# COVID-19 Antigen Rapid Test (Swab)

**Package Insert**

**REF: ICOV-502S**

**Number: 146976300** **Date: 2023-07-19**

For Self-testing | English

Before testing, scan the QR code to watch the "how to use" video.
https://www.citestdiagnostics.com/Home/ProductInfo/499

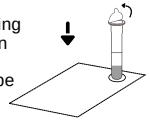
A rapid test for the qualitative detection of SARS-CoV-2 Nucleocapsid Protein antigens present in nasal swab specimen.

For self-testing *in vitro* diagnostic use.

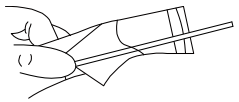
## TESTING PROCEDURE

**01** Wash hands thoroughly before testing.

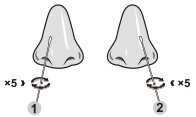
**02** Remove the cover of the tube containing the extraction buffer.
Place the tube in the tube holder.



**03** Remove the swab from the pouch.
**Do not touch the "cotton" tip.**

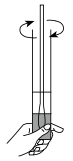


**04** Insert the swab into your nostril. Do not exceed **2 cm.**
Firmly rub the swab in a circular motion around the inside wall of each nostril 5-10 times.

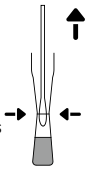



**Note:** This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain.
When the nasal mucosa is damaged or bleeding, nasal swab collection is not recommended.
If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.

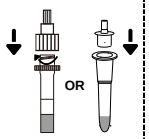
**05** Immediately insert the swab into the bottom of tube containing the extraction buffer.
Stir the swab to mix well.
Press the tip of the swab in the tube.
Rotate the swab for **10-15 seconds.**



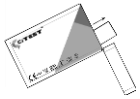
**06** Pull out the swab while pinching the tube. Release the sample on the swab in the tube as much as possible.



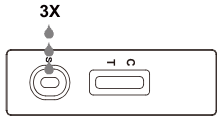
**07** Close the cap or fit the tube tip onto the tube.



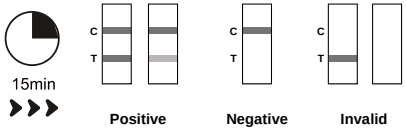

**08** Remove the test cassette from the sealed foil pouch and use it within one hour.
P|ace the test cassette on a clean and level surface.



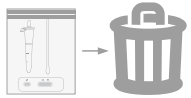
**09** Invert the tube and add **3 drops of solution** to the specimen well(S) of the test cassette and start the timer.
Do not move the test cassette during test.




**10** **Read the result at 15 minutes.**
Do not interpret the result after 20 minutes.




**11** After the test is completed, place all the components of the test kit in a plastic bag and tightly sealed, then dispose of them according to the local regulations.
Do not reuse any used components of the kit.

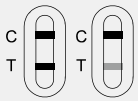


**12** Wash hands thoroughly after test disposal.

## READ RESULTS

Refer to your relevant health authority for advice on whether a PCR test is required to confirm your result and carefully follow your local COVID guidelines/requirements.

Refer to your relevant health authority for advice on whether a PCR test is required to confirm your result.




**POSITIVE: You can see two colored lines. One colored line appears in the control line area (C), and the other line appears in the test line area (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 shade of color in the test region (T) should be considered positive.

The positive result means that you are most likely to suffer from COVID-19, but the results should be confirmed. Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance

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**NEGATIVE: You can see only one colored line appears in the control line area(C).** There is no line appears in the test line area (T). This means 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. In addition, it is recommended to repeat the test in 1-2 days, because the coronavirus cannot be accurately detected at all stages of the 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.

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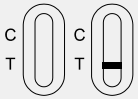


**INVALID: There is no line appears in the control line area (C).** The most likely reason for this situation is insufficient specimen size or incorrect process operation. It is recommended to review the procedure, and then re-operate with a new test. Stop using the test kit if the problem is not resolved, and contact your local COVID-19 Center.

## WARNINGS AND PRECAUTIONS

**Read all the information in this package insert before performing the test.**

1. For self-testing *in vitro* diagnostic use only.
2. Test for children should be used under the supervision of an adult.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Use the test only once, do not reuse the test. Do not use after expiration date.
5. Do not use test if pouch is damaged.
6. Wash hands thoroughly before and after handling.
7. Refer to your relevant health authority for advice on whether a PCR test is required to confirm your result and carefully follow your local COVID guidelines/requirements. Refer to your relevant health authority for advice on whether a PCR test is required to confirm your result.
8. **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.
9. The used test should be disposed according to local regulations.
10. Collect of sample from nasal of infants or small children may be painful and harmful. It is recommended that infants or new-borns might be tested with the guidance of medical staff. When collecting of sample from nasal of children you may need another person to steady the child's head while swabbing, you may not need to insert the swab as far into the nostril.

## STORAGE

Store the test at 35.6-86°F (2-30°C). Do not open the pouch until ready for use. **DO NOT FREEZE.** Keep dry. **Do not use after expiry date.** The shelf life of this product is 24 months.

**For Customer Support Helpline: Call (+61) 2-9959-2400 9am-7pm (AEST) 7 days per week for information on the correct use of this test and for interpretation of the test**

## INTENDED USE

The COVID-19 Antigen Rapid Test (Swab) is a single-use test kit intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19 in self-collected nasal swab specimen from symptomatic individuals who are suspected of being infected with COVID-19 within the first 7 days of symptom onset. This test is designed for the use by layperson.

Results are for the detection of SARS-CoV-2 Nucleocapsid protein Antigens. An antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status.

A positive result indicates the presence of SARS-CoV-2. Individuals whose test results are positive should self-isolate and seek help from relevant healthcare institutions. A positive result may also be caused by bacterial infection or co-infection with other viruses. A negative result may also be infected with SARS-CoV-2. Individuals whose test results are negative continue to experience COVID-like symptoms should seek follow-up help from relevant healthcare institutions.

The COVID-19 Antigen Rapid Test (Swab) only indicates a preliminary result to aid for diagnosis of COVID-19. The confirmation of the final result should be based on the clinical diagnosis.

## BACKGROUND

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.

## TEST PRINCIPLE

The COVID-19 Antigen Rapid Test (Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 Nucleocapsid protein Antigens in human nasal swab specimen.

## REAGENTS

The test contains monoclonal anti-SARS-CoV-2 antibody and goat anti-mouse IgG as the capture reagent and monoclonal anti-SARS-CoV-2 antibody and mouse IgG as the detection reagent.

## MATERIALS

### Materials Provided

- Test cassette
- Extraction buffer
- Package insert
- Sterile swab
- Biosafety bag (optional)
- Tube holder

### Materials required but not provided

- Timer

## LIMITATIONS

1. Failure to follow these procedures may affect test performance.
2. The COVID-19 Antigen Rapid Test (Swab) only indicates the presence of SARS-CoV-2 antigens in the specimen.
3. Negative results cannot rule out SARS-CoV-2 infections, especially in those who have been exposed to the virus. 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 to test again with a new kit or test with PCR to rule out infection in these individuals.
4. Negative result may be due to testing not being performed within the 7 days of symptom onset.
5. Positive results of COVID-19 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors. Need for follow-up clinical care.
6. If the virus concentration in the specimen is too low, false negative results may occur.
7. The COVID-19 Antigen Rapid Test (Swab) is less reliable in the later phase of infection, it is recommended to use the test within the first 7 days of symptom onset.
8. The test is less reliable in asymptomatic individuals.
9. A positive result can not necessarily determine whether a person is infectious.
10. A negative result does not rule out infection with another type of respiratory virus.

## PERFORMANCE

### Clinical performance

A clinical evaluation was conducted comparing the results obtained using the COVID-19 Antigen Rapid Test with RT-PCR (nasopharyngeal swab) test result.

The clinical trial included 648 nasal specimens. The results demonstrated 97.3% sensitivity and 99.8% specificity with an overall accuracy of 99.2%.

| | PCR (nasopharyngeal swab) confirmed | Correct identified |
|---|---|---|
| Positive sample | 148 | 144 |
| Negative sample | 500 | 499 |
| total | 648 | 643 |
| Relative Sensitivity | 97.3% (95%CI: 93.2%~99.3%) | |
| Relative Specificity | 99.8% (95%CI: 98.9%~99.9%) | |
| Accuracy | 99.2% (95%CI: 98.2%~99.8%) | |

97.3% Sensitivity: In total 148 PCR confirmed positive samples: 144 PCR confirmed positive samples were correctly detected by Citest COVID-19 Antigen Rapid Test. There are 4 false negative cases.

99.8% Specificity: In total 500 PCR confirmed negative samples: 499 PCR confirmed negative samples were correctly detected by Citest COVID-19 Antigen Rapid Test. There are 1 false positive case.

99.2% Accuracy: In total 648 PCR confirmed samples, 643 PCR confirmed samples were correctly detected by Citest COVID-19 Antigen Rapid Test.

The observed accuracy may vary depending on the prevalence of the virus in the population.

| Days since symptom onset | RT-PCR positive | COVID-19 Antigen Rapid Test Positive | PPA |
|---|---|---|---|
| 0~3 | 84 | 83 | 98.8% |
| 4~7 | 64 | 61 | 95.3% |

| Ct Value | RT-PCR positive | COVID-19 Antigen Rapid Test Positive | PPA |
|---|---|---|---|
| ≤27 | 83 | 83 | 100% |
| 27~30 | 26 | 25 | 96.2% |
| >30 | 40 | 37 | 92.5% |

### Variants

Variant Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1.2), VUI-21ARP-03 (B.1.617.3), Delta (B.1.617.2) and Omicron (B.1.1.529, BA.2, BA.4&BA.5) could be detected out with COVID-19 Antigen Rapid Test.

The lowest concentration tested that still led to a 95% inactivated SARS-CoV-2 virus (XBB.1.5) detection rate was 150$TCID_{50}$/mL.

### Cross-reactivity

Test results will not be affected by other respiratory viruses and commonly encountered microbial flora and low pathogenic coronaviruses listed in table below.

| | | | |
|---|---|---|---|
| Adenovirus type 3 | Human Rhinovirus 2 | *Candida albicans* | *Pseudomonas aeruginosa* |
| Adenovirus type 7 | Human Rhinovirus 14 | *Escherichia coli* | *Staphylococcus epidermidis* |
| Human coronavirus OC43 | Human Rhinovirus 16 | *Haemophilus influenzae* | *Streptococcus pneumoniae* |
| Human coronavirus 229E | Measles | *Legionella pneumophila* | *Staphylococcus aureus subspaureus* |
| Human coronavirus NL63 | MERS-coronavirus Florida | *Mycobacterium tuberculosis* | *Streptococcus sp group F* |
| Human coronavirus HKU1 | Mumps | *Bordelella pertussis* | *Streptococcus salivarius* |
| Influenza A H1N1 | Parainfluenza virus 2 | *Streptococcus pyogenes* | Respiratory syncytial virus |
| Influenza A H3N2 | Parainfluenza virus 3 | *Neisseria lactamica* | SARS Coronavirus |
| Influenza B | *Arcanobacterium* | *Neisseria subflava* | / |

### Interfering Substances

Test results will not be interfered by following substances:

| | | | | | |
|---|---|---|---|---|---|
| Whole Blood | Dexamethasone | Rebetol | Tobramycin | Zicam | Fluticasone Propionate |
| Mucin | Mupirocin | Relenza | Biotin | Alkalol | Nasal block gel |
| Budesonide Nasal Spray | Oxymetazoline | Tamiflu | Menthol | Sore Throat Phenol Spray | Strepsils (flurbiprofen) |
| Flunisolide | Phenylephrine | HAMA | Benzocaine | CVS Nasal Spray (Cromolyn) | / |

## EXTRA INFORMATION

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 self-collected swab specimens. When the control line(C) appears, it means the test unit 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 result after 20 minutes.
3. **When is the best time to run the test?**
   Test can be done at any time of the day.
4. **Can the result be wrong? Are there any factors that can affect the test result?**
   The results will only give accurate results as far as the fresh human nasal swab is used and followed the instructions carefully. Nevertheless, the result can be incorrect.
   Non-SARS-CoV-2 coronavirus strains or other interference factors may cause a preliminary Positive Result.
5. **How to read the test if the color and the intensity of the lines are different?**
   The color and intensity of the lines have no importance for result interpretation. The test should be considered as Positive whatever the color intensity of the test line (T) is.
6. **What do I have to do if the result is positive?**
   A positive result means the presence of SARS-CoV-2 antigens. A positive results means it is very likely you have COVID-19 and the result should be confirmed. Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance
7. **What 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.
   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, mitigation/traveling, attending events and etc should follow your local COVID guidelines/requirements.

**For CUSTOMER SUPPORT HELPLINE: Call (+61) 2-9959-2400 9am-7pm (AEST) 7 days per week**
**For information on the correct use of this test and for interpretation of the test results.**

### LOCAL CONTACT DETAILS

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

**STATE AND TERRITORY CONTACT NUMBERS**

Confirmatory testing of positive results by a laboratory PCR test is required.
To locate your nearest Covid testing center and Laboratory please contact

| | |
|---|---|
| Australian Capital Territory Coronavirus Helpline (8am-8pm daily ) | 02 6207 7244<br>https://health.act.gov.au/ |
| New South Wales Coronavirus Helpline (Service NSW 24/7) | 137 788<br>https://www.health.nsw.gov.au/ |
| Northern Territory Coronavirus National Hotline ( National Helpline) | 1800 020 080<br>https://health.nt.gov.au/ |
| Queensland Coronavirus Helpline (134COVID) | 134 268<br>https://www.health.qld.gov.au/ |
| South Australia Coronavirus Helpline ( 9am -5 pm Daily) | 1800 253 787<br>https://www.sahealth.sa.gov.au/ |
| Tasmanian Public Health Hotline (Coronavirus) | 1800 671 738<br>https://www.health.tas.gov.au/ |
| Victoria Coronavirus Hotline (24/7) | 1800 675 398<br>https://www.dhhs.vic.gov.au/ |
| Western Australia Coronavirus Hotline 13COVID (8am- 6pm Mon-Fri) | 1800 595 206<br>https://www.healthywa.wa.gov.au/ |

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)

### LITERATURE REFERENCES

1. BACKINGER, C.L. and KINGSLEY, P.A., Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care, Rockville, MD, U.S. Food and Drug Administration, Center for Devices and Radiological Health, HHS Pub. FDA 93-4258.

### INDEX OF SYMBOLS

| | | | |
|---|---|---|---|
| IVD | *In vitro* diagnostic medical device | Σ | Tests per kit |
| 2°C 30°C | Temperature limit 2-30°C | | Use by |
| | Do not use if package is damaged | LOT | Batch code |
| | Manufacturer | | Consult Instructions For Use |
| | Do not reuse | REF | Catalog # |
| | Keep dry | | |

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Statement: Information about manufacturer of sterile swab is placed on the packaging.