SecurePlus®

Package insert

SecurePlus COVID-19 Antigen Test Cassette

Version 4 Effective date: 11/2021

【INTENDED USE】

The SecurePlus 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 5 days of symptom onset.

【PRINCIPLE】

The SecurePlus 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、5 Package insert
20Tests/box	20 Test device、20 Extraction tubes with Extraction buffer、20 Nasal swab、4 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, refer to your relevant health authority for advice on whether a PCR test is required to confirm your result.

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 refer to your relevant health authority for advice on whether a PCR test is required.

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 B.1.1、Epsilon B.1.427、Beta B.1.351、Eta B.1.525、Gamma P.1、Lota B.1.526、Kappa B.1.6.17.1、Theta P.3、Mu B.1.621、Zeta P.2、Lambda G37、Omicron*B.1.1.529 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 SecurePlus COVID-19 Antigen Test Cassette has been tested for other Strain and virus (Table below). The results showed no cross-reactivity.

Strain	
Staphylococcus epidermidis	Nesseria subllava
Corynebacterium	Pseudomonas aeruginosa
Streptococcus pneumoniae	Arcanobacterium
Escherichia coli	Mycoplasma pneumoniae
Streptococcus pyrogenes	Bordetella pertussis
Moraxella catarrhalis	Mycobacterium tuberculosis
Streptococcus salivarius	Legionella pneumophila
Neisseria lactamica	Chlamydia pneumoniae
Streptococcus sp group F	Haemophilus influenzae
virus	
Adenovirus	Human Rhinovirus 14
Human Metapneumovirus	Human Rhinovirus 16
Enterovirus	Measles
Human Coronvirus OC43	Mumps
Human Coronvirus NL63	Parainfluenza virus 1
Rhinovirus	Parainfluenza virus 2
Respiratory syncytical virus	Parainfluenza virus 3
Influenza A H1N1	Parainfluenza virus 4
Influenza A H3N2	Human coronavirus 229E
Influenza B	MERS
Haemophilus influenza	Pool human nasal wash
Human Rhinovirus 2	Human Rhinovirus 14

【INTERFERING SUBSTANCES】

The following compounds have been tested using the SecurePlus 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 SecurePlus 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 SecurePlus 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 Independent laboratory. PCR Tests were collected from all 100 participants by a professional using nasopharyngeal swabs after completing their self-test. The participants include children (age 10-17), adults(18-84)and elders(age over 85).

The Clinical performance was evaluated using samples that were professional tested. This included 375 participants in one study whereby each sample was taken using a nasal swab and a 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	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 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:
Plus Medical Pty Ltd
1A Coronation Ave., Kings Park NSW 2148, Australia
Tel: +61-2-9881 0368
Web: http://www.plusmedical.com.au

For support and user assistance, Contact us on:
1300 885 823
The service is available between 9 am and 7 pm (AEST)or 9am and 8pm (AEDT),7 days a week.

Video Guide

IFU

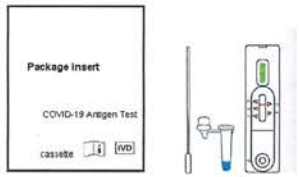
SecurePlus®

Quick guide

①

Wash your hands

②



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

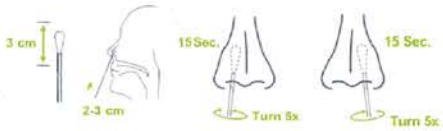
③

Place the extraction tube in the Workstation

④

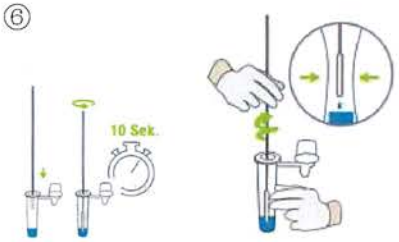
Peel off aluminum foil seal from the top of the extraction tube containing the extraction buffer

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 right after the sample is taken and do not leave it standing.

⑥

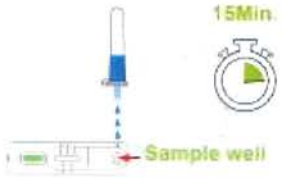


Place the swab in the extraction tube. Rotate the swab for about 10 seconds , Rotate the swab against the extraction tube, pressing the head of the swab against the inside of the tube while squeezing the sides of the tube to release as much liquid as possible from the swab.

⑦

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

⑧



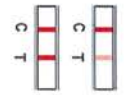
Mix thoroughly by flicking the bottom of the tube. Place 3 drops of the sample vertically into the sample window of the test cassette. Read the result after 15 minutes.
Note : Read the result within 20 minutes. Otherwise, a repetition of the test is recommended

⑨

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

INTERPRETATION OF TEST RESULT

Positive

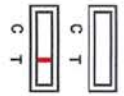


Two colored line appear.One colored line appears in the control region (C) and one colored line appears in the test region (T).
NOTE : The result is considered positive even a faint line appears in the test region.
A positive result means that SARS-CoV-2 antigens were detected in your sample, and you are likely to be infected and presumed to be contagious. Please refer to your relevant health authority for advice on whether a PCR test is required to confirm your result.

Negative

One colored line appear in the control region (C). No apparent colored line appear in the test region (T).
NOTE : Negative results should be treated as presumptive only and may not mean you are not infectious.If you are experiencing COVID symptoms, please refer to your relevant health authority for advice on whether a PCR test is required.

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).
NOTE:Invalid result indicates 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. It is recommend to repeat the test with a new test kit. Or please refer to your relevant health authority for advice on whether a PCR test is required.

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

Video Guide

Australian Authorised Representative:
Plus Medical Pty Ltd
1A Coronation Ave.,
Kings Park NSW 2148
Australia
Tel: +61-2-9881 0368
Web: http://www.plusmedical.com.au

For support and user assistance Contact us on:
1300 885 823

The service is available between 9 am and 7 pm (AEST)or 9am and 8pm (AEDT),7 days a week