COVID-19 Antigen Rapid Test (Oral Fluid) Package Insert For Self-testing

REF ICOV-802H	English

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

INTENDED USE

The COVID-19 Antigen Rapid Test (Oral Fluid) is a single-use test kit intended to detect the SARS-CoV-2 nucleocapsid protein antigens that causes COVID-19 in human oral fluid. The test is intended for use in symptomatic individuals meeting the case definition for COVID-19 within the first 7 days of symptom onset. The COVID-19 Antigen Rapid Test (Oral Fluid) obtain a preliminary results only, an aid diagnosis of COVID-19, for the final confirmation should be based on clinical diagnostic results.
The COVID-19 Antigen Rapid Test (Oral Fluid) 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.

PRINCIPLE

The COVID-19 Antigen Rapid Test (Oral Fluid) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein antigens in human oral fluid specimen.

REAGENTS

The test device contains anti-SARS-CoV-2 antibodies.

WARNING

1. **Read the entire package insert prior to performing test.**
2. For self-testing *in vitro* diagnostic use only.
3. The test is for one time use only, do not reuse the test. Do not use after expiration date.
4. Do not eat, drink or smoke in the area where the specimens or kits are handled.
5. **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.
6. Do not use test if pouch is damaged.
7. Wash hands thoroughly before and after handling.
8. If the result is preliminary positive, Contact your State or Territory Coronavirus testing services to get a laboratory PCR test.
9. Test for children and young people should be used with an adult.
10. The used test should be discarded according to local regulations.

STORAGE

Store the test at 35.6-86°F (2-30°C). Do not open the pouch until ready for use. **DO NOT FREEZE.**

ITEMS PROVIDED

	Kit size	1T/kit	5T/kit	10T/kit	20T/kit
Components	Test device	1	5	10	20
	Collection device (Funnel, tube and tube tip)	1	5	10	20
	Buffer	1	5	10	20
	Package insert	1	1	2	4
	Biosafety Bag	1	5	10	20

ITEMS NOT PROVIDED

•Timer

LIMITATIONS

1. Failure to follow the testing steps may give inaccurate results.
2. The COVID-19 Antigen Rapid Test (Oral Fluid) is for self-testing *in vitro* diagnostic use only.
3. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
4. 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.
5. Positive results of COVID-19 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.
6. The COVID-19 Antigen Rapid Test (Oral Fluid) is less reliable in the later phase of infection, it is recommend to use the test within the first 7 days of symptom onset.
7. Tests are less reliable in asymptomatic individuals.
8. Negative results may not mean that a person is not infectious and if symptoms are present you must seek immediate further testing Via the PCR Method.
9. A negative result does not rule out infection with another type of respiratory virus.
10. The test is for one time use only, do not reuse the test.
11. Test for children and young people under the age of 16 should be supervised with an adult.
12. Please keep out of reach of children.
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 COVID-19 Antigen Rapid Test (Oral Fluid) 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.
16. A negative result does not rule out infection with another type of respiratory virus.
17. 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.

PERFORMANCE CHARACTERISTICS

Clinical performance

A clinical evaluation was conducted comparing the results obtained using the COVID-19 Antigen Rapid Test with RT-PCR test result.
The clinical trial included 406 oral fluid specimens. The results demonstrated 99.3% specificity and 90.1% sensitivity with an overall accuracy of 97.0%.

	PCR confirmed sample number	Correct identified	Rate
Positive sample	101	91	90.1%(sensitivity)
Negative sample	305	303	99.3%(Specificity)
Total	406	394	97.0%(Total Accuracy)

90.1% Sensitivity: In total 101 PCR confirmed positive samples: 91 PCR confirmed positive samples were correctly detected by COVID-19 Antigen Rapid Test. There are 10 false negative cases.
99.3% Specificity: In total 305 PCR confirmed negative samples: 303 PCR confirmed negative samples were correctly detected by COVID-19 Antigen Rapid Test. There are only 2 false positive cases.
97% Accuracy: In total 406 PCR confirmed samples: 394 PCR confirmed samples were correctly detected by COVID-19 Antigen Rapid Test.
The observed accuracy may vary depending on the prevalence of the virus in the population.

Lay-user Study

213 lay-user participate in COVID-19 Rapid Test lay-user study at three different sites, including Germany, Italy and Slovenia. Of the 213 participants, 212 participants obtained valid results (99.5%), and all participants read the results correctly when compared with supervisor read, far surpassing the valid result and correct result read acceptance criteria.
Lay-users in different education backgrounds, different age distribution and different gender could collect samples, perform tests, obtain valid results, and read correct results using the package insert as guide to perform the test. COVID-19 Antigen Rapid Test (Oral Fluid) product design and performance can be used for self-testing.

Limitation of Detection

The COVID-19 Antigen Rapid Test can detect out SARS-CoV-2 heat-inactivated virus strain as low as $8X10^2$ $TCID_{50}$/mL.

Variant

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 COVID-19 Antigen Rapid Test at specific concentrations.

Specificity Testing with Various Viral Strains

The COVID-19 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, Influenza B,Adenovirus type 7, Measles, Human coronavirus OC43,Mumps, Human coronavirus 229E, Parainfluenza virus 2, Human coronavirus NL63, Parainfluenza virus 3, Human coronavirus HKU1, Respiratory syncytial virus, MERS-coronavirus Florida,Enterovirus Type 68 (2007 Isolate), Influenza A H1N1, Haemophilus influenzae type b, Influenza A H3N2.

Cross-reactivity

The following organism were tested, and all found to be negative when tested with COVID-19 Antigen Rapid Test (Oral Fluid):
Arcanobacterium,Staphylococcus epidermidis, Candida albicans, Streptococcus pneumonia, Corynebacterium, Streptococcus pygenes, Escherichia coli, Streptococcus salivarius, Moraxella catarrhalis, Streptococcus sp group F, Neisseria lactamica, Chlamydia pneumoniae, Neisseria subflava, Legionella pneumophila Philadelphia, Pseudomonas aeruainosa, Bordetella pertussis A639, Staphylococcus aureus subspaureus, Mycoplasma pneumoniae M129.
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 following substances were tested with COVID-19 Antigen Rapid Test (Oral Fluid) and no interference was observed.
Dexamethasone, Tea, Mucin, Milk, Flunisolide, Orange juice, Mupirocin, Mouthwash, Oxymetazoline, Caffeine, Phenylephrine, Coca Cola, Rebetol, Toothpaste, Relenza, Whole Blood, Tamiflu, HAMA, Tobryamycin, Biotin.

Q&A

1. How do I know if the Test worked well?
COVID-19 Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens present in human oral fluid. When the control line(C) appears, it means the test unit is performing well.
2. How soon can I read my results?
You can read your results after 15 minutes as long as a colored line has appeared next to the Control region(C), do not read result after 20 minutes.
3. When is the best time to run the test?
Test can be done at any time of the day. However It is recommended to collect the first oral fluid in the morning.
4. Can the result be wrong? Are there any factors that can affect the test result?
The results will only give accurate results as far as the fresh human oral fluid is used and followed the instructions carefully. Nevertheless, the result can be incorrect.
Non-SARS-CoV-2 coronavirus strains or other interference factors may cause a preliminary Positive Result.
5. How to read 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 test should be considered as Positive whatever the color intensity of the test line (T) is.
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 and the result should be confirmed. 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. 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. Even with a negative test result, distance and hygiene rules must be observed.
8. Information of how to contact locally available support services.
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).

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.

REFERENCES

1. BACKINGER, C.L. and KINGSLEY, P.A., Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care, Rockville, MD, U.S. Food and Drug Administration, Center for Devices and Radiological Health, HHS Pub. FDA 93-4258.

INDEX OF SYMBOLS

	Consult instructions for use or consult electronic instructions for use		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

Distributed by:
Australia Health Products Central Pty Ltd
604/ 3 Waverley St Bondi Junction Sydey NSW 2022
Web: www.ahpcpharmacyoutlet.com.au
Tel: 02 8054 5535

Number: 14603249100
Revision date: 2025-09-24

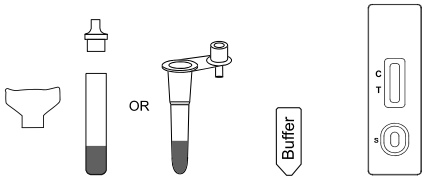
COVID-19 Antigen Rapid Test (Oral Fluid) Instruction Guide

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

BEFORE TESTING

Do not place anything in the mouth including food, drink, gum or tobacco products for at least 10 minutes prior to collection.
Wash your hands with soap and water for at least 20 seconds before testing. If soap and water are not available, use hand sanitizer with at least 60% alcohol.

MATERIALS PROVIDED



Collection Device Buffer Test Device

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

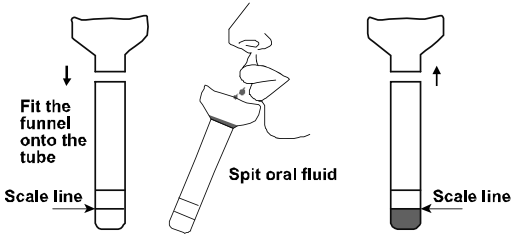
PREPARE FOR THE TEST

Check the expiration date on the box. Do not use if the kit has expired.
Ensure the 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.

1. SPECIMEN COLLECTION

Remove the funnel and plastic tube; fit the funnel onto the tube.
Deeply cough 3-5 times.

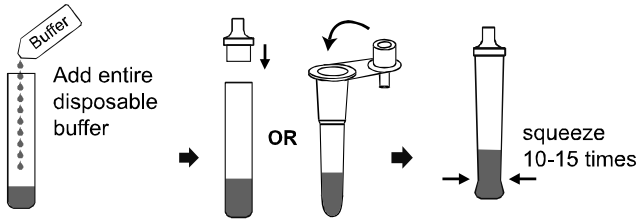
Note: Wear a face mask or cover your mouth and nose with a tissue when you are coughing and keep distance with other people.
Gently spit oral fluid into the funnel.
The oral fluid (non-bubble) should just reach the height of **scale line.**



Note:
*If there's not enough oral fluid collected, repeat the above **specimen collection** steps.*
Place the used funnel into a biosafety bag.

2. SPECIMEN PREPARATION

Tear to open the buffer and add **entire buffer** to the tube with oral fluid. Fit the tube tip onto the tube. Gently squeeze the tube **10-15 times** to mix well.



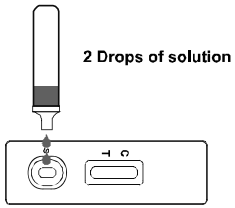
3. TESTING

Remove the test device 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.

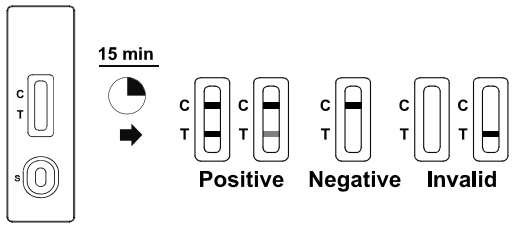
Invert the tube and add **2 drops of solution** to the specimen well(S) of the test device and then start the timer.

! Do not touch the Test Device during this period.



4. WAIT FOR RESULTS

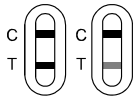
Read the result at 15 minutes. Do not interpret the result after 20 minutes.
After test is completed, place the all the components of the test kit in a biosafety bag and dispose according to local regulation. Do not reuse any used components of the kit.



5. READ RESULTS

Please share your test result with your healthcare provider.

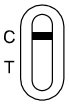
POSITIVE:* Two colored lines appear.



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. 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.

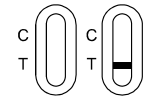
NEGATIVE: One colored line appears in the control region (C).

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 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.

6. 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.
Wash hands thoroughly after test disposal.

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.