TESTSEALABS®
Rapid Test Kit

Package insert

COVID-19 Antigen Test Cassette - Self Test

INTENDED USE

The TESTSEALABS COVID Antigen Test Cassette is a rapid test for the qualitative detection of SARS-Cov-2 nucleocapid antigen in anterior human nasal swab specimens collected directly from individuals suspected of COVID 19. It is used to aid in the diagnosis of SARS-CoV-2 infection that may lead to COVID-19 disease. The test is single use only and intended for self-testing. Recommended for symptomatic individuals only. It is recommended to use this test within 7 days of symptom onset. It is supported by the clinical performance assessment.
It is recommended that the self test is used by persons 18 years and over and that individuals under 18 years should be assisted by an adult. **Do not use the test on children under the age of 2.**

PRINCIPLE

The COVID-19 Antigen Test Cassette is a qualitative immunoassay based on a membrane for the detection of SARS-CoV-2 Nucleocapsid (N) antigen in human nasal swabs. In this assay, an anti-SARS-CoV-2-N antibody is immobilised in the test zone of the membrane. After a sample is placed in the sample well, it reacts with anti-SARS-CoV-2-N antibody coated particles that are on the sample pad. This mixture migrates chromatographically along the length of the test membrane and interacts with the immobilised anti-SARS-CoV-2-N antibody. If the sample contains SARS-CoV-2 antigen, a coloured line appears in the test line region, indicating a positive result. If the sample does not contain SARS-CoV-2 antigen, no coloured line appears in this area, indicating a negative result. As a procedural control, a coloured line always appears in the control line region, indicating that the correct sample volume has been added and the membrane has been wetted through.

REACTION SYSTEM

The test contains an anti-SARS-CoV-2-N antibody as capture reagent and another anti-SARS-CoV-2-N antibody as detection reagent. A goat anti-mouse antibody is used in the control line system

REAGENTS AND MATERIALS PROVIDED

Pack Size:

1 Test/box	1 Test Cassette, 1 Sterile Swab, 1 Buffer Tube, 1 Extraction Tube, 1 Instructions For Use
5 Test/box	5 Test Cassette, 5 Sterile Swab, 5 Buffer Tube, 5 Extraction Tube, 5 Instructions For Use
20 Test/box	20 Test Cassette, 20 Sterile Swab, 20 Buffer Tube, 20 Extraction Tube, 20 Instructions For Use

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (4-30℃) . The test is stable to the expiration date printed on the pouch until use. DO NOT FREEZE. Do not use beyond the expiration date

QUALITY CONTROL

Internal quality controls are included in the test. The colour line appearing in the control area (C) is an internal positive procedure control which confirms adequate specimen volume and correct procedure technique.

MATERIAL REQUIRED BUT NOT PROVIDED

Timer

PRECAUTIONS

1. Do not use after the expiry date.
2. Read the Package insert carefully before use and use only the ingredients included in this test cassette
3. This test is intended to aid in the diagnosis of a current COVID 19 infection. Please contact your State or Territory Covid 19 advice lines to discuss your results or if any additional testing is required
4. Make sure that the foil pouch containing the test cassette is not damaged before opening it for use. The test cassette should be used within 30 minutes after opening the foil pouch.
5. Do not eat, drink or smoke in the area where the samples and kits are handled.
6. Do not use nasal sprays for a least 30 mins before collecting the sample
7. Do not reuse any kit components. Do not use with multiple specimens
8. Carry out the test at a room temperature of 15-30℃
9. Humidity and Temperature can influence the resutls.

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. A negative result does not rule out infection with another type of respiratory virus
4. This test detects both replicable and nonreplicable SARS-CoV-2 viruses. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral load
5. Positive test results do no rule out bacterial infection or co-infection with other viruses
6. Positive test results do not differentiate between SARS-CoV-1 and SARS-CoV-2 Virus
7. A false negative test may result if the level of antigen in the sample is below the detection limit of the test or if the sample was collected incorrectly
8. If the result is positive, please contact the relevant state or territory health authority for guidance on confirmation testing.
9. The test is less reliable in the later phase of infection and in asymptomatic individuals
10. Children aged 2-17 years old should have the samples collected and tested by an adult. Do not use on Children under 2 years of age.
11. A postive result cannot determine weather you are infectious
12. False negative results are more likely to occur if the test is performed after 5 days of symptom onset
13. Even if the result is negative, you still need to observe all protective and hygienic measures
14. Repeat Testing is recommended (between 24-48 hours after your first test) if there is ongoing suspicion of infection, being high risk settling or where there is an occupational risk or other requirement

VARIANTS DETECTABLE BY THIS TEST

The test has been tested and proven to detect multiple Variants of COVID-19, including but not limited to, Alpha, Beta, Gamma, Delta. 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

The COVID-19 Antigen Test Cassette has been tested for other respiratory viruses listed below. The results showed no cross-reactivity, as long as they are at certain concentration levels: Candida Albicans, Staphylococcus Epidermidis, Corynebacterium, Streptococcus Pneumoniae, Escherichia Coli, Streptococcus Pygenes, Moraxella Catarrhalis, Streptococcuss Salivarius, Neisseria Lactamica, Streptococcus SP Group F, 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 2, Parainfluenza Virus 3, Respiratory Syncytial Virus, 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 Jamach PTYLTD on email or phone (details found at the bottom of document)

INTERFERING SUBSTANCES

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

Whole Blood	Phenylephrine
Mucin	Rebetol
Budesonide Nasal Spray	Relenza
Dexamethasone	Tamiflu
Flunisoline	Tobryaycin
Mupirocin	HAMA
Oxymetazoline	Biotin

LIMIT OF DETECTION

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

PERFORMANCE CHARACTERISTIC

The clinical performance of the COVID-19 Antigen Test Cassette for patient self-testing was evaluated using nasal swab samples collected from 100 study participants in multiple prospective studies. The clinical evaluations were performed by the manufacturers and an independent laboratory. A PCR Test was collected from all 100 participants by a professional using a nasal swab after completing their self-test. The participants included ages 0-17, 18-84 and greater than 85 and 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 and second nasopharyngeal swab PCR testing.. The clinical evaluations were again performed by the manufacturer and independent laboratory. Two samples were taken during this test, the first nasal swab was professionally taken and evaluated using the COVID-19 Antigen Test cassette, and the second nasopharyngeal swab samples were also professionally collected for RT-PCR testing, the samples were compared.

Test Sensitivity and Specificity

For the self-testing study, 35 PCR-positive and 99 PCR-Negative study participants were evaluated using COVID-19 Antigen Test Cassettes. The Cassettes correctly identified 97% of the infected study participants and 98% of the non-infected study participants who conduced their test using the self-testing method. The relative sensitivity was 97% and the relative specificity was 98% on these clinical trials that were performed for self-testing. For all the Professional Test participants,125 PCR-Positives and 250 PCR-negative study paticipants were evaluated using 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.

USABILITY REPORT

A usability study was conducted with a pool of 130 lay persons in the self-testing environment. The sensitivity was found to be >90% and the specificity was confirmed to be 100% in the hand of the lay person, comparing with a professional PCR test. Therefore the Summative Evaluation has proven that the usability of the SARS-CoV-2 Antigen Test Cassette by Testsealabs ensures a safe and proper use of the device.

Clinical performance with nasal swab

Self-test Clinical Result				
	Antigen	PCR	sensitivity	specificity
Positive	34	35	97%	/
Negative	97	99	/	98%
95% confidence interval			84.1%-99.9 %	88.4%-100 %
Professional Clinical Result				
	Antigen	PCR	sensitivity	specificity
Positive	118	125	94.4%	/
Negative	249	250	/	99.6%
95% confidence interval			88.7%-99.5%	97.5%-99.9%

State Government COVID Support Lines:

ACT:	(02) 6207 7244	www.health.act.gov.au
NSW:	13 77 88	www.health.nsw.gov.au
VIC:	1800 675 398	www.health.vic.gov.au
NT:	1800 490 484	www.health.nt.gov.au
QLD:	13 42 68	www.health.qld.gov.au
SA:	1800 253 787	www.sahealth.sa.au
TAS:	1800 020 080	www.health.tas.gov.au
WA:	13 26 843	www.healthywa.wa.gov.au

If there are poor performance or availability issues: Use Medical Device incident Report
Call 1800809361 or E-mail iris@tga.gov.au

Manufacturer:
HANGZHOU TESTSEA BIOTECHNOLOGY CO.,LTD. 3rd Floor, Building 6,No.8-2 Keji Road,Yuhang District,Hangzhou,China, 311100

WEB:www.testsealabs.com
Australian Authorised Representative:
Jamach PTY LTD

Suite 102, 25 Angas St, Meadowbank, NSW, 2114, Australia
www.jamach.com.au/product/rat
hello@jamach.com.au

For support and user assistance, contact us on:
(02) 9131 2727
hello@jamach.com.au

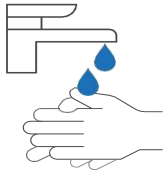
Support is available between 8am-8pm (AEST) or 8am-8pm (AEDT), 7 days a week.

Video Guide

TESTSEALABS®
Rapid Test Kit

SARS-CoV-2 Antigen Rapid Test (Nasal Swab) Self-Test Instruction Guide

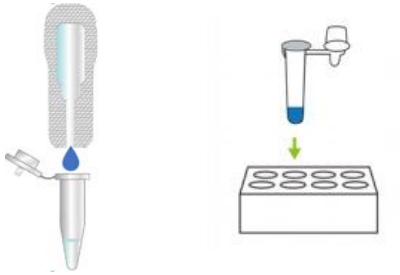
① Wash your hands



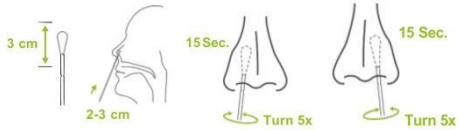
② Check the kit contents before testing,

③ Check the expiry found on the cassette foil pouch and remove the cassette from the pouch.

④ Open the buffer tube that contains fluid and squeeze fluid into the extraction tube. Place extraction tube into the hole on back of box.



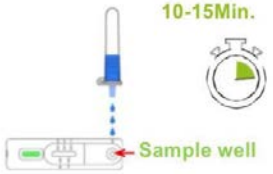
⑤ Carefully remove the swab without touching the tip. Insert the entire tip of the swab, 2 to 3 cm into a nostril. Rub the inside of the nostril in circular movements 5 times for at least 15 seconds, Now take the same nasal swab and insert it into the other nostril and repeat.



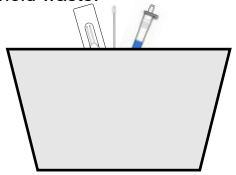
⑥ Place the swab in the extraction tube. Rotate the swab for about 10 seconds and stir 10 times while pressing the swab against the inside of the tube to squeese out as much liquid as possible

⑦ Close the extraction tube with the provided cap.

⑧ Mix thoroughly by flicking the bottom of the tube. Place 3 drops of the sample vertically into the sample window of the test cassette. Read the result after 10-15 minutes. Note: The result must be read within 20 minutes, otherwise, a repeat test is recommended



⑨ Carefully wrap the used test kit components and swab samples, and place into a waste bag prior to disposal into a household waste.



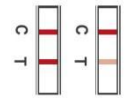
Product Support Line

Australian sponsor for support services:
Jamach Pty Ltd
Website: www.jamach.com.au/product/rat
Phone: (02) 9131 2727

Video Guide

INTERPRETATION OF TEST RESULT

Positive

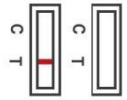


Two coloured lines will appear. One in the control region (C) and one in the test region (T). **NOTE: the test is considered positive as soon as even a faint line appears.** Positive result means that SARS-CoV-2 antigens were detected in your sample, and you're likely to be infected and presumed to be contagious. Refer to your relevant health authority for advice on whether a PCR test is required to confirm your result.

Negative

One colored line appears in the control region (C). No apparent colored line appears in the test region (T). This means that no SARS-CoV-2 antigen was detected and you are unlikely to have COVID-19. Continue to follow all local guidelines and measures when in contact with others as you may be infected. If symptoms continue repeat the test after 1-2 days as SARS-Cov-2 antigen cannot be precisely detected in all phases of an infection

Invalid



No coloured lines appear in the control region (C). The test is invalid even if there is no line in the test region (T). Invalid 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 Rapid Antigen Test Kit. If you still have symptoms you should self isolate at home and avoid contact with others prior to the re-test.

IVD	Medical in vitro diagnosis		Expiry date		Do not reuse
	Manufacturer		Date of manufacture	AU REP	Authorised Representative in Australia
LOT	Batch code		Storage temperature Limits (4-30°C)	REF	Catalogue number
	Follow the Package insert	Σ	Tests per set		Indicates that you should keep the product dry

Manufacturer:
HANGZHOU TESTSEA BIOTECHNOLOGY CO.,LTD.
3rd Floor, Building 6,No.8-2 Keji Road,Yuhang District,Hangzhou,China, 311100
WEB:www.testsealabs.com

Australian Authorised Representative:
Jamach PTY LTD
Suite 102, 25 Angas St, Meadowbank, NSW, 2114, Australia
www.jamach.com.au/product/rat
hello@jamach.com.au

For support and user assistance, contact us on: (02) 9131 2727
hello@jamach.com.au
Support is available between 8am-8pm (AEST) or 8am-8pm (AEDT), 7 days a week.