MyCOVIDTest

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

REF ICOV-802H	English

Before testing, scan the QR code to watch the how to use video, or visit www.mycovidtest.com.au/how-it-works/
For additional language instructions please visit www.mycovidtest.com.au/product-resources

INTENDED USE

The COVID-19 Antigen Rapid Test (Oral Fluid) is a single-use test kit intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19 in human oral fluid. This test is designed for home use[1] with self-collected oral fluid samples from symptomatic individuals who are suspected of being infected with COVID-19 within the first 7 days of symptom onset.
The COVID-19 Antigen Rapid Test (Oral Fluid) obtain a preliminary result only, 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 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, share your test result with your healthcare provider and carefully follow your local COVID guidelines/requirements.
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

•Test device •Buffer •Package insert •Biosafety Bag •Collection device (Funnel, tube and tube tip)

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, 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 go to the hospital to rule out infection.
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. 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.
8. A negative result does not rule out infection with another type of respiratory virus
9. The test is for one time use only, do not reuse the test.
10. Test for children and young people should be supervised with an adult.
11. Please keep out of reach of children
12. If a Positive result is given the immediate requirement is to present to your nearest Covid Testing Clinic for a confirmatory PCR Test. For advice on how to seek medical help or get tested for coronavirus (COVID-19) Please refer to last page of this Instruction for use to see your state or territory contact details .
13. 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 36

PERFORMANCE CHARACTERISTICS

Sensitivity, Specificity and Accuracy

The COVID-19 Antigen Rapid Test (Oral Fluid) has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the COVID-19 Antigen Rapid Test (Oral Fluid). Specimens were considered positive if the individuals were indicated positive results by
RT-PCR. Specimens were considered negative if the individuals were indicated negative results by RT-PCR

Oral Fluid Specimen

COVID-19 Antigen Rapid Test (Oral Fluid)		RT-PCR		Total
		Positive	Negative	
COVID-19 Antigen	Positive	91	2	93
	Negative	10	303	313
Total		101	305	406

Relative Sensitivity	90.1% (95%CI*:82.5%~95.1%)
Relative Specificity	99.3% (95%CI*: 97.7%~ 99.9%)
Accuracy	97.0% (95%CI*:94.9%~98.5%)

*Confidence Intervals

Days since symptom	RT-PCR	COVID-19 Antigen Rapid Test Positive	Agreement (%)
0 – 3	39	33	84.6%
4 – 7	62	58	93.5%

CT Value	RT-PCR Positive	COVID-19 Antigen Rapid Tet Positive	Agreement (%)
Ct≤20	8	8	100%
20<Ct≤25	43	42	97.7%
25<Ct≤30	46	40	87.0%
Ct>30	4	1	25%

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 SARS-CoV-2 Antigen Rapid Test at specific concentrations

WHO LABEL , Pango Lineages ,(Conc), ALPHA **, B.1.1.7**, (10^2viral RNA copies/μL), BETA , **B.1.351**, (10 viral RNA copies/μL), VUI-21ARP-03, **B.1.6173**, (0.21ng/ml), GAMMA, **B.1.1.28**, (10^2 viral RNA copies/μL), DELTA, **B.1.617.2**, (10^5 viral RNA copies/μL)

Hook Effect

The highest concentration of SARS-CoV-2 inactivated virus was tested. There was no Hook effect detected

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 these concentrations.

Description, (Conc), Adenovirus type 3, (*3.16 x 10^4 $TCID_{50}$/ml)*, Influenza B, (*3.16 x 10^6 $TCID_{50}$/ml)* Adenovirus type 7,(*1.58 x 10^5 $TCID_{50}$/ml)*, Measles, (*1.58 x 10^4 $TCID_{50}$/ml),* Human coronavirus OC43, (*1 x 10^6 $TCID_{50}$/ml)*, Mumps, (*1.58 x 10^4 $TCID_{50}$/ml),* Human coronavirus 229E, (*5 x 10^5 $TCID_{50}$/ml)*, Parainfluenza virus 2, (*1.58 x 10^7 $TCID_{50}$/ml),* Human coronavirus NL63, (*1 x 10^6 $TCID_{50}$/ml)*, Parainfluenza virus 3, (*1.58 x 10^8 $TCID_{50}$/ml),* Human coronavirus HKU1, (*1 x 10^6 $TCID_{50}$/ml)*, Respiratory syncytial virus, (*8.89 x 10^4 $TCID_{50}$/ml)* MERS-coronavirus Florida, (*1.17 x $10^4$$TCID_{50}$/ml),* Enterovirus Type 68 (2007 Isolate), (*1.51 x 10^6 $TCID_{50}$/ml)* Influenza A H1N1, (*3.16 x 10^5 $TCID_{50}$/ml)*, Haemophilus influenzae type b, (*1.35 x 10^8 CFU/ml),* Influenza A H3N2, (*1 x 10^5 $TCID_{50}$/ml)*
$TCID_{50}$ = Tissue Culture Infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated.

Precision
Intra-Assay&Inter-Assay

Within-run and Between-run precision ha been determined by using three specimens of COVID-19 standard control. Three different lots of COViD-19 Antigen Rapid Test (Oral Fluid) have been tested using negative SARS-CoV-2 Antigen weak and SARS-CoV-2 Antigen strong. Ten replicates of each level were tested each day for 3 consecutive days. The specimens were correctly identified >99% of the time.

Cross-reactivity

The following organism were tested, and all found to be negative when tested with COVID-19 Antigen Rapid Test (Oral Fluid):
Description, (Conc),- Arcanobacterium, (1.0x10^8 CFU/ml),- Staphylococcus epidermidis, (1.0x10^8 CFU/ml), Candida albicans, (1.0x10^8 CFU/ml),- Streptococcus pneumonia, (1.0x10^8 CFU/ml), Corynebacterium, (1.0x10^8 CFU/ml),- Streptococcus pygenes, (1.0x10^8 CFU/ml), Escherichia coli, (1.0x10^8 CFU/ml),- Streptococcus salivarius, (1.0x10^8 CFU/ml), Moraxella catarrhalis, (1.0x10^8 CFU/ml),- Streptococcus sp group F, (1.0x10^8 CFU/ml), Neisseria lactamica, (1.0x10^8 CFU/ml),- Chlamydia pneumoniae, (1.73x10^8 CFU/ml), Neisseria subflava, (1.0x10^8 CFU/ml), Legionella pneumophila Philadelphia, (1.91x10^{10} IFU/ml), Pseudomonas aeruainosa, (1.0x10^8 CFU/ml), Bordetella pertussis A639, (6.43x10^8 CFU/ml), Staphylococcus aureus subspaureus, (1.0x10^8 CFU/ml), Mycoplasma pneumoniae M129, 2.70x10^8 CCU/ml

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.

Description, (Conc), Dexamethasone, (0.8mg/ml), Tea, (33.3mg/ml), Mucin, (50μ/ml), Milk, (11.2%), Flunisolide, (6.8ng/ml), Orange juice, (100%), Mupirocin, (12mg/ml), Mouthwash, (2%), Oxymetazoline, (0.6mg/ml), Caffeine, (1mg/ml), Phenylephrine, (12mg/ml), Coca Cola,(/), Rebetol, (4.5μg/ml), Toothpaste,(/), Relenza, (282ng/ml), Whole Blood, (20μg/ml) Tamiflu, (1.1μg/ml), HAMA, (1mg/ml), Tobryamycin, (2.43mg/ml), Biotin,(0.1mg/ml)

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. Immediately go into self-isolation in accordance with the local guidelines and immediately contact your general practitioner / doctor or the local health department in accordance with the instructions of your local authorities. Your test result will be checked by a PCR confirmation test and you will be explained the next steps.
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 medical facility 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, migration/traveling, attending events and etc should follow your local COVID guidelines/requirements.
8. 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, or call the coronavirus (COVID-19) helpline on 1800 020 080 at any time or visit the website: https://www.australia.gov.au/phone-contacts.
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).

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.

For Customer Support Call: 1800 472 743

For information on the correct use of this test and for interpretation of the test results.
Customer Service Hours:
24 Hours , 7 Days

LOCAL CONTACT DETAILS

TO LOCATE YOUR NEAREST COVID TESTING CENTRE AND LABORATORY PLEASE CONTACT

STATE AND TERRITORY CONTACT NUMBERS

Confirmatory testing of positive results by a laboratory PCR test is required.

Australian Capital Territory Coronavirus Helpline (8am-8pm daily)	02 6207 7244
New South Wales Coronavirus Helpline (Service NSW 24/7)	137 788
Northern Territory Coronavirus National Hotline (National Helpline)	1800 020 080
Queensland Coronavirus Helpline (134COVID)	134 268
South Australia Coronavirus Helpline (9am -5 pm Daily)	1800 253 787
Tasmanian Public Health Hotline (Coronvirus)	1800 671 738
Victoria Coronavirus Hotline (24/7)	1800 675 398
Western Australia Coronavirus Hotline 13COVID (8am- 6pm , Mon-Fri)	1800 595 206

Confirmatory testing of positive results by a laboratory PCR test is required.

INDEX OF SYMBOLS

IVD	For in vitro diagnostic use only	Σ	Tests per kit	2	Do not reuse
30°C 2°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		

Sponsored By:
AM Diagnostics Pty Ltd
Unit 8, 25 Wicks Street
Bayswater, WESTERN AUSTRALIA 6053
PH: 1800 472 743

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

www.mycovidtest.com.au

Number: 146561800 Date: 2021-10-11

MyCOVIDTest

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

Before testing, scan the QR code to watch the how to use video, or
Visit www.mycovidtest.com.au/how-it-works/
For additional language instructions please visit www.mycovidtest.com.au/product-resources

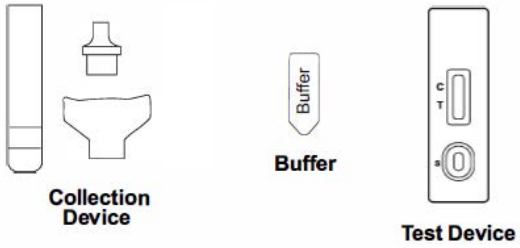
BEFORE STARTING

Before collecting oral fluid, nothing is to be placed in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection.

Was or sanitise your hands.

Make sure they are dry before starting.

MATERIALS PROVIDED



1 PREPARE FOR THE TEST

1A. Check the expiration date on the box. Do not use if the kit has expired.

1B. 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.

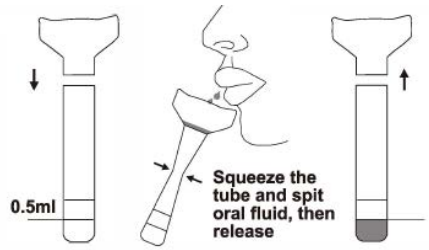
Note: A time device (clock, timer, etc) is required, but not provided.

2 COLLECT SAMPLE

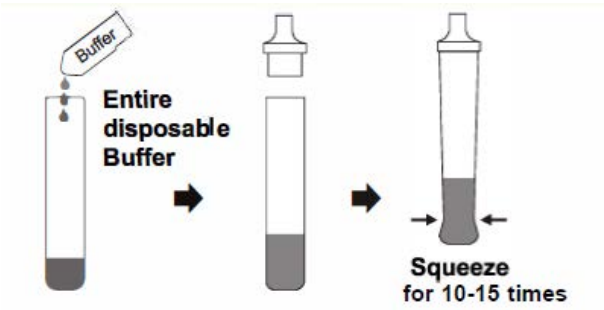
2A. Deeply cough 3 – 5 times

Note: Wear a face mask or cover your mouth and nose with a tissue when you are coughing and keep distance with other people.

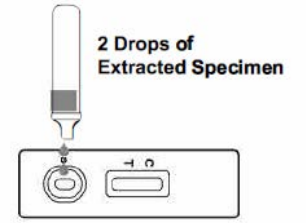
2B.



3 ADD BUFFER



4 ADD DROPS



5 WAIT FOR RESULTS

Do not touch the Test Device during this period.

Read the result at 15 minutes.

Do not read the result earlier than 15 minutes or after 20 minutes.

Note: A control (C) line may appear in the result window within a few minutes, but a test (T) line may take as long as 15 minutes to appear.

Note: After 20 minutes the result might become inaccurate.

For Customer Support Call 1800 472 743 for information on the correct use of this test and for interpretation of the test results. Customer service hours are: 24 Hours , 7 Days

6 READ TEST RESULT

Please share your test result with your healthcare provider and carefully follow your local COVID guidelines/requirements

INVALID RESULT (Test did not work)

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 our COVID-19 test centre.

POSITIVE RESULT

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

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

A positive result means it is very likely you have COVID-19, but the positive samples should be confirmed to reflect this. Immediately go into self-isolation in accordance with the local guidelines and immediately contact your general practitioner/doctor or the local health department in accordance with the instructions of your local authorities.

Your test result will be check by a PCR confirmation test and you will be explained the next steps.

For ALL Positive results a Confirmatory PCR test by a laboratory is required. Please contact your local COVID Help Line on the reverse side of these instructions.

NEGATIVE RESULT

No apparent coloured 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 medical facility according to the rules of our 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 corona virus cannot be precisely detected in all phases of an infection.

Even with a negative test result, distance yourself and hygiene rules must be observed, migration/traveling, attending events, etc, you should follow your local COVID guidelines/requirements.

7 DISPOSE THE TEST KIT

7A. After the test is complete, place all the components into the plastic Bio-Safety bag (supplied)

7B. Dispose according to local regulations