Package Insert

COVID-19 Antigen Test Cassette

Version 3 Effective date: 11/2021

【INTENDED USE】

The COVID-19 Antigen Test Cassette is a rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid antigen in anterior nasal swabs. It is used to aid in the diagnosis of SARS-CoV-2 infection that may lead to COVID-19 disease.

The test is suitable for people with symptoms. Minors must be tested with the assistance of an adult.

The test is single use only and intended for self-testing，it is recommended to use this test within 7 days of symptom onset.

【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 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

【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 sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

【REAGENTS AND MATERIALS PROVIDED】

Pack size:

1 Test/box	1 Test device 、 1 Extraction tube with Extraction buffer、1 Nasal swab、1 Package insert
2 Tests/box	2 Test device 、 2 Extraction tubes with 2 Extraction buffer、2 Nasal swab、2 Package insert
5 Tests/box	5 Test device 、 5 Extraction tubes with 5 Extraction buffer、5 Nasal swab、1 Package insert
15 Tests/box	15 Test device、15 Extraction tubes with 15 Extraction buffer 、 15 Nasal swab 、 15 Package insert

【MATERIALS 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 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.
4 Do not eat, drink or smoke in the area where the samples and kits are handled.
5 Carry out the test at a room temperature of 15 - 30 °C.
6 Humidity and temperature can influence the results.

【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.

【LIMITATIONS】

1 Each test can only be used once
2 Interpretation of any result after 20 minutes may result in wrong test results
3 Children aged 2 to 15 years old should have their samples collected and tested by an adult. Do not use the test for anyone under 2 years of age
4 A positive result cannot determine whether you are infectious
5 Positive results do not rule out bacterial infection or co-infection with other viruses.
6 If the result is positive，one must still confirm the results immediately by a laboratory PCR test.
7 False negative results are more likely to occur if the test is performed after 5 days of symptom onset
8 False negative results are more likely to occur in the later phase of infection and in asymptomatic individuals
9 A negative result does not rule out infection with another type of respiratory virus
10 Negative results does not preclude SARS-CoV-2 infection and the person not being infectious. If symptoms persist , please confirmed via a laboratory PCR-test.
11 Even if the result is negative, you still need to observed all protective and hygienic measures
12 The test cannot differentiate between SARS-CoV-1 and SARS-CoV-2 Virus
13 Repeat testing is recommend（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

【VARIANTS DETECTABLE BY THIS TEST】

The test has been tested and proven to detect multiple Variants of COVID-19, including Alpha, beta, Gamma, Kappa, Mu， 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】

The COVID-19 Antigen Test Cassette has been tested for other Strain and virus (Table below). The results showed no cross-reactivity.

Candida albicans	Influenza A H3N2
Staphylococcus epidermidis	Influenza B
Corynebacterium	Human Rhinovirus 12
Streptococcus pneumoniae	Human Rhinovirus 14
Escherichia coli	Human Rhinovirus 16
Streptococcus pygenes	Measles
Moraxella catarrhalis	Mumps
Streptococcus salivarius	Parainfluenza virus 2
Neisseria lactamica	Parainfluenza virus 3
Streptococcus sp group F	Respiratory syncytial virus
Nesseria subflava	Human coronavirus 229E
Pseudomonas aeruginosa	MERS
Arcanobacterium	Human coronavirus OC 43
Influenza A H1N1	Human coronavirus NL 63

please note that the concentration levels are not listed above。however ，if one would like obtain this information，please contact Cellife Health Care Pty Ltd email or phone（detail can be at the bottom of the document）

【INTERFERING SUBSTANCES】

The following compounds have been tested using the COVID-19 Antigen Test Cassette and no interference was observed with Whole Blood、Mucin、Mupirocin、Oxymetazoline、Dexamethasone、Flunisolide、Budesonide Nasal Spray、Phenylephrine、Rebetol、Relenza

【LIMIT OF DETECTION】

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

【PERFORMANCE CHARACTERISTICS】

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 mutiple prospective studies.

The clinical evaluations were performed by the manufacturers and

Independent laboratory， A PCR Test was collected from all 100 participants by a professional using a nasopharyngeal swab

after completing their self-test，the participant include children（age 10-17），adults（18-84）and elders（age over 85）

And the Clinical performance was evaluated using samples that were professional tested，This included 375 participarts in one study whereby all samples were taken using a nasal swab and second nasopharyngeal swab for PCR testing.

Clinical performance with nasal swab

Self-test Clinical Result				
	Antigen	PCR	sensitivity	specificity
Positive	34	35	97%	/
Negative	64	65	/	98%
95% confidence interval			84.1%-99.9%	91.0%-99.9%
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%

If there are poor performance or usability issues, please contact the TGA to report an issue via the Users Medical Device Incident Report, email iris@tga.gov.au or call 1800 809 361.

【SUPPORT SERVICES】

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

Australian Capital Territory Department of Health
02 62077244 https://www.health.act.gov.au/
New South Wales Department of Health
137788 https://www.health.nsw.gov.au/
Northern Territory Department of health
1800020080 https://www.health.nt.gov.au/
Queensland Department of health
134268 https://www.health.qld.gov.au/
South Australian Department of Health
1800253787 https://www.sahealth.sa.gov.au/
Tasmanian Department of Health
1800671738 https://www.health.tas.gov.au/
Victorian Department of Health
1800675398 https://www.dhhs.vic.gov.au/
Western Australian Department of Health
1800595206 https://www.healthywa.wa.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：
Cellife Health Care Pty Ltd
ABN 64616730888
POBOX 1090, Burwood North
NSW 2134 Australia
info@cellifehealthcare.com.au
For support and user assistance，Contact us on：
+1800235543
The service is available between 9 am and 7 pm (AEST)or 9am and
8pm (AEDT),7 days a week

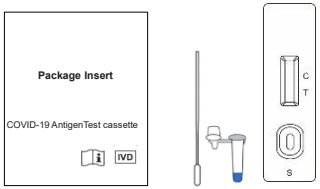
https://cellifehealthcare.com.au/shop/covid-19-antigen-test-cassette/cellife-covid-19-antigen-test-cassette-pack-of-2/
or Scan QR Code

Quick guide

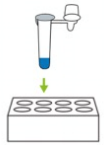
①

Wash your hands

②



Check the kit contents before testing,include Package insert、Test device、buffer、swab



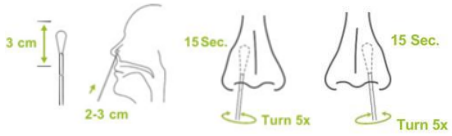
③

Place the extraction tube in the Workstation

④

Peel off aluminum foil seal from the top of the extraction tube containing the extraction tube containing the extraction buffer

⑤



Carefully remove the swab without touching the tip.Insert the entire tip of the swab 2 to 3 cm into the right nostril.Note the breaking point of the nasal swab. You can feel this with your fingers when inserting the nasal swab or check it in the mirror. 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. Swab the inside of the nostril in a circular motion 5 times for at least 15 seconds. Please perform the test directly with the sample and do not leave it standing

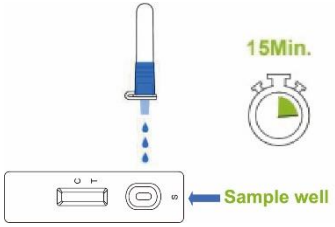
⑥

Place the swab in the extraction tube. Rotate the swab for about 10 seconds，Rotate the swab against the extraction tube, pressing the head of the swab against the inside of the tube while squeezing the sides of the tube to release as much liquid as possible from the swab

⑦

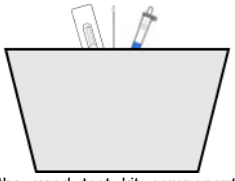
Close the vial with the provided cap and push firmly onto the vial

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 15 minutes.
Note： Read the result within 20 minutes. Otherwise, a repetition of the test is recommended

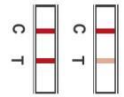
⑨



Carefully wrap the used test kit components and Swab samples and dispose in normal household waste

INTERPRETATION OF TEST RESULT

Positive

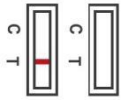


Two colored line appear.One colored line appears in the control region (C) and one colored line appears in the test region (T).
NOTE：The test is considered positive as soon as even a faint line appears. A positive result means that SARS-CoV-2 antigens were detected in your sample.
A positive test result indicates that antigens from SARS-CoV-2 were detected，and you are likely to be infected and presumed to be contagious. you may be to follow the relevant State or Territory health authority advice

Negative

one colored line appear in the control region (C). No apparent colored line appear in the test region (T).
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

Invalid



No colored line appears in the control region (C). The test is invalid even if there is one line in the test region (T).
Invalid result indicate that your test has experienced an error and is unable to interpret the result of test. insufficient sample volume or incorrect handling are the most likely reasons for this，**recommend to repeat test with a New test kit**. you will need to get a laboratory PCR-test if symptoms persist, 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	EC REP	Authorised Representative in the European Community
LOT	Batch code		Storage temperature Limits (4-30°C)	REF	Catalogue number
	Follow the Package insert		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

For support and user assistance
Contact us on：1800235543
The service is available between
9 am and 7 pm (AEST)or 9am and
8pm (AEDT),7 days a week

Australian Authorised Representative：
Cellife Health Care Pty Ltd
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NSW 2134 Australia