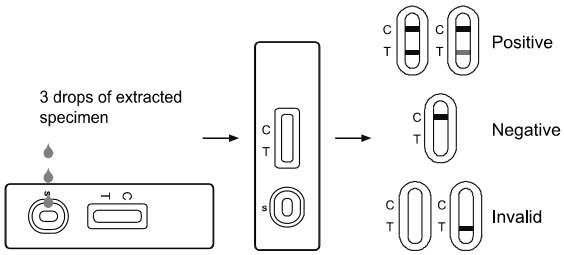
3. TESTING

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

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

3. **Read the result at 15 minutes.**

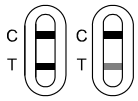
Do not read the result after 20 minutes.



! **Do not touch the Test Device during this period.**

Please share your test result with your healthcare provider.

POSITIVE:* Two distinct colored lines appear.



One colored line should be in the control region (C) and another colored line should be in the Test region (T).

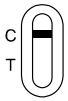
***NOTE:** The intensity of the color in the test line region (T) will vary based on the amount of SARS-CoV-2 antigen present in the sample. So **any faint colored lines in the test region (T) should be considered positive**.

A positive results means it is very likely you have COVID-19, but the positive samples should be confirmed to reflect this. 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.

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

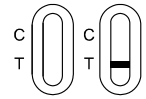


You are unlikely to have COVID-19. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19. This means you could possibly still have COVID-19 even though the test is negative.

If you experience symptoms such as headaches, migraines, fever, loss of sense of smell or taste, contact the nearest Covid test centre according to the rules of your local authority. 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 cannot be precisely detected in all phases of an infection.

Even with a negative test result, distance and hygiene rules must be observed.

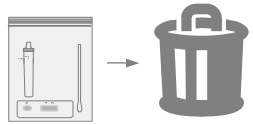
INVALID: Control line fails to appear.



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 your doctor or a COVID-19 test center.

5. DISPOSE THE TEST KIT

After the test is complete, place all the components in a biosafety bag and tightly sealed, then dispose in household waste or rubbish bin. Dispose according to local regulations.



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.