GENEDIAN

Package Insert

COVID-19 Antigen Test Cassette

For Self-testing

【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
5 Tests/box	5 Test device, 5 Extraction tubes with Extraction buffer, 5 Nasal swab, 1 Package insert
25 Tests/box	25 Test device, 25 Extraction tubes with Extraction buffer, 25 Nasal swab, 25 Package insert, 1 Workstation

【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. 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 at least 30 minutes 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 results.

【QUALITY CONTROL】

Internal quality controls are included in the test. The coloured 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 Test results must be read at 15 minutes and no later than 20 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-CoV2 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 not rule out bacterial infection or co-infection with other viruses.

6 Positive test results do not differentiate between SARS-CoV-1and 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 positive result cannot determine whether you are infectious.

12 False negative results are more likely to occur if the test is performed after 7 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 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 but not limited to, Alpha, Beta, Gamma, Delta and Omicron. 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 compounds have been tested using the COVID-19 Antigen Test Cassette and no interference was observed with Whole Blood, Mucin, Budesonide Nasal Spray, Dexamethasone, Flunisolide, Mupirocin, Oxymetazoline, Phenylephrine, Rebetol, Relenza, Tamiflu, Tobryamycin, HAMA(Human anti-mouse antibodies), Biotin, Nasal gel, Throat lozenges.

【LIMIT OF DETECTION】

The limit of detection for COVID-19 Antigen Test Cassette was determined to be 100 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 135 study participants in mutiple prospective studies. The clinical evaluations were performed by the manufacturers and Independent laboratory, A PCR Test was collected from all 135 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 1 test has been excluded for being invalid due to incorrect testing procedures and inability to retest so the final clinical count is 134.

And the Clinical performance was evaluated using samples that were professional tested. This included 684 participants 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	97	99	/	98%
95% confidence interval			84.1%-99.9 %	91.0%-99.9 %
Professional Clinical Result				
	Antigen	PCR	sensitivity	specificity
Positive	214	225	95.1%	/
Negative	459	459	/	100%
95% confidence interval			91.36%-97. 34%	99.0%-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 1300 593 089.

【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/

Australian Sponsor / Distributor :

Nationwide Asset Management Consolidated Pty Limited
Address: 600 St Kilda Rd Melbourne Vic 3004 Australia
P.O. BOX 6009 Melbourne 3004 Vic Australia
E-mail : support@genedian.com.au
Web: www.genedian.com.au
Telephone: 1300 593 089

For support and user assistance, Contact us on：
1300 593 089
The service is available between 9 am and 7 pm (AEST) or 9 am and 8 pm (AEDT),7 days per week

Manufacturer:

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

Product Operation Instructions：

Please Scan Me

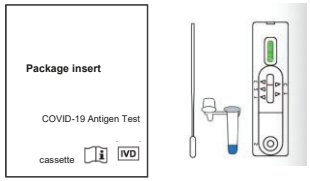
GENEDIAN

QUICK GUIDE

①

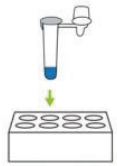
Wash your hands.

②



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

③

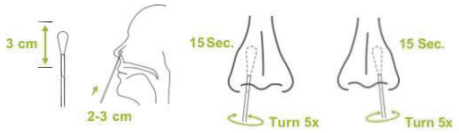


Place the extraction tube in the Workstation.

④

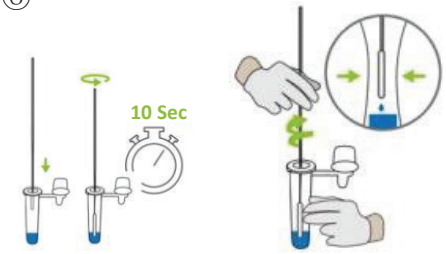
Peel off aluminum foil seal from the top of the extraction tube containing the extraction tube containing the extraction buffer.

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

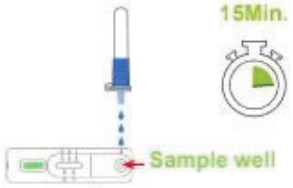


Place the swab in the extraction tube. Rotate the swab for about 10 seconds. Rotate the swab against the extraction tube, pressing the head of the swab against the inside of the tube while squeezing the sides of the tube to release as much liquid as possible from the swab.

⑦

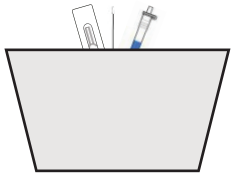
Close the vial with the provided cap and push firmly onto the vial.

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.

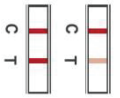
⑨



Please dispose of the test materials in a closed plastic bag with the household refuse. If there are local regulations, please follow them. And wash your hands thoroughly after test completion.

INTERPRETATION OF TEST RESULT

Positive

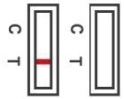


Two coloured lines will appear. One in the control region (C) and one in the test region (T).
NOTE: The test is considered positive as soon as even a faint line appears. Positive result means that SARS-CoV-2 antigens were detected in your sample, and you're likely to be infected and presumed to be contagious. Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

Negative

One colored line appears in the control region (C). No apparent colored line appears in the test region (T).
NOTE: 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 one line in the test region (T).
NOTE: 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. Speak to customer support below on helping using the 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: 1300 593 089
The service is available between 9 am and 7 pm (AEST) or 9 am and 8 pm (AEDT),7 days per week

Australian Sponsor / Distributor :
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