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 use by healthcare professionals who have received training in performing the test.

The COVID-19 Antigen Rapid Test (Oral Fluid) obtain a preliminary result only, the final confirmation should be based on clinical diagnostic results.

**ITEMS PROVIDED**
- Test device
- Buffer package
- Instructions for use
- Package insert
- Biosafety flag
- Collection device (Funnel, tube and tube tip)

**ITEMS NOT PROVIDED**
- Personal protective equipment
- Personal hand sanitizer
- Personal hand wipes
- Personal protective eyewear
- Personal protective shoes

**LIMITATIONS OF DETECTION**
- The COVID-19 Antigen Rapid Test can detect SARS-CoV-2 heat-inactivated virus as low as 8 x 10^5 TCID50/mL.
- The test is for one-time use only; do not reuse the test.
- Do not use test if lipozomes are damaged.
- Wash hands thoroughly before and after handling.
- The result is preliminary positive.
- The test result with your healthcare provider and carefully follow your local public health guidelines.
- Test for children and young people should be used with an adult.
- The used test should be discarded according to local regulations.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not mix the buffer in the kit. Carefully handle the buffer and avoid it contacting skin or eyes.
- The test results 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 COVID-19.
- The test results will only give accurate results as far as the fresh human oral fluid is used and followed the instructions carefully.

**STORAGE**
- Store the test at 35-68°F (2-20°C).
- Do not open the pouch until ready for use. Do not FROZEN.

**TEST RESULTS**
- Negative
- Positive
- Damaged

**INTERPRETATION**
- The results obtained with the test should be considered with other clinical findings from other laboratory tests and confirmatory testing of positive results by a laboratory PCR test is required. For advice on how to seek medical help or get tested for coronavirus (COVID-19) please visit 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 809 369).

**REFERENCES**
- For Customer Support Call: 24 Hours, 7 Days.

**LOCAL CONTACT DETAILS**
- TO LOCATE YOUR NEAREST COVID TESTING CENTRE AND LABORATORY PLEASE CONTACT:
  - Northern Territory Coronavirus National Hotline (National Helpline) 1800 020 080
  - South Australia Coronavirus Helpline (24/7) 1800 727 727
  - Victoria Coronavirus Hotline (24/7) 1800 675 388
  - South Australia Coronavirus Helpline (9am - 5pm Daily) 1800 253 787
  - Queensland: 1300 137 000
  - Victoria Coronavirus Hotline 13COVD (8am - 6pm, Mon-Fri)

**CONFIRMATORY TESTING OF POSITIVE RESULTS BY A LABORATORY PCR TEST IS REQUIRED**
- The COVID-19 Antigen Rapid Test (Oral Fluid) does not replace a confirmed test result by a laboratory PCR test.
- False negative results may occur, especially for samples taken from patients in the early stage of infection.
- False positive results may occur due to non-SARS-CoV-2 coronavirus strains or other interference factors.
- The test is for one-time use only; do not reuse the test.
- Test for children and young people should be used with an adult.
- Wash hands thoroughly before and after handling.
- The result is preliminary positive.
- The test result with your healthcare provider and carefully follow your local public health guidelines.

**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 lines was observed at these concentrations.

**ACCURACY**
- The COVID-19 Antigen Rapid Test (Oral Fluid) has been tested using negative SARS-CoV-2 oral fluid and SARS-CoV-1 oral fluid. No false positive results were observed.
- The color and intensity of the lines have no importance for result interpretation.
- The test should be considered as Positive when the color and the intensity of the lines are different.
- A preliminary result may be given to a negative result that is incorrect (a false negative) in some patients with COVID-19. If you could possibly still have COVID-19 even though the test is negative.
- Negative result means that you are negative or that the viral load is too low to be recognised by the test. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some patients with COVID-19. If you are negative, you could possibly still have COVID-19 even though the test is negative.
- False negative results may occur, especially for samples taken from patients in the early stage of infection.
- False positive results may occur due to non-SARS-CoV-2 coronavirus strains or other interference factors.

**INTERFERING SUBSTANCES**
- The following substances were tested with COVID-19 Antigen Rapid Test (Oral Fluid) and no interference was observed.

**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).
- Sensitivity and Specificity were calculated if the individuals were indicated positive results by RT-PCR. Specificity was calculated if the individuals were indicated negative results by RT-PCR.
- Positive Relative Sensitivity was 99.6% (95% CI: 92.6-99.5), 99.5% (95% CI: 92.6-99.5).
- Negative Relative Specificity was 99.0% (95% CI: 94.9-99.5).
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

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.

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. 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 coronavirus 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