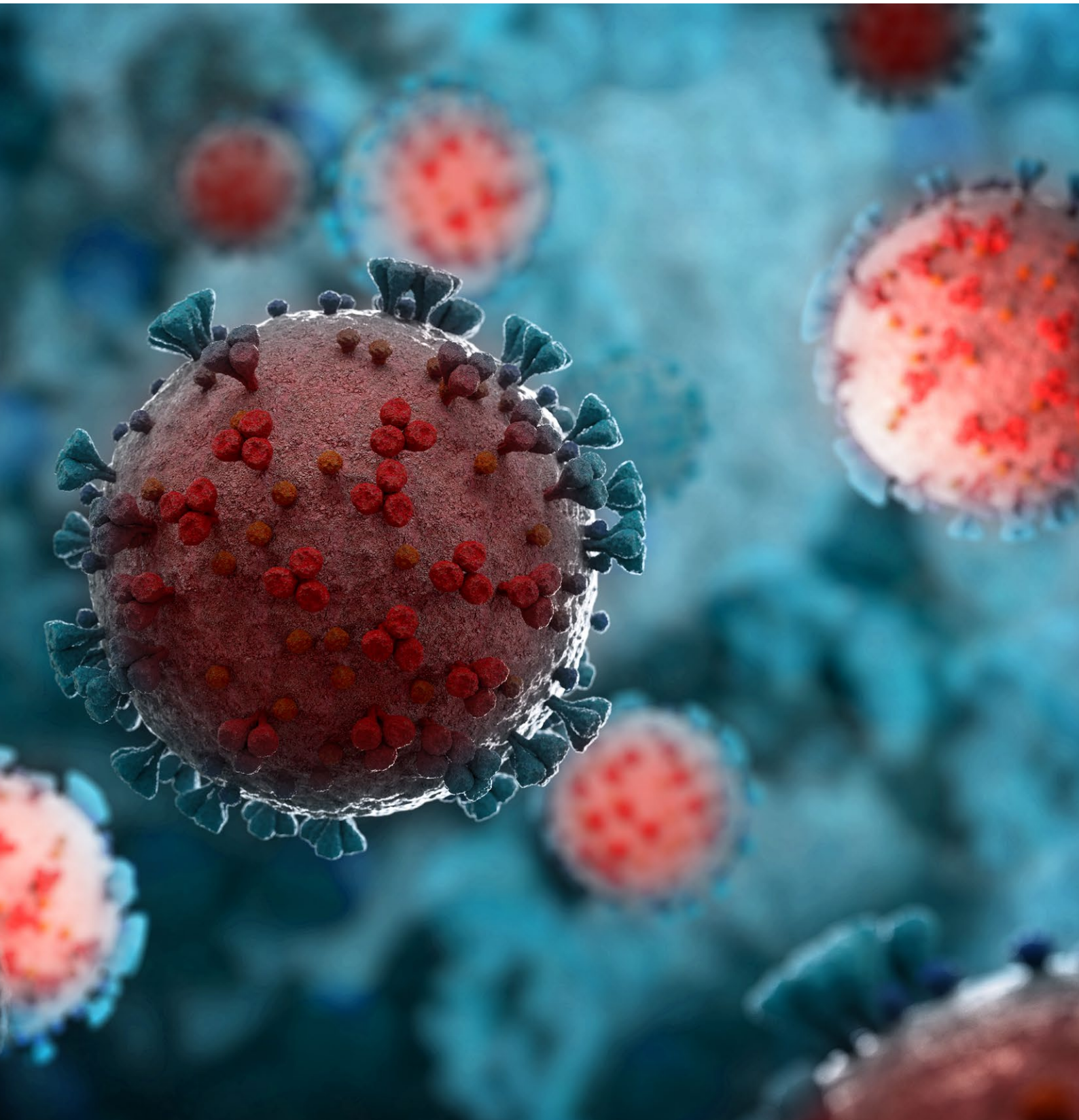


PharmaSUL



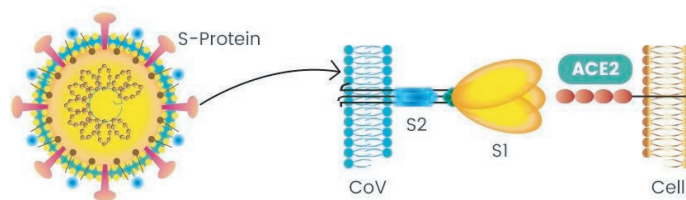
COVID-19 RAPID ANTIGEN TEST



# WHAT IS COVID-19?



Coronaviruses are a large family of viruses that cause respiratory infections. These can range from the common cold to more serious diseases. COVID-19 is a disease caused by a form of coronavirus. The novel coronavirus invades human cells by the specific binding of its spike glycoprotein (ligand) to the ACE2 receptor located on human cellular membrane.



Symptoms of COVID-19 can range from mild illness to pneumonia. Some people will recover easily, and others may get very sick very quickly. People with coronavirus may experience:

## **MOST COMMON SYMPTOMS:**

- Fever
- Dry cough
- Tiredness

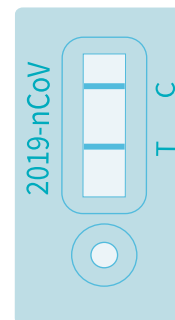
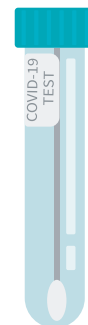
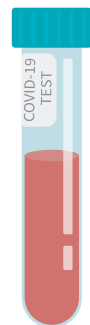
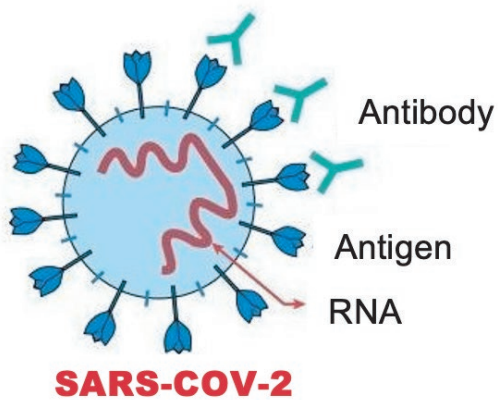
## **LESS COMMON SYMPTOMS:**

- Aches and pains
- Sore throat
- Diarrhoea
- Conjunctivitis
- Headache
- Loss of taste or smell
- A rash on skin
- Discolouration of fingers/toes





# CURRENT DIAGNOSTIC METHODS



## ANTIGEN TEST

Detects the antigen of the virus, indicating the active viral infection

## RT-PCR

Detects the RNA of the virus, indicating the active viral infection

## ANTIBODY TEST

Detects the antibody generated by immune response after viral infection, indicating the active or past viral infection



# CURRENT DIAGNOSTIC METHODS

TEST METHOD	PCR	IgM / IgG ANTIBODY RAPID TEST	ANTIGEN RAPID TEST (LATEX)
ENVIRONMENTAL REQUIREMENTS	High requirements for laboratory environment	Low environmental requirements, not necessarily performed in the laboratory	Low environmental requirements, not necessarily performed in the laboratory
OPERATIONAL REQUIREMENTS	Professional testing personnel; Require special and expensive equipment	The procedure is simple and no instrument is needed	The procedure is simple and no instrument is needed
SAMPLE TYPE	Nasopharynx swab, high sampling requirements, painful in instances	Blood samples, invasive sampling	Oropharyngeal saliva, sputum and samples of the posterior oropharynx
PERFORMANCE	Gold standard of diagnosis	Auxiliary diagnosis; Good sensitivity and specificity	Auxiliary diagnosis; Higher sensitivity and 100% specificity
DETECTION TIME	2 - 3+ hours	15 minutes	10 - 15 minutes
COST	Expensive	Affordable	Affordable
APPLICABILITY	Applicability to all periods	Weeks after symptom onset	Early detection and mass screening of suspected population

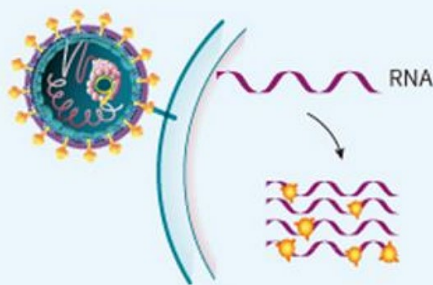


# COVID-19 ANTIGEN TEST

## MAIN MECHANISM OF ANTIGEN INTO BLOOD

When SARS-CoV-2 invades the lung cells, it will express a large amount of self protein to reassemble the virus particles, causing cell damage and forming inflammation virus protein expressed in excess and the virus protein released from the disintegration of virus particles killed by the body in the lesions will enter the blood circulation through the vessel wall with increased permeability due to inflammation in the lesions.

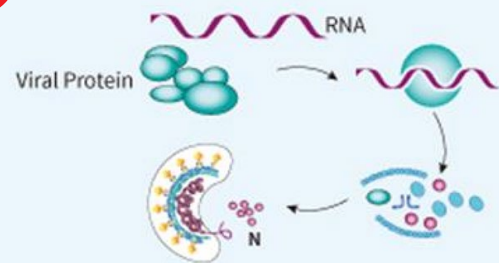
1



### REPLICATION

One RNA replicates to many chains and synthesize many antigens at the same time

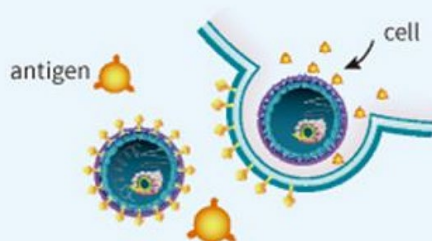
2



### COMPOSITION

Successfully replicated RNA + viral protein

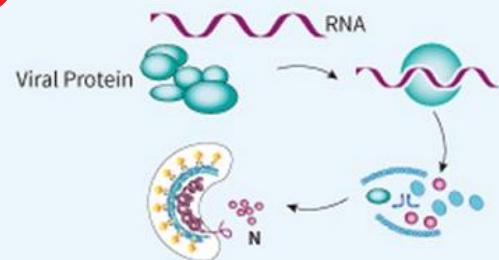
3



### EMISSION

Virus comes out from disintegrated cells, at the same time, many redundant antigens come out

4



### TRANSMISSION

Disintegrated viral proteins enter the blood circulation through the blood vessel wall



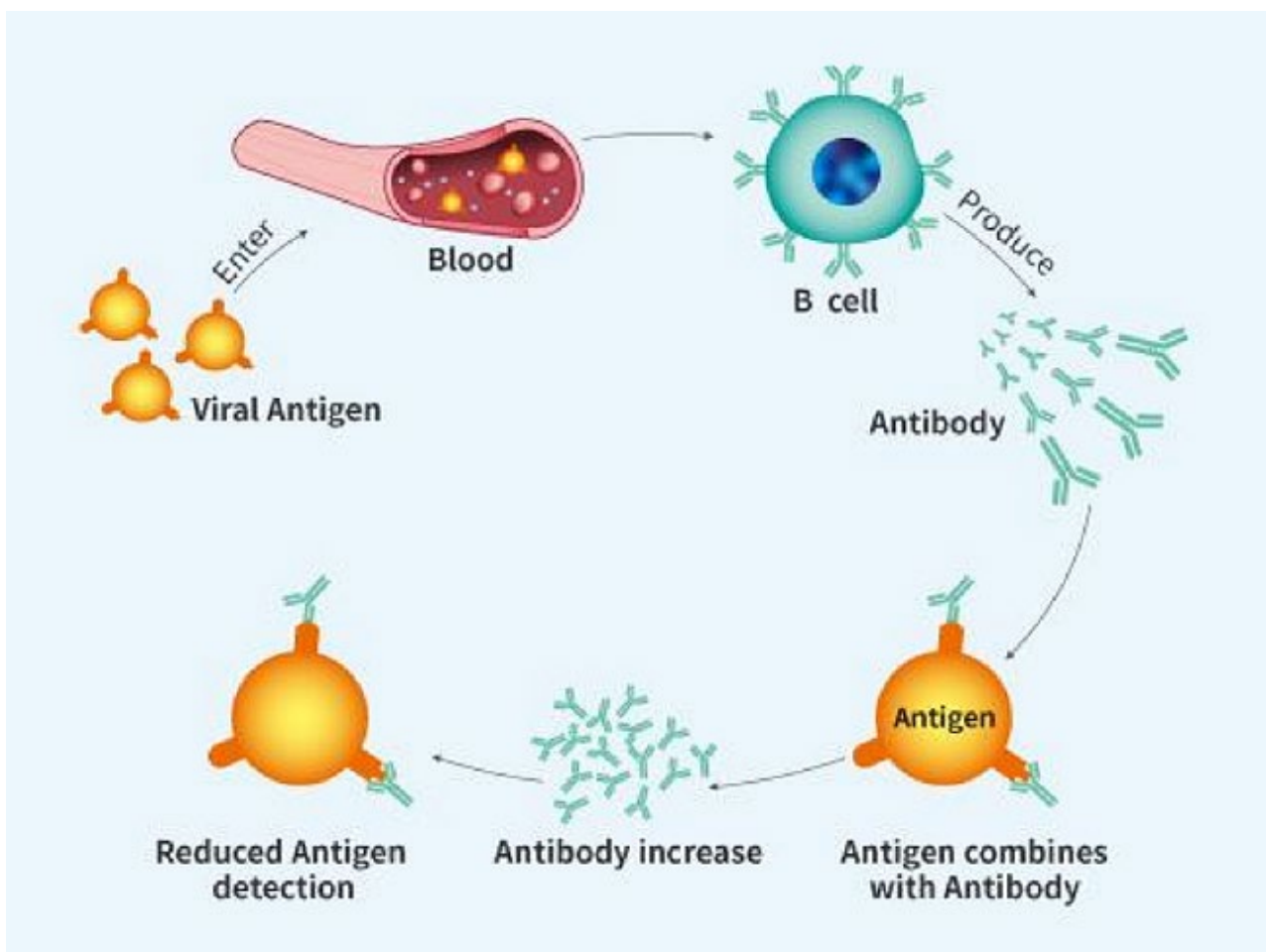
# COVID-19 ANTIGEN TEST

## MECHANISM OF REDUCTION AND ELIMINATION OF ANTIGEN IN BLOOD

The virus antigen will stimulate the patient's body to produce the corresponding antibody, and the antibody will produce the specific combination with the corresponding antigen, forming the antigen antibody immune complex to be cleared by the body's immune system.

As the amount of antibody produced by the patient increases gradually, the amount of antigen cleared will also increase synchronously.

With the activation of the immune system, the ability to destroy the virus is enhanced, the viral load in the body will gradually decrease and the production of virus and blood antigen will gradually decrease.





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

3



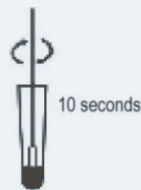
Gently rub and rotate the swab approx 10 times for about 15 seconds to absorb secretions.

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



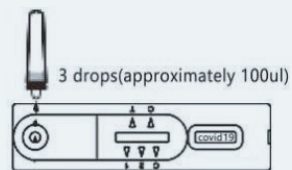
Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

7



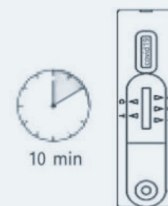
Place the nozzle cap onto the extraction tube and make sure it is firmly in place.

8



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

9

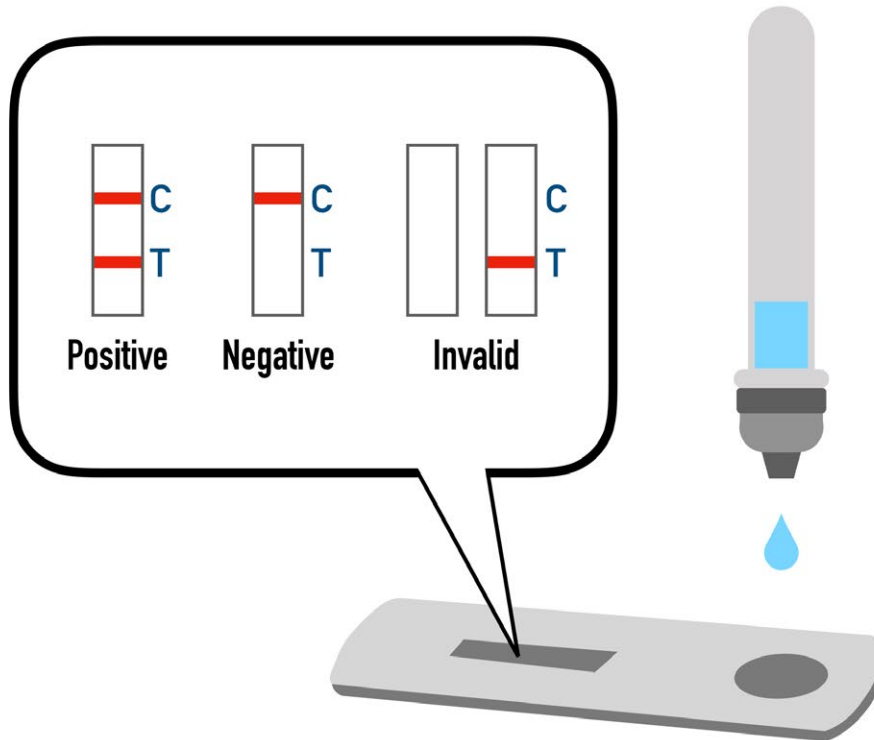


Interpret the test results at 10 minutes. Do not read results after 20 minutes.





# 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

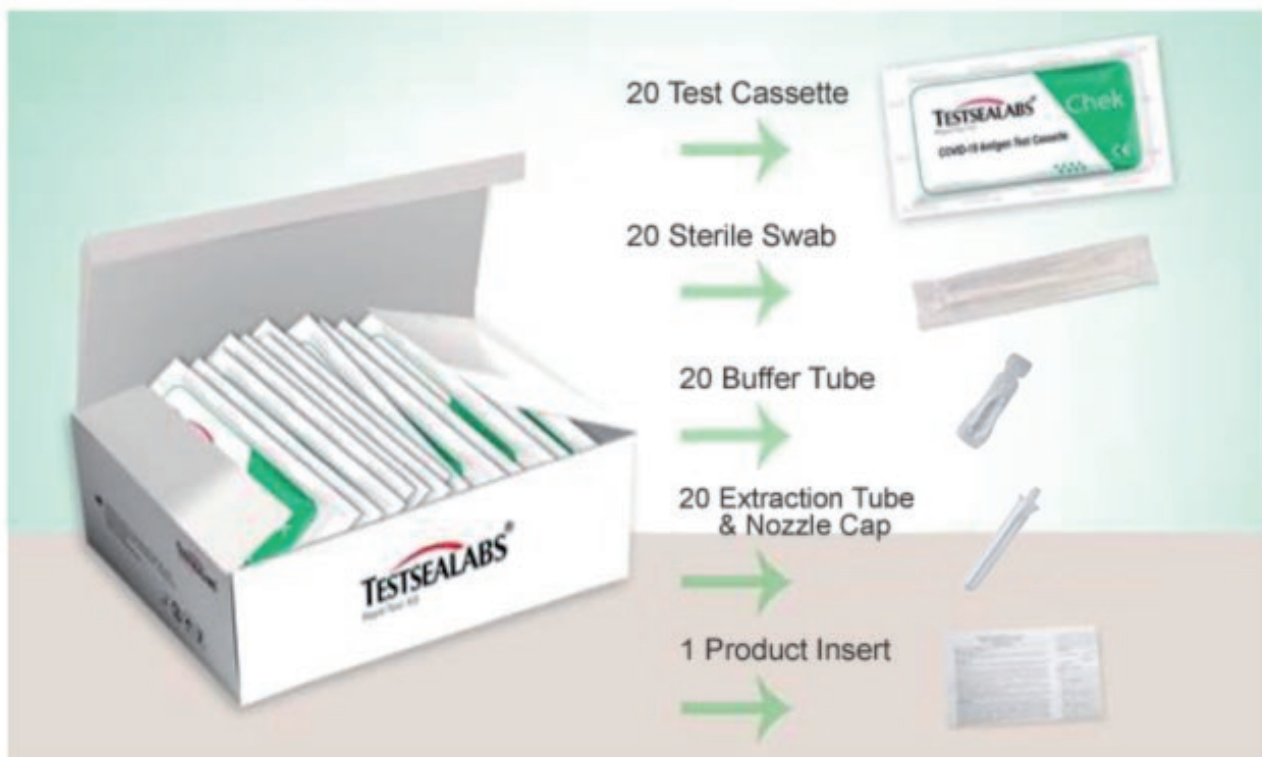
## TESTSEALABS® COVID-19 ANTIGEN TEST CASSETTE KIT SPECIFICATIONS:

20 Tests/Box

600 Tests / CTN

47 x 43 x 34.5cm

9 / 10.5 KG







The TESTSEALABS® COVID-19 Antigen Test Cassette is being sold based on the following pricing and volume breaks (all prices exclude shipping):

<b>150 - 500 UNITS</b>	<b>1,000 UNITS</b>	<b>2,500 UNITS</b>
\$13.00 ex GST per test	\$12.50 ex GST per test	\$12.00 ex GST per test
<b>5,000 UNITS</b>	<b>10,000 UNITS</b>	<b>20,000 UNITS</b>
\$11.00 ex GST per test	\$10.50 ex GST per test	\$10.00 ex GST per test

## ORDERING PROCESS

1. Please email [info@pharmasoul.com.au](mailto:info@pharmasoul.com.au) to request an official Order Form
2. Once the official Order Form is complete, please email a copy to [info@pharmasoul.com.au](mailto:info@pharmasoul.com.au) and your order will be dispatched upon approval and once deposit has been received
3. All orders are subject to Special 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.



# COVID-19 RAPID ANTIGEN TEST



<b>DESCRIPTION:</b>	TESTSEALABS® COVID-19 Antigen Test Cassette
<b>PRODUCT CODE:</b>	TSL-RAT
<b>FEATURES:</b>	<ul style="list-style-type: none"><li>• Rapid Antigen Test</li><li>• Instant results in 10 mins</li><li>• Easy to use</li><li>• High sensitivity</li><li>• High specificity</li><li>• No equipment required</li></ul>
<b>CERTIFICATIONS:</b>	<ul style="list-style-type: none"><li>• TGA</li><li>• CE</li><li>• ISO</li></ul>
<b>CASE SPECIFICATIONS:</b>	<ul style="list-style-type: none"><li>• 20 Tests per Box</li><li>• 600 Tests / CTN</li><li>• Dimensions: 47 x 43 x 34.5cm (10.5kg)</li></ul>
<b>SHIPPING:</b>	Price excludes shipping
<b>TESTING SERVICE:</b>	Optional testing service can be provided Please enquire for details

# PharmaSUL



**KEEPING YOU SAFE AND PROTECTED.**

**CONTACT US:**

300 Oxford Street Bondi Junction NSW 2022

PO Box 117 Vaucluse NSW 2030

[info@pharmasoul.com.au](mailto:info@pharmasoul.com.au)

0413 209 836