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 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) is intended to be used by laypersons as a self-test for home and workplace (in offices, for sporting events, airports, schools, etc.).

The novel coronavirus belongs to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally contagious from first appearance of symptoms to 10 days after symptoms. Coronavirus infection is mainly transmitted via respiratory droplets and asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period of the novel coronavirus SARS-CoV-2 is reported to be 2-14 days, mostly 3-7 days. The main manifestations include fever, fatigue, and dry cough. Nasal congestion, soreness, sore throat, myalgia and arthralgia are found in a few cases.

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

**REAGENTS**

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

**WARNING**

1. Read the entire package insert prior to testing.
2. For self-testing in-vitro diagnostic use only.
3. The test is for one 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 product is damaged.
7. Handwash 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 health authority’s guidelines.
9. Test for children and young people should be used with an adult’s assistance.
10. The test kit should be discarded according to local regulations.

**STORAGE**

Store the test at 35-68°F (2-20°C). Do not open the pouch until ready for use. DO NOT FREEZE.

**ITEMS PROVIDED**

- Test device
- Buffer package
- Biohazard flag
- Collection device (Funnel, tube and tip)

**ITEMS NOT PROVIDED**

- Timer
- Hypodermic needle
- Labeled sharps container
- A clean surface to run the test
- Suitable place to read the test
- A private, quiet environment

**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 that you consult your doctor before dot 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 an infection, it is recommended to use the test within the first 7 days of symptom onset.
7. Negative results may mean that a person is not infected and 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 use only, do not reuse the test.
10. Test for children should be supervised by an adult.
11. Please keep out of reach of children.

**INTERFERING SUBSTANCES**

Interfering substances were found to be 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 contact your local 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 809 381).

**REFERENCES**

2. For Customer Support: Call 1800 473 742.
3. For information on the correct use of this test and for interpretation of the test results. Customer Service Hours: 24 Hours Daily.

**LOCAL CONTACT DETAILS**

TO LOCATE YOUR NEAREST COVID TESTING CENTRE AND LABORATORY PLEASE CONTACT:

STATE AND TERRITORY CONTACT NUMBERS

**Austalian Capital Territory Coronavirus National Hotline (Local line) 1800 020 080**

Northern Territory Coronavirus National Hotline (Local line) 1800 100 892

Queensland Coronavirus National Hotline (Local line) 1800 032 522

South Australia Coronavirus National Hotline (Local line) 1800 487 276

Tasmania Coronavirus National Hotline (Local line) 1800 345 694

Victoria Coronavirus National Hotline (247) 1800 565 074

Western Australia Coronavirus National Hotline (Local line) 1300 1300 02 (8am - 6pm, Mon - Fri)

**CONFIRMATORY TESTING**

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

**INDEX OF SYMBOLS**

- For in vitro diagnostic use only
- Use by
- Catalog #
- Lot Number

**SPECIAL INFORMATION FOR USE**

1. How do I know if the Test worked well?
2. How soon can I read my results?
3. How do I read the test if the color and the intensity of the lines are different?
4. What do I do if the result is positive?
5. What do I do if the result is negative?

- A positive result means that the SARS-CoV-2 antigen is present in human oral fluid. If the control line (C) appears, it means the test 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 test result before 20 minutes.
- 3. What 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 factors that can affect the test result?
- The results will only give accurate results as far as the fresh human oral fluid used and is followed the instructions correctly.
- Non-SARS-CoV-2 coronavirus strains or other interference factors may cause a preliminary Positive Result.
COVID-19 Antigen Rapid Test (Oral Fluid) Instruction Guide

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.

Wash 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.

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

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.

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