TESTSEALABS®
COVID-19 ANTIGEN TEST CASSETTE

EN

COVID-19 Antigen Home Test Quick Reference Instructions

Fast result in 10 minutes | Nasal Test

TESTSEALABS®

Study the Instructions for Use and User Manual thoroughly before using Quick Reference Instructions. This is not a complete Instructions for Use.

After viewing the video guide via the QR code and familiarising yourself with how to use the rapid antigen test, follow the instructions below:

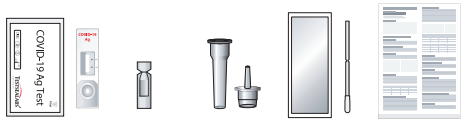
Video Guide

STEP 1 PREPARATION

1 Wash your hands.

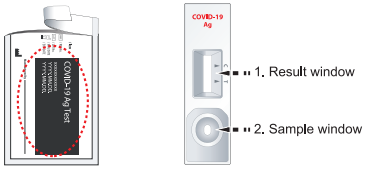
! It is recommended to wear gloves when using the product.

2 Check the kit contents before testing.



Test cassette | Buffer tube | Extraction tube & Nozzle cap | Sterile swab | Instructions for Use & Quick Reference Instructions

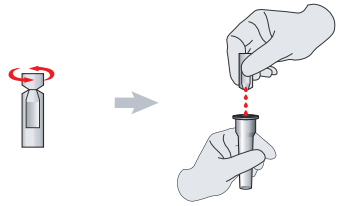
3 Check the expiry date shown on the foil pouch packaging. Check that the test cassette inside is intact and that it contains one test strip framed within the result window.



Foil pouch | Test cassette

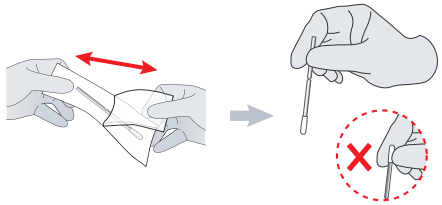
STEP 2 SAMPLE COLLECTION

4 Twist the top off the buffer tube to open and pour all the extraction buffer solution into the extraction tube.



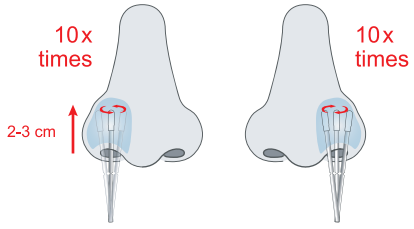
5 Place the extraction tube in the workstation.

6 Open the sterile swab pouch and hold the swab.



! Do not touch swab tip when handling swab sample.

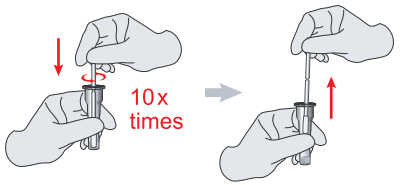
7 Insert the sterile swab and rotate around all sides of both nostrils approx 10 times for about 15 seconds. The sterile swab should be inserted about 2-3 cm into the nostril, parallel to the palate until the resistance is met and turbinates.



! Do not soak the swab in the extraction tube or other liquid until you have finished in the nasal cavity.

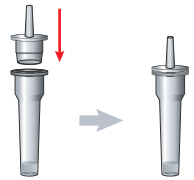
STEP 3 TEST PROCEDURE

8 Place the swab in the extraction tube. Rotate the swab for at least 10 seconds and stir for 10+ times while pushing the swab tip against the sides of the tube to squeeze out the solution from the swab.

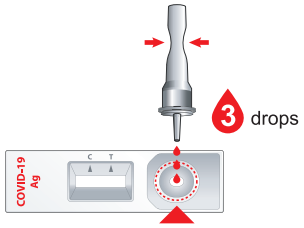


! In case of contact with your skin or eyes, wash immediately with plenty of water.

9 Screw the cap onto the extraction tube and make sure it is firmly in place.



10 Place 3 drops of the sample solution vertically into the sample window of the test cassette.



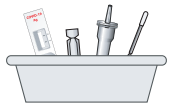
! Do not squeeze out all of the sample solution in the extraction tube.

11 Read the test results after 10 minutes has passed.

Read in **10-15 minutes**

! Do not read test results after 20 minutes.

12 Carefully wrap the used test kit components and swab samples and dispose in normal household waste.



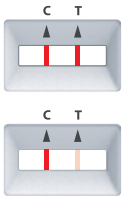
STEP 4 INTERPRETATION OF TEST RESULT

Negative

Negative result: A coloured band will appear in the control line (C) result window only.

Negative results should be treated as presumptive only and may not mean you are not infectious. If you are experiencing COVID symptoms, you must seek immediate further laboratory PCR testing and follow-up clinical care.

Positive

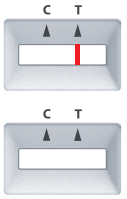


Positive result: Coloured bands will appear in both the control line (C) and test line (T) result windows.

IMPORTANT: Look very closely! The color intensity in the test region will vary. Any faint coloured line in the result window should be considered as positive.

A positive test result indicates that antigens from SARS-CoV-2 were detected, and you are likely to be infected and presumed to be contagious. You must immediately undergo a laboratory PCR test at a COVID-19 respiratory clinic. COVID-19 respiratory clinics are dedicated health centres located around the country, focusing on testing people who may have COVID.

Invalid



Re-test: If the control line (C) has not appeared in the result window, it is an invalid result.

Re-test using a new swab sample and test cassette.

An invalid test result indicates that your test has experienced an error and is unable to interpret the result of the test. Insufficient sample volume or incorrect handling are the most likely reasons for this.You will need to re-test with a new test or contact your State or Territory Coronavirus testing services to get a laboratory PCR test. If you still have symptoms, you should self-isolate at home and avoid contact with others prior to the re-test.

CUSTOMER SUPPORT

For assistance regarding the use of the product and interpretation of test results call 1800 773 463.
This service is available between 9am and 7pm (AEST) or 9am and 8pm (AEDT), 7 days a week.

TESTSEALABS®

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EN

TESTSEALABS® COVID-19 ANTIGEN TEST CASSETTE

Self-Diagnostic Use

Fast result in 10 minutes | Nasal Test

TESTSEALABS®

Video Guide

Instructions for Use

Product Name: TESTSEALABS® COVID-19 Antigen Test Cassette

INTENDED USE

TESTSEALABS® COVID-19 Antigen Test Cassette employs immunochromatography technology to detect the SARS- CoV-2 antigen in human nasal swab specimen. This test is single use only and intended for self-testing. It is recommended to use this test within 7 days of symptom onset. It is supported by the clinical performance assessment.

When to use this product:

Do use -

- if you are concerned that you may have COVID-19
- if you want to diagnose current COVID-19 infection

Do not use -

- if you cannot collect sample in the suggested way
- if you are prone to nose bleeds

EXPLANATION AND SUMMARY

The TESTSEALABS® COVID-19 Antigen Test Cassette is a qualitative membrane strip based immunoassay for the detection of SARS-CoV-2 nucleocapsid antigen in human nasal swab. Nasal swab specimen requires a sample preparation step in which the sample is eluted into the extraction buffer. In this test procedure, anti-SARS-CoV-2 nucleocapsid antigen antibody is immobilised in the test line region of the device. After a nasal swab specimen is placed in the specimen well, it reacts with anti-SARS-CoV-2 nucleocapsid antigen antibody coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilised anti-SARS-CoV-2 nucleocapsid antigen antibody.

If the specimen contains SARS-CoV-2 nucleocapsid antigen, a coloured line will appear in the test line zone indicating a positive result. If the specimen does not contain SARS-CoV-2 nucleocapsid antigen, a coloured line will not appear in this zone, indicating a negative result. To serve as a procedural control, a coloured line will always appear at the control line zone indicating that proper volume to specimen has been added and membrane wicking has occurred.

REAGENTS AND MATERIALS PROVIDED

Test Cassette Device, Extraction Buffer, Extraction Tube, Nasal Swab, Workstation, Instructions For Use, Quick Reference Instructions.

MATERIALS REQUIRED BUT NOT PROVIDED

Timer.

PRECAUTIONS

1. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens and kits are handled.
3. Do not re-use any contents in the kit as they are single-use only.
4. Handle all specimens as if they contain infectious agents.
5. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing, if possible, when specimens are collected, prepared and assessed.
7. Follow standard biosafety guidelines for handling and disposal of potential infective materials.
8. Humidity and temperature can adversely affect results.
9. The test should be performed immediately after the sample is collected. Do not leave the sample at room temperature for more than 1 hour.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (4-30ºC). The test is stable up to the expiration date printed on the sealed foil pouch. The test must remain in the sealed pouch until use.

DO NOT FREEZE.

Do not use beyond the expiration date.

QUALITY CONTROL

Internal Control

Internal quality controls are included in the test. The colour line appearing in the control zone (C) is an internal positive procedure control which confirms an adequate amount of the extraction buffer sample solution has been applied and correct procedural steps have been followed.

WARNINGS AND LIMITATIONS

1. Each test can only be used once.
2. Test results must be read at 10 minutes and no later than 15 minutes.
3. Interpretation of any result after 20 minutes may yield inaccurate test results.
4. If you receive a positive result, you must immediately seek a laboratory PCR test and follow-up care.
5. A positive result cannot determine whether you are infectious.
6. False negative results are more likely to occur if the test is performed after 5 days of symptom onset.
7. False negatives are more likely to occur in the later phase of infection and in asymptomatic individuals.
8. A negative result does not rule out infection with another type of respiratory virus.
9. Negative results should be treated as presumptive only and may not mean you are not infectious. If you are experiencing any COVID symptoms you must seek immediate further laboratory PCR testing and follow up clinical care.
10. Repeat testing is recommended (between 24-48 hours after your first test) if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or other requirement.
11. Children aged 2 to 12 years old should have their samples collected and tested by an adult. Do not use the test for anyone under 2 years of age.

SUPPORT SERVICES

Information regarding available support services can also be obtained by contacting your local state and territory health department at:

ACT:	02 5124 9213	www.health.act.gov.au
NSW:	1300 066 055	www.health.act.gov.au
NT:	08 8922 8044	www.health.nt.gov.au
QLD:	13 432 584	www.health.qld.gov.au
SA:	1300 232 272	www.sahealth.sa.gov.au
TAS:	1300 135 513	www.health.tas.gov.au
VIC:	1300 650 172	www.dhhs.vic.gov.au
WA:	08 9222 4222	www.healthywa.wa.gov.au

COVID-19 INFORMATION

What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness although some people infected with COVID-19 may have no symptoms at all. Serious outcomes of COVID-19 can include hospitalisation or even death. Older adults and people of any age with underlying medical conditions have a higher risk of severe illness from COVID-19. A full list of symptoms of COVID-19 can be found here: *https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert#symptoms*

COVID-19 is contagious and can be spread even before a person shows symptoms of being sick (eg. fever, coughing, difficulty breathing). Some people may test positive for COVID-19 but not have symptoms of infection. These people are considered asymptomatic but may still be able to transmit infection to others. Studies have suggested that asymptomatic infection may be common.

What are the common symptoms of COVID-19?

Symptoms may appear 2-14 days after exposure and may include fever, cough, shortness of breath, fatigue, muscle or body aches, headaches, loss of sense of taste or smell, sore throat, congestion or a runny nose, nausea or vomiting or diarrhea. It is possible for an infected person to experience no symptoms at all.

How does the virus spread?

The virus that causes COVID-19 is thought to spread mainly from person to person, through respiratory droplets produced when an infected person coughs or sneezes. These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs. These respiratory droplets contain virus particles which can also survive on surfaces for several hours. This is another important source of spread with COVID-19 when people touch these infected surfaces and then touch their faces (mouth, nose, eyes). Spread is more likely when people are in close contact with one another (within about 6 feet). COVID-19 seems to be spreading easily and sustainably in the community ("community spread") in many affected georgraphic areas. Community spread means people have been infected with the virus in an area, including some who are not sure how or where they became infected.

What can I do to stay healthy during the COVID-19 pandemic?

To protect your friends, family, community, and yourself, follow these hygiene practices to help stop the spread of infections:

- Clean and wash your hands often with soap and water or an alcohol-based hand sanitiser.
- Clean all frequently touched surfaces daily with household disinfectants.
- Wear a face covering if you must be around other people in public places, in close contact with people outside of your household or where social distancing of 1.5 metres is difficult to maintain.
- Sneeze or cough into your elbow or into a tissue. Discard the tissue after using and wash your hands.
- Avoid close contact with people who are sick. This is especially important if you are in the high-risk group.
- If you become sick, avoid other household members where possible, isolate yourself in your own room and avoid sharing bathrooms and personal items such as cups, plates and cutlery.

When should I seek medical attention?

If you develop any of the emergency warning signs for COVID-19 you must seek medical attention. Emergency warning signs include*:

- Trouble breathing
- Persistent chest pain
- New confusion or inability to wake up or stay awake
- Bluish lips or face

In addition, if you are in the high-risk group or your symptoms are persisting or worsening, or you have concerns, you should seek medical attention.

* This list is not all inclusive. Contact your State or Territory Coronavirus testing services to get a laboratory PCR test. For up-to-date information on COVID-19, please visit the Australian Government Department of Health website: *https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert*

VARIANTS DETECTABLE BY THIS TEST

This test has been tested and proven to detect multiple variants of COVID-19, including Alpha, Beta and most importantly, the Delta variant. It should be noted that the manufacturer's R&D team is constantly working to ensure that these tests can detect any new variants that become known.

CROSS-REACTIVITY

Test results will not be affected by other respiratory viruses and commonly encountered microbial flora and low pathogenic coronavirus listed here, as long as they are at certain concentration levels: Candida Albicans, Staphylococcus Epidermidis, Corynebacterium, Streptococcus Pneumoniae, Escherichia Coli, Streptococcus Pygenes, Moraxella Catarrhalis, Streptococcus Salivarius, Parainfluenza Virus 3, Neisseria Lactamica, Streptococcus SP Group F, Respiratory Syncytial Virus, Nesseria Subflava, Pseudomonas Aeruginosa, Arcanobacterium, Influenza A H1N1, Influenza A H3N2, Influenza B, Human Rhinovirus 12, Human Rhinovirus 14, Human Rhinovirus 16, Measles, Mumps, Parainfluenza Virus, Parainfluenza Virus, Respiratory Syncytial, Human Coronavirus 229E, MERS, Human Coronavirus OC 43, Human Coronavirus NL63.

Please note that the concentration levels are not listed above, however, if one would like to obtain this information, please contact Pharma Soul Pty Ltd via email or phone (details can be at the bottom of this document).

INTERFERING SUBSTANCES

The following compounds have been tested using the TESTSEALABS® COVID-19 Antigen Test Cassette and no interference was observed.

Analytes	Conc.	Analytes	Conc.
Whole Blood	20µl/ml	Oxymetazoline	0.6mg/ml
Mucin	50µg/ml	Phenylephrine	12mg/ml
Budesonide Nasal Spray	200µl/ml	Rebetol	4.5µg/ml
Dexamethasone	0.8mg/ml	Relenza	282ng/ml
Flunisolide	6.8ng/ml	Tamiflu	1.1µg/ml
Mupirocin	12mg/ml		

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

The clinical performance of the TESTSEALABS® COVID-19 Antigen Test Cassette for patient self-testing was evaluated using nasal swab samples collected from 135 study participants in multiple prospective studies. The clinical evaluations were performed by the manufacturer and an independent laboratory. The study cohort included children (aged 10-17), symptomatic adults (aged 18-64) and elders (aged over 65) who were clinically suspected of having a SAR-CoV-2 infection. In the patient self-testing group, the study participants followed written instructions with illustrations for taking a nasal swab sample and performing the test by themselves. The samples were collected and the tests performed under the observation of healthcare professionals, who did not intervene at any stage. Another nasopharyngeal swab sample was collected for RT-PCR testing. The nasal sampling by the self-testers and the nasopharyngeal sampling for RT-PCR tests were compared.

Furthermore, the clinical performance was evaluated using samples that were Professionally Tested. This included 375 participants in one study whereby all samples were taken using a nasal swab. The clinical evaluations were again performed by the manufacturer and an independent laboratory. Two samples were taken during this test - the first nasal swab sample was professionally taken and evaluated using the TESTSEALABS® COVID-19 Antigen Test Cassette; and the second nasopharyngeal swab sample was also professionally and collected for RT-PCR testing. The samples were again compared.

Test Sensitivity and Specificity

For all the self-testing study participants, 35 PCR-positive and 99 PCR-negative study participants were evaluated using TESTSEALABS® COVID-19 Antigen Test Cassette. The cassette correctly identified 97% of the infected study participants and 98% of the non-infected study participants who conducted their test using the self-testing method. The relative sensitivity was 97% (CI 95%: 88.4% -100%) and the relative specificity was 98% (CI 95%: 88.4% -100%) based on these clinical trials performed for self-testing.

Furthermore, for all the Professional Test participants, 125 PCR-positives and 250 PCR-negative study participants were evaluated using the TESTSEALABS® COVID-19 Antigen Test Cassette. The cassette correctly identified 94.4% of the infected study participants and 99.6% of the non-infected study participants whose tests were conducted by a professional.

In summary, the combined rate at which the test can detect if you are COVID POSITIVE is 95% and the combined rate at which the test can detect if you are COVID NEGATIVE is 99%.

SYMBOL

REF	Reference number		Caution		Use By	LOT	Batch Code		Consult Instructions for Use		Do not re-use
IVD	In Vitro Diagnostics		Note		Manufacturer		Date of Manufacture	Σ	Contains Sufficient for <n> Tests		Keep away from sunlight
	Indicates that you should keep the product dry.		Indicates the temperature limitations in which the transport package has to be kept and handled				Do not use if packaging is damaged				

CLINICAL PERFORMANCE WITH POSITIVE NASAL SWAB

	Antigen Positive/ PCR Positive	Antigen Negative/ PCR Negative	Relative Sensitivity (95% CI)	Relative Specificity (95% CI)
Combined Self-Test Clinical Trials	34 out of 35	97 out of 99	97%	98%
Professional Test	118 out of 125	249 out of 250	94.4%	99.6%
Combined Totals	152 out of 160	346 out of 349	95%	99%

LIMIT OF DETECTION

The limit of detection for TESTSEALABS® COVID-19 Antigen Test Cassette was determined to be 50 TCID50/ml using inactivated SARS-CoV-2 Virus.

REPORT PERFORMANCE OR USABILITY ISSUES

If you would like to report an issue, you can do so via the Users Medical Device Incident Report.
Email iris@tga.gov.au or call 1800 809 361.

TESTSEALABS®

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For support and user assistance, contact us on:
1800 773 463 **help.covid19@pharmasoul.com.au**
This service is available between 9am and 7pm (AEST), or 9am and 8pm (AEDT), 7 days a week.