COVID-19 Antigen Rapid Test (Oral Fluid) is a single-use test kit intended to detect the SARS-CoV-2 coronavirus antigens in human oral fluid. It is intended for self-testing in diagnostic use only. 

1. How do I know if the Test worked well? 

The 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 worked well. The test can be done at any time of the day. However, it is recommended to collect the first oral fluid in the morning. 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 results after 20 minutes. 

2. For self-testing in oral diagnostic use only. 

3. When is the best time to run the test? 

The results will only give accurate results as far as the fresh human oral fluid is used and followed the instructions precisely. Therefore, the test should be performed within 2 days after collection of oral fluid. 

4. The test is for one time use only. Do not re-use the test. 

5. Test for children and young people should be used with an adult. 

6. The COVID-19 Antigen Rapid Test (Oral Fluid) is less reliable in the later phase of infection, 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. 

7. When 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. 

8. Which steps should I take if the test is positive? 

If you are positive, you will need to self-isolate immediately. The COVID-19 Antigen Rapid Test (Oral Fluid) is intended for use only as a preliminary test and design performance can be used for self-testing. 

9. 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. 

10. The test should be discarded according to local regulations. 

11. A positive result does not rule out infection with other type of respiratory virus. 

12. Do not use test if pouch is damaged. 

13. Wash hands thoroughly before and after handling. 

14. If the result is preliminary positive, contact your State or Territory Coronavirus testing services to get a confirmatory laboratory PCR test and carefully follow your local COVID guidelines/requirements. 

15. The used test should be discarded according to local regulations. 

16. A negative result does not rule out infection with another type of respiratory virus. 

17. If a Positive result is given the immediate requirement is to present to your nearest Covid Testing Clinic for confirmation of a positive test. In the event of a medical decision to proceed with a Polymerase Chain Reaction (PCR) test please refer to this page of the guidelines on how to see your state or territory contact details. 

18. 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 


15. A negative result means that you are negative or that the viral load is too low to be recognized by the test. 

16. A positive result does not rule out infection with another type of respiratory virus. 

17. If a Positive result is given the immediate requirement is to present to your nearest Covid Testing Clinic for confirmation of a positive test. In the event of a medical decision to proceed with a Polymerase Chain Reaction (PCR) test please refer to this page of the guidelines on how to see your state or territory contact details. 

18. 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).
COVID-19 Antigen Rapid Test (Oral Fluid) Instruction Guide

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 is 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 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 and carefully follow your local COVID guidelines/requirements.

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. Immediately go into self-isolation in accordance with the local guidelines and immediately Contact your State or Territory Coronavirus testing services to get a laboratory PCR test and you will be explained the next steps.

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, migration/traveling, attending events and etc should follow your local COVID guidelines/requirements.

FALSE NEGATIVE: One colored line appears in the test region (T).
There is 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.