



PRODUCT OVERVIEW



TESTSEALABS® COVID-19 ANTIGEN TEST CASSETTE



TGA, CE & ISO Approved



Nasal or nasopharyngeal
swab sample



Instant result
in 10 minutes



Easy to use
No equipment required
No PCR Lab needed



Room temperature
storage (4-30 °C)

TESTSEALABS®
Rapid Test Kit





TEST PROCEDURE

TAKE NASAL SWAB FOR EXAMPLE

1



Place an extraction tube in the workstation. Open buffer tube and pour solution into the extraction tube.

2



Tilt patient's head back about 70°. Insert sterilised swab 2-3 cm into one nostril parallel to the palate.

3



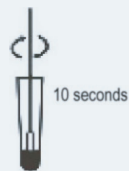
Gently rub and rotate the swab approx 10 times for about 15 seconds to absorb secretions.

4



Slowly remove swab while rotating it. Repeat process in the other nostril.

5



Insert the swab into the extraction tube. Rotate the swab for 10 seconds and stir for 10+ times while pushing swab tip against tube sides.

6



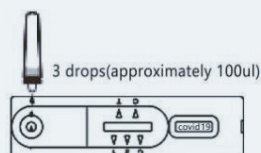
Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

7



Place the nozzle cap onto the extraction tube and make sure it is firmly in place.

8



Transfer 3 drops (approx. 100UL) to the sample window of the test cassette.

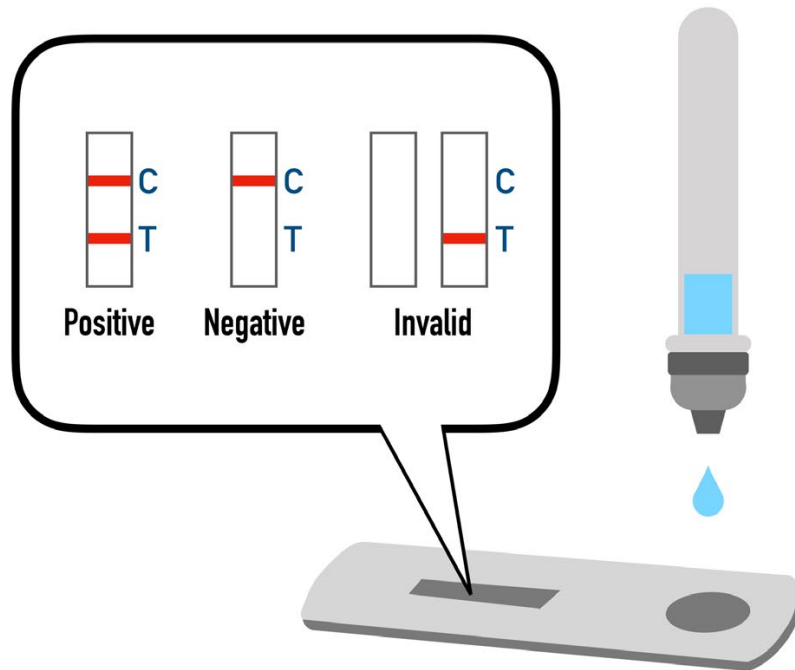
9



Interpret the test results at 10 minutes. Do not read results after 20 minutes.



INTERPRETATION OF RESULTS



POSITIVE:

Two lines appear. One line should always appear in the control line region (C), and another one apparent coloured line should appear in the test line region.

NOTE: The intensity of the colour in the test line regions may vary depending on the concentration of COVID-19 antibodies present in the specimen. Therefore, any shade of color in the test line region should be considered positive.

NEGATIVE:

**One coloured line appears in the control region (C).
No apparent coloured line appear in the test line region.**

INVALID:

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure.

Review the procedure and repeat the test with a new test device.

If the problem persists, discontinue using the test kit immediately and contact Pharma Soul.



PRODUCT PERFORMANCE



A side-by-side comparison was conducted using the SARS-CoV-2 Antigen Test Cassette and referencing reagent Vitassay Healthcare S.L.U. kit (PCR).
The comparison (RT-PCR) yielded the following:

RELATIVE SENSITIVITY

The Relative Sensitivity of the TESTSEALABS® COVID-19 Antigen Test Cassette is:

95%

RELATIVE SPECIFICITY

The Relativity Specificity of the TESTSEALABS® COVID-19 Antigen Test Cassette is:

99%

OVERALL AGREEMENT

The Overall Agreement of the TESTSEALABS® COVID-19 Antigen Test Cassette is:

97%

The test results meet the recommended performance standards as listed by the World Health Organisation.

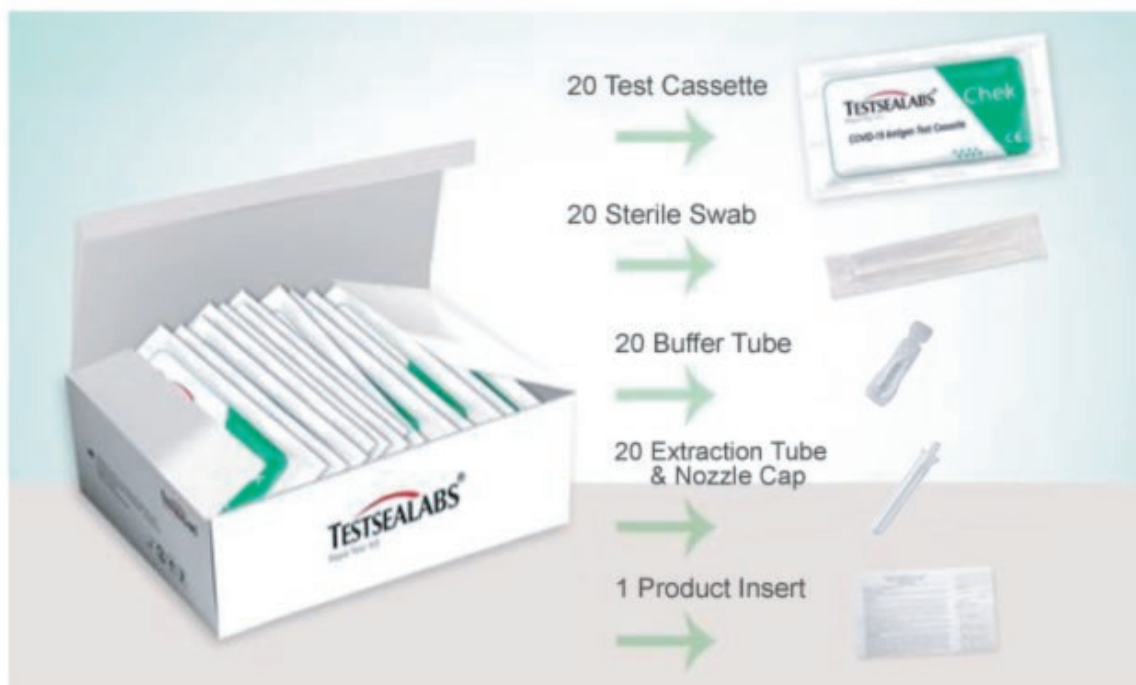
Reference: WHO Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays Interim guidance:
<https://www.who.int/docs/default-source/coronaviruse/corrigenda-ig-2020-1-antigen-detection-2020-09-11-corr-2020-10-27-en.pdf>



PACKAGING SPECIFICATIONS

TESTSEALABS® COVID-19 ANTIGEN TEST CASSETTE KIT SPECIFICATIONS:

20 Tests/Box
600 Tests / CTN
47 x 43 x 34.5cm
9 / 10.5 KG





COVID-19 RAPID ANTIGEN TEST



DESCRIPTION:	TESTSEALABS® COVID-19 Antigen Test Cassette
PRODUCT CODE:	TSL-RAT
FEATURES:	<ul style="list-style-type: none">• Rapid Antigen Test• Instant results in 15 mins• Easy to use• High sensitivity• High specificity• No equipment required
CERTIFICATIONS:	<ul style="list-style-type: none">• TGA• CE• ISO
CASE SPECIFICATIONS:	<ul style="list-style-type: none">• 20 Tests per Box• 600 Tests / CTN• Dimensions: 47 x 43 x 34.5cm (10.5kg)
SHIPPING:	Price excludes shipping
TESTING SERVICE:	Optional testing service can be provided Please enquire for details

All orders are subject to Special Conditions of Pharma Soul Pty Ltd and further Specific Conditions which must be adhered to in accordance with the Therapeutic Goods Administration. Any deviation from these Special Conditions may result in immediate termination of a sale or contract.