

**Instructions for Use**

For use with Gardian T3 COVID-19-SARS-CoV-2 Antigen Saliva Self Test kit.

For self-testing in-vitro diagnostic use only.

Store between 2°C - 30°C.

Single use only.

Test within the first 7 days of symptom onset.

Do not smoke, eat or drink for at least 30 minutes prior to taking your test.



Please scan the QR code or use the URL to: download a digital copy of the instructions, [watch the instructional video](#) on how to perform the test, as well as information on how to access support services.

<https://www.gardiant3.com/get-started>



SCAN ME

**Kit Contents**

**Kit Size**

- 1 Test 1 x Test Cassette, 1 x Bio-Safety Bag, 1 x Instructions for use and for downloading software.
- 5 Tests 5 x Test Cassette, 5 x Bio-Safety Bag, 1 x Instructions for use and for downloading software.
- 20 Tests 20 x Test Cassette, 20 x Bio-Safety Bag, 4 x Instructions for use and for downloading software.

**Download the Gardian Self Check App**

The Gardian T3 COVID-19-SARS-CoV-2 Antigen Saliva Self Test kit includes the Gardian Self Check companion mobile app to assist you with completing your test. Please follow the instructions below to download the app.

To download the mobile application, click on the Google Play store or Apple store button to download and install the app on your device, or scan the QR code to visit the website to download the app.

<https://www.GardianT3.com.au/get-started/>

Follow the step by step instructions in the app to complete your Gardian T3 COVID-19-SARS-CoV-2-Antigen Saliva Self Test kit.

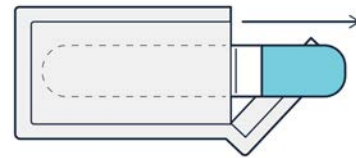


SCAN ME

**A. Prepare for the test.**

1. Check the expiry date. **DO NOT USE** if expired.
2. Wash your hands with soap and water or use a hand sanitiser.
3. Use the test within 1 hour of opening the kit contents.

**1**



Remove the test cassette from the foil pouch.

**CAUTION:** The test kit must be used within 1 hour after removing the test cassette from the foil pouch.

**2**



Remove the blue lid from the test cassette.

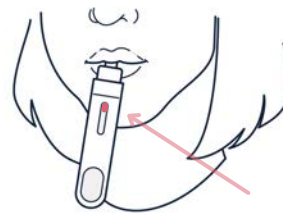
**B. Collect sample.**

**3**



Place the whole saliva collector into your mouth with the testing window facing up.

**4**



Place your tongue against the saliva collector for 60 seconds until you can see the test strip turn pink. Do not suck on the saliva collector.

**5**



Place the lid back onto the test cassette and place on a clean, flat surface.

**C. Wait 10 minutes for result.**

**6**



Use the Gardian Self Check App timer to start countdown.

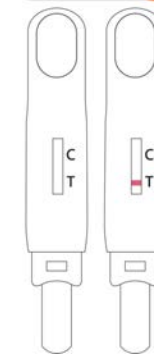
**Result will appear in 10 minutes. Do not read the result after 20 minutes.**

**D. Read test result.**

**Invalid**

If a control line (C) is not visible or a test line (T) is the only line that is visible, the result is invalid. You may have performed the test incorrectly. Carefully read the Instructions for Use and repeat the test with a new test device.

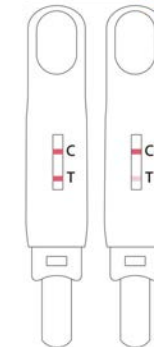
Invalid



**Positive**

If a **red test line (T)** is visible together with a **red control line (C)**, this means that the **result is positive**. Look carefully at the result: The test should be considered positive if two red lines are visible - even if the test line is faint. A positive test result means it is very likely that you have COVID-19. Follow your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

Positive



**Negative**

If a control line (C) is visible (regardless of how faint it is) and a test line (T) is not visible, this means that the result is **negative**. It is unlikely that you have COVID-19. However, even if your test is negative, continue to observe all hygiene and safety measures.

Negative



Follow your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

**E. Dispose of the test cassette.**

**7**



Place the used test in the bio-safety bag provided. Seal the bag tightly and dispose of it in your household waste (not recycling) or according to your local guidelines.

Once you have disposed of the test kit, sanitise the surface the kit was laying on, and wash or sanitise your hands.

**Explanation of the symbols used**

IVD	In vitro diagnostic medical device		Use by date
	Consult instructions for use		Do not use if damaged
LOT	Batch code		Temperature limit at 2-30°C
	Manufacturer		Sponsor
	Date of Manufacture		Do not re-use
<b>STERILE</b> Sterile product, uses irradiation sterilization			

**Need assistance?**

**Call Customer Support.**

For more support, you can call our customer care team on 1800 996 929.

Operating Hours: Our office operates between 9am and 7pm (AEST), 7 days per week.

**Visit Website.**

You can find information, including videos and answers to frequently asked questions by visiting the website at <https://www.GardianT3.com>.

**Manufacturer**  
Jiangsu Medomics Medical Technology Co., Ltd.  
F3, Building C,  
No. 3 - 1 Xinjinhu Road,  
Jiangbei New Area,  
Nanjing Jiangsu, China

**Sponsor** Global Sponsor  
Gardian Technologies Pty Ltd  
Level 3, 26 Marine Parade  
Southport BC, QLD, 4215,  
Australia  
Tel: +61 7 5616 8493  
or 1800 996 929

## Intended Use

Gardian T3 COVID-19 SARS-CoV-2 Antigen Saliva Self Test is a qualitative lateral flow immunoassay intended to detect SARS-CoV-2 nucleocapsid antigens present in human saliva samples *in vitro*. The test is intended as an aid in diagnosis of symptomatic individuals meeting the case definition for COVID-19 within the first 7 days of symptom onset, and to test individuals suspected of COVID-19 due to contact with a confirmed COVID-19 case or probable cases, and at-risk health workers. Positive results are indicative of the presence of SARS-CoV-2. Positive results do not rule out a bacterial infection or co-infection with other viruses. Negative results do not rule out SARS-CoV-2 infection. Follow your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

## Summary

At the end of 2019, a novel virus was discovered in a cluster of pneumonia cases.<sup>1</sup> This virus belongs to the large family of Coronaviruses, and has been named SARS-CoV-2 because its genetic sequence is closely related to the virus that caused the SARS outbreak in 2013.<sup>2</sup> The disease caused by SARS-CoV-2 is called COVID-19 (Coronavirus Disease 2019).<sup>3</sup> The course of SARS-CoV-2 infections can vary widely. Some infected individuals do not have any symptoms, others experience relatively mild symptoms such as fever, cough, loss of taste or smell, or diarrhoea. But it can also cause more serious symptoms such as difficulty in breathing or even death.<sup>4,5</sup> Usually, it takes 5 - 6 days for symptoms to develop after an exposure to SARS-CoV-2, but sometimes it can take as long as 14 days.<sup>5</sup>

## Test Principle

Gardian T3 COVID-19 SARS-CoV-2 Antigen Saliva Self Test is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 antigens in human saliva samples. When the antigen in the sample reaches the Test area (T) of the membrane, it will form a coloured line. Absence of this coloured line suggests a negative result. To ensure the test is carried out properly, a coloured line will appear at the Control area (C), if the test has been performed correctly.

## Storage and Stability

1. Store the packaged test between 2°- 30° C. If below 2° C, bring to room temperature before use. Do not freeze.
2. Keep away from direct sunlight, moisture and heat > 30° C.
3. The product expiry is 9 months from date of manufacture. Do not use beyond the expiry date.

## References

- 1) Wu et al. Nature. 2020. 579:265-9.
- 2) Coronaviruses. European Centre for Disease Prevention and Control. <https://www.ecdc.europa.eu/en/covid-19/latest-evidence/coronaviruses>. Accessed 6 Jan 2021.
- 3) Coronaviridae Study Group of the International Committee on Taxonomy of Viruses. Nat Microbiol. 2020. 5:536-44.
- 4) WHO. <https://www.who.int/publications-detail-redirect/diagnostic-testing-for-sars-cov-2>. Accessed 6 Jan 2021.
- 5) Centers for Disease Control and Prevention. <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>. Accessed 6 Jan 2021.

## Test Limitations

- The test procedure, precautions, and interpretation of results for this test must be strictly followed when testing. Failure to do so may adversely affect test performance and/or produce invalid results.
- The test should be used for the detection of SARS-CoV-2 antigen in human saliva swab samples. Other specimen types may lead to incorrect results and must not be used.
- The test should be undertaken within the first 7 days from the onset of symptoms, or close contact.
- The detection of SARS-CoV-2 nucleocapsid antigen is dependent upon proper specimen collection, handling, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results.
- False negative test results may occur if the specimen was collected incorrectly.
- Negative results may be caused by low concentration of SARS-CoV-2 antigens in the saliva and therefore cannot completely rule out possibility of infection.
- Negative results do not rule out a SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including decisions about infection control. Individuals who have tested negative and continue to show COVID-19-like symptoms should follow the guidance of local State or Territory Health Department on confirmation testing if necessary, and if unwell seek medical assistance.
- A negative result does not rule out infection with another type of respiratory virus.
- Positive results indicate the presence of viral antigens. However, a clinical correlation with the case history and other diagnostic information are required to determine the status of the infection.
- Positive results do not exclude the possibility that a bacterial infection or a co-infection with another virus is present.
- False positive results may occur from improper sample collection, not following this instruction guide.
- The Gardian T3 COVID-19 SARS-CoV-2 Antigen Saliva Self Test is less reliable in the later phase of infection.
- Reading the test result before 10 minutes and after 20 minutes may give incorrect results.

## Precautions and Warnings

- This test kit is used for *in vitro* diagnosis only.
- This test kit is used for home or self use.
- Test kits can only be used once.
- Do not use the test kit if the date has expired.
- Read these instructions carefully.
- Do not freeze. Bring the kit to room temperature before testing.
- Remove the test kit from the sealed pouch only when you are ready to perform the test.
- Do not use the test kit if the pouch is damaged, the seal is broken or the test cassette has been exposed to sunlight, is wet or damaged.
- Handle all specimens as though they contain infectious agents.
- 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 saliva collector included in the kit.
- Do not suck on the saliva collector.
- Do not interpret the result before 10 minutes. Do not read the result after 20 minutes.
- Results observed after 20 minutes are invalid.
- This test is for presumptive screening only. Follow 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, close contact, 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.
- Dispose of the kit components in the bio-safety bag and into your household waste (not recycling) or according to your local guidelines.
- Keep out of the reach of children.
- Test can only be performed by adults over 18 years of age. Any persons or children under 18 years will require adult supervision or assistance. Not to be performed on children under 4 years of age.

## Frequently Asked Questions

### 1. How accurate is the test?

A clinical evaluation was conducted comparing the results obtained using the Gardian T3 SARS-CoV-2-Antigen Saliva Self Test with RT-PCR test. The clinical trial included 594 saliva swab samples. The results demonstrated 98.95% specificity, 96.64% sensitivity with an overall accuracy of 98.48%.

### Usability Study

190 people self-sampled and self-tested using the Gardian T3 SARS-CoV-2-Antigen Saliva Self Test. 90 people were also tested with a PCR. The tests correctly identified 96.7% (29 out of 30 people) of positive samples and 98.33% (59 out of 60 people) of negative samples.

Gardian T3 SARS-CoV-2-Antigen Saliva Self Test	Comparative RT-PCR Test Result				
	Positive	Negative	Total	Results	Confidence Interval 95%
Detected Positive	115	4	119	96.64%	99.08%
Detected Negative	5	470	475	98.95%	99.66%
Total	120	474	594		

### 2. Can the test detect different variants of COVID-19?

Yes, the following SARS-CoV-2 variants can be detected with the Gardian T3 SARS-CoV-2-Antigen Saliva Self Test:  
B.1.1.7 (Alpha) and sub-lineages; B.1.351 (Beta) and sub-lineages B.1.351; P.1 (Gamma) and sub-lineages P.1 ; B.1.617.2 (Delta) and sub-lineages AY. Please visit the website at <https://www.GardianT3.com/clinical> for the most recently analysed variant list.

### 3. Will other viruses and microorganisms affect the test result?

Results showed that the Gardian T3 SARS-CoV-2-Antigen Saliva Self Test was not interfered with by the following viruses:

Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, Human coronavirus HKU1, MERS-coronavirus, SARS-coronavirus, Influenza A H1N1, Influenza A H3N2, Influenza A H5N1, Influenza A H7N9, Influenza B Victoria/2/87, Influenza B Yamagata/16/88, Parainfluenza virus Type 1, Respiratory syncytial virus, Enterovirus CA 16e, Adenovirus, Mycoplasma pneumonia, Staphylococcus aureus (NCCP 14647), Staphylococcus epidermidis (KCCM 35494), Bordetella pertussis (ATCC 10231), Legionella pneumophila (ATCC VR-2282), Streptococcus pneumoniae, Haemophilus influenzae (NCCP 14581), Mycobacterium tuberculosis, and Candida albicans (ATCC 10231).

### 4. When is the best time to perform the test?

It is recommended to carry out the test first thing in the morning. Do not smoke, eat or drink for at least 30 minutes prior to taking your test.

### 5. How do I know if I have generated enough saliva for the test to work?

Keep generating saliva until the test strip starts to turn pink. In some cases, this can take up to 90 seconds.

### 6. Can I use the same test more than once?

No. The test is single use only.

## Important Contacts

To report poor performance or usability issues please contact the TGA via the online form: [Users Medical Device Incident Report](#), via email [iris@tga.gov.au](mailto:iris@tga.gov.au) or call 1800 809 361 (08:30am to 5:00pm Monday to Friday).

Testing locations can be found by calling the numbers below or visiting these websites:

**Australian Capital Territory Department of Health**  
General Enquiries: 02 5124 9213  
Coronavirus helpline (8am to 8pm daily): 02 6207 7244  
Website: <https://health.act.gov.au/>

**New South Wales Department of Health**  
General enquiries: 1300 066 055  
Coronavirus hotline (Service NSW, 24/7): 137 788  
Website: <https://www.health.nsw.gov.au/>

**Queensland Department of Health**  
General enquiries: 13HEALTH or 13 432 584  
Coronavirus hotline: 134COVID or 134 268  
Website: <https://www.health.qld.gov.au/>

**Victorian Department of Health Department of Health and Human Services:** 1300 650 172  
Victorian coronavirus hotline (24/7) : 1800 675 398  
Website: <https://www.dhhs.vic.gov.au/>

### 7. What is the Limit of Detection (LoD)?

The limit of detection (LoD) is defined as the lowest concentration of an analyte in a sample that can be consistently detected with a stated probability (typically at 95% certainty). The limit of detection of Gardian T3 SARS-CoV-2-Antigen Test Kit Saliva Self Test for SARS-COV-2 virus is 10 TCID 50/ML

### 8. What should I do if I get a negative result but have symptoms?

A negative result may mean that the viral load is too low to be recognised by the test. If you have symptoms but have produced a negative result, self isolate and repeat the test in 1 - 3 days. Follow the guidance from your local State or Territory Health Department on confirmation testing if necessary, and if unwell seek medical assistance.

### 9. What should I do if I get a positive result?

A positive result means it is very likely you have COVID-19. Follow the guidance from your local State or Territory Health Department on confirmation testing if necessary, and if unwell seek medical assistance.

### 10. How do I know that the test was done correctly?

A red line will appear in the control area (C) if the test has been done correctly. If the red line is NOT VISIBLE in the control area (C), the test is INVALID. You may have performed the test incorrectly. Carefully read the Instructions for Use and repeat the test with a new test device.

### 11. Do these substances interfere with the test?

Results showed that the Gardian T3 SARS-CoV-2-Antigen Saliva Self Test was not interfered with by the following substances: Acarbose, Acetylsalicylic acid, Albuterol, Alkalol, Amoxicillin, Anti-nuclear antibody, Beclomethasone, Benzocaine, Biotin, Budesonide, Chloroquine phosphate, Chlorothiazide, Chlorpheniramine, Cromolyn, Dexamethasone, Diphenhydramine, Ephedrine, Fluconazole, Flunisolide, Fluticasone Propionate, Galphimia glauca, Glimperide (Sulfonylureas), Guaicol glycerol ether, Haemoglobin lbumoprotein, Icteric (Bilirubin), Indapamide, Ivermectin, Lopinavir, Menthol, Mucin, Mupirocin, Oseltamivir, Oxymetazolin hydrochloride, Oxymetazoline, Phenol, Phenylephrine hydrochloride, Pregnancy, Rheumatoid factor, Ribavirin, Ritonavir, Sabadilla, Sodium chloride, Sulfur, Tamiflu (Oseltamivir Phosphate), Tobramycin, Total IgA, Total IgG, Total IgM, Triamcinolone, Triglycerides, Whole Blood, Zanamivir, Zincum gluconium (i.e., Zicam).

### 12. Where can I find more information?

You can locate more Frequently Asked Questions by scanning the QR code or visiting the website: <https://www.GardianT3.com/faq>



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