# SARS-COV-2 Antigen Home Test (Oral Fluid)

REF ACO-1003

User instructions
For home-testing
English

Plus Daily

## FOR HOME-TESTING ONLY

Note: Use test only one time. Test within first 7 days of symptoms. Testing By adult or under adult supervision.
Customer Support Helpline: 1300 898 958 Available 24 hours, 7 days

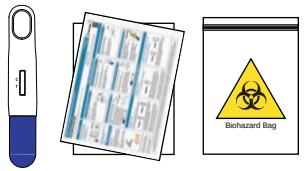
## Instruction Video

Before testing, scan the QR code to watch the How to Use video, or visit https://plusdaily.com.au/sars-cov-2-antigen-home-test-oral-fluid/

## TEST KIT

### Materials provided:

1 x Test kit (packaged in foil pouch)
1 x Instructions for use
1 x Biohazard Specimen Bag




### Materials required but not provided:

Timer

## BEFORE TESTING:

### Important:

Before collecting your saliva sample, do not place anything in the mouth including food, drink, gum or tobacco products for at least 10 minutes prior to collection.

Wash or sanitise your hands before testing and ensure they are dry prior to starting 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.

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

## TEST PROCEDURE STEPS

### Step 1: Deeply cough 3 - 5 times

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 your distance from other people.

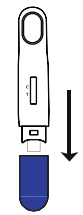
### Step 2: Deeply cough 3 - 5 times

Remove the test device from the sealed foil pouch and remove the cap by pulling.

This will expose the absorbent collection pad.

Use device within one (1) hour of opening.

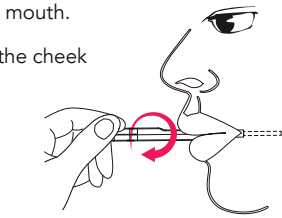
Best results will be obtained if the test is performed immediately after removing the test device from the foil pouch.



### Step 3: Gently rub 10-15 times

Hold the end of the device and place the absorbent collection pad into the mouth.

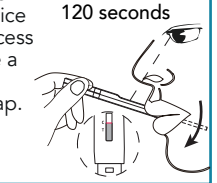
Gently rub the collection pad on the cheek and tongue in circular motions (approximately 10-15 times).

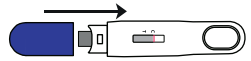


### Step 4: Place under the tongue for 2 min

Place the collection pad under the tongue (with lips closed) for approximately two (2) minutes.

During this time, observe whether a line is visible in the C (control) region of the device test window. If not, repeat the above process until a line in the C region is visible. Once a line is visible in the C region, remove the device from the mouth and replace the cap.



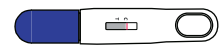
### Step 5: Read the result in 15 min

Then place the device on a flat/ level surface.

Read the test result in 15 minutes.
Do not interpret the result after 20 minutes.

Note: Keep the test device level during sampling. The hand-held part should not be lower than the sponge. Do not move the test device around during testing or whilst awaiting your result.


**In 15 min but not after 20 min**



### Step 6: Dispose in household rubbish

Once you have completed the test and obtained your result, place all components of the test kit in the biohazard specimen bag provided and seal accordingly.

Once sealed, please dispose of this bag in your household rubbish. Please wash/ sanitise your hands after completing the test and disposing of test kit contents.


## READING YOUR TEST RESULT

### Positive result

POSITIVE: Two coloured lines appear.
One coloured line will appear in the control (C) region and another coloured line will appear in the test (T) region.

**Positive** 


**Positive** 


*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. Therefore 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, please follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

### Negative Result

NEGATIVE: One coloured line appears in the control region (C).
No line will appear in the test (T) region.

**Negative** 


A negative result indicates that 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 your test is negative.

In addition, you can repeat the test with a new test kit. In case of suspicion, repeat the test after 1-3 days, as the corona virus cannot be precisely detected in all phases of an infection.

### Invalid Result (Test did not work)

INVALID: Control line fails to appear.
No line will appear in the Control (C) region.

**Invalid** 


**Invalid** 


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 device or contact our COVID-19 helpline.

***Warning:** There is a risk of a false negative result, particularly if testing is not performed within the first 7 days of symptom onset. The test is less reliable in the later phase of infection and in asymptomatic individuals. A negative result does not rule out infection with another type of respiratory virus. If you experience symptoms such as headaches, migraines, fever, loss of sense of smell or taste, contact the nearest medical facility according to guidelines provided by your local authority. Even with a negative test result, distance yourself and observe hygiene rules. In relation to migration/traveling, attending events, etc, you should follow your local COVID guidelines/ requirements.

## Disposing of your test kit

After completing your test, place all components into the plastic biohazard specimen bag provided and seal. You can then dispose of this sealed bag in your household waste (not recycling) or according to your local guidelines.

## Precautions

- Read the entire package insert (Instructions for Use) prior to performing the test.
- Use the test kit once only. Do not reuse the device.
- Please keep out of reach of children.
- Remove the test device from the sealed pouch only when you are ready to perform the test.
- Do not use the test kit if the pouch is damaged or if the kit has reached its expiration date.
- Do not eat, drink or smoke in the area where saliva samples are collected or test kit is handled.
- Use only the components of this test kit.
- Inadequate or improper sample collection may lead to inaccurate or false results.
- Do not use any of the test components in the body with the exception of the absorbent pad in the kit.
- Do not swallow any of the components.
- This test is for presumptive screening only. Please follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
- If your test result is positive you must follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
- Repeat testing is recommended (e.g. within 1-3 days) if there is an ongoing suspicion of infection, being in a high risk setting, or where there is an occupational risk or other requirement.
- Even if your test result is negative, continue to observe all applicable hygiene and safety measures. Even with a negative result, you may still be infectious. If you are showing symptoms follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
- Dispose of the kit components in your household waste (not recycling) or according to your local guidelines.

## Storage and Stability

Store the SARS-COV-2 Antigen Home Test (Oral Fluid) device at 2-30°C. Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging.

## Intended use

The SARS-COV-2 Antigen Home Test (Oral Fluid) is a chromatographic immunoassay for the qualitative detection of N antigen from SARS-CoV-2 present in human saliva within the first 7 days of symptom onset. This test is for self-testing purposes, as an aid to diagnosis of SARS-CoV-2 infection.

## 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 SARS-COV-2 Antigen Home Test (Oral Fluid) is a qualitative membrane-based immunoassay. Results appear in 10-20 minutes in the form of a red line that develops in the test (T) region of the device window in response to the presence of SARS-CoV-2 antigen within the saliva sample.

## Reagents

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

## Limitations

1. Failure to follow the testing steps may give inaccurate results.
2. This SARS-COV-2 Antigen Home Test (Oral Fluid) is for self-testing in vitro diagnostic use only.
3. The test is for one time use only, do not reuse the device.
4. Tests for children and young people should be supervised by an adult or a guardian.
5. If the test result is negative or non-reactive and clinical symptoms persist, it is because very early viral infection may not be detected. It is recommended to test again with a new test 1-3 days later and follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
6. There is a risk of a false negative result, particularly if testing is not performed within the first 7 days of symptom onset.
7. The tests are less reliable in the later phase of infection and in asymptomatic individuals.
8. Negative results may not mean that a person is not infectious and if symptoms are present please follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
9. A negative result does not rule out infection with another type of respiratory virus.
10. If a positive result is observed please follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
11. Positive results of COVID-19 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.
12. A positive result cannot necessarily determine whether a person is infectious.
13. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
14. For advice on how to seek medical help or get tested for coronavirus (COVID-19) please refer to the Instructions for use to see your state or territory contact details.

## Performance Characteristics

### Clinical performance

A clinical evaluation was conducted comparing the results obtained using the SARS-COV-2 Antigen Home Test (Oral Fluid) with RT-PCR test results.
The clinical trial included 579 oral fluid specimens. The results demonstrated 99.4% specificity and 94.6% sensitivity with an overall accuracy of 97.4%.

| | PCR confirmed sample number | Correct identified | Rate |
|---|---|---|---|
| Positive sample | 222 | 210 | 94.6%(sensitivity) |
| Negative sample | 357 | 355 | 99.4%(Specificity) |
| total | 579 | 565 | 97.4%(Total Accuracy) |

**94.6% Sensitivity**: In total 222 PCR confirmed positive samples: 210 PCR confirmed positive samples were correctly detected by SARS-COV-2 Antigen Home Test (Oral Fluid). There were 12 false negative cases.
**99.4% Specificity:** In total 357 PCR confirmed negative samples: 355 PCR confirmed negative samples were correctly detected by SARS-COV-2 Antigen Home Test (Oral Fluid). There were only 2 false positive cases.
**97.4% Accuracy:** In total 579 PCR confirmed samples: 565 PCR confirmed samples were correctly detected by SARS-COV-2 Antigen Home Test (Oral Fluid). The observed accuracy may vary depending on the prevalence of the prevalence of the virus in the population.

A usability study was performed with 105 lay people. The test results showed that laymen can read a range of results from negative over weak positive to positive and that they can identify results as well. 93.17% (98/105) of the results were correct with sensitivity of 100 % (32/32) and specificity of 100% (69/69). The results show that the instructions provided with the test kit made it easy for the user to understand. The test is therefore suitable for lay user.

## Limitation of Detection

The SARS-COV-2 Antigen Home Test (Oral Fluid) can detect out SARS-CoV-2 heat-inactivated virus strain as low as 800 TCID50/ml.

## Variant

The SARS-CoV-2 variants 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), Beta (South Africa B.1.351) and Omicron (South Africa B.1.1.529(BA.1)+BA.2) could be detected out by the SARS-COV-2 Antigen Home Test (Oral Fluid) at specific concentrations.
**WHO LABEL, Pango Lineages ,(Conc)**, ALPHA , B.1.1.7, BETA , B.1.351, VUI-21ARP-03, B.1.617.3, GAMMA, B.1.1.28, DELTA, B.1.617.2, Omicron, B.1.1.529(BA.1)+BA.2.

## Cross-reactivity

Test results will not be affected by other respiratory viruses and commonly encountered microbial flora and low pathogenic coronaviruses listed below:
**Viruses:** Adenovirus type 3, Adenovirus type 7, Human coronavirus OC43, Human coronavirus 229E, Human coronavirus NL63, Human coronavirus HKU1, Influenza A H1N1, Influenza A H3N2, Influenza B, Parainfluenza virus 2, Parainfluenza virus 3, Respiratory syncytial virus, MERS-coronavirus, Human Rhinovirus 2, Human Rhinovirus 14, Human Rhinovirus 16, Measles, Mumps, Enterovirus Type 68 (2007 Isolate),
**Microbial flora:** Arcanobacterium, Candida albicans, Corynebacterium, Escherichia coli, Moraxella catarrhalis, Neisseria lactamica, Neisseria subflava, Pseudomonas aeruginosa, Staphylococcus aureus subspaureus, Staphylococcus epidermidis, Streptococcus pneumoniae, Streptococcus salivarius, Streptococcus sp group F, Haemophilus influenzae type b, Chlamydia pneumoniae, Legionella pneumophila Philadelphia, Bordetella pertussis A639, Mycoplasma pneumoniae M129

## Interfering Substances

Test results will not be interfered with by the following substances:
**Food:** Caffeine, Coca Cola, Milk, Mouthwash, Orange juice, Tea, Toothpaste
**Medication:** Biotin, Dexamethasone, Flunisolide, Mupirocin, Oxymetazoline, Phenylephrine, Rebetol, Relenza, Tamiflu, Tobryamycin
**Others:** HAMA (Human Anti-Mouse Antibodies), Mucin, Whole Blood

## Important Contact

In the event you are experiencing problems with the test, please contact Plus Daily Ltd. Additionally, you may wish to report poor performance or usability issues directly to the Therapeutic Goods. Administration (TGA) via the Medical Device Incident Reporting scheme, email iris@tga.gov.au or call 1800 809 361. To contact your local state/territory health department go to the following link:
https://www.health.gov.au/about-us/contact-us/local-state-and-territory-health-departments

**Contact details and websites of the local State or Territory Health Department:**
Australian Capital Territory Department of Health, General Enquiries: 02 5124 9213
Coronavirus helpline (8am to 8pm) : 02 6207 7244 https://health.act.gov.au/
New South Wales Department of Health, General enquiries: 1300 066 055
Coronavirus hotline (Service NSW, 24/7): 137 788 https://www.health.nsw.gov.au/
Northern Territory Department of Health, General enquiries: 08 8922 8044
Coronavirus hotline (National helpline): 1800 020 080 https://health.nt.gov.au/
Queensland Department of Health, General enquiries: 13HEALTH or 13 432 584
Coronavirus hotline: 134COVID or 134 268 https://www.health.qld.gov.au/
South Australian Department of Health, General enquiries: 1300 232 272
Coronavirus hotline (9am to 5pm): 1800 253 787 https://www.sahealth.sa.gov.au/
Tasmanian Department of Health, General enquiries: 1300 135 513
Public Health Hotline (coronavirus): 1800 671 738 https://www.health.tas.gov.au/
Victorian Department of Health, General enquiries: 1300 650 172
Victorian coronavirus hotline (24/7) : 1800 675 398 https://www.dhhs.vic.gov.au/
Western Australian Department of Health, General enquiries 08 9222 4222
Coronavirus hotline: 13COVID (8am to 6pm, M-F) https://www.healthywa.wa.gov.au/

## Index of Symbols

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

## Manufactured by:

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## Customer Suport Helpline:

Plus Daily Ltd's Customer support: 1300 898 958,
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