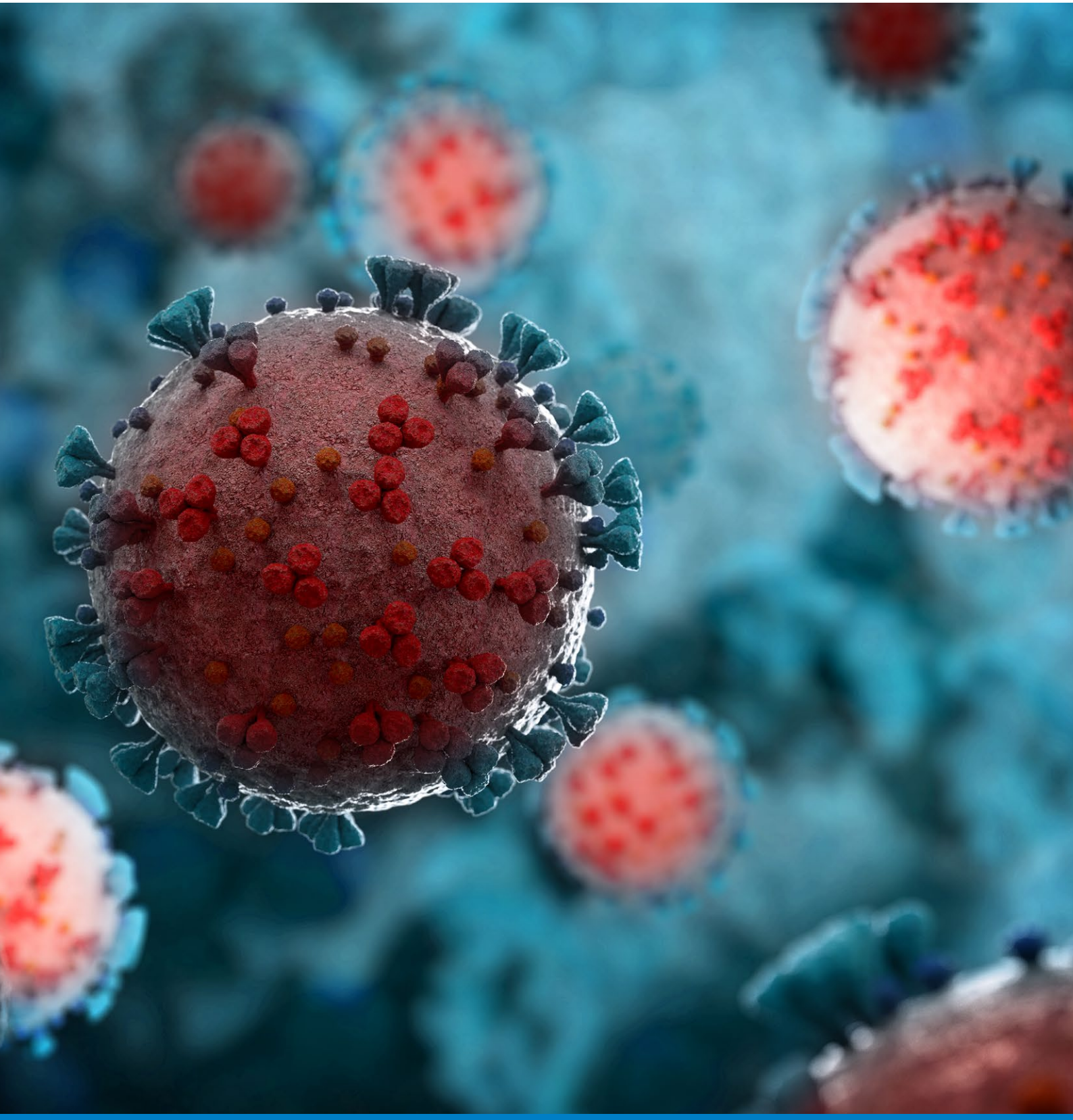
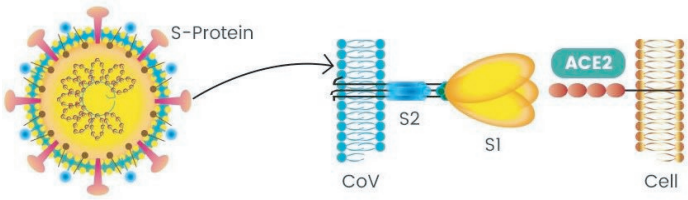
PharmaSOUL



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:

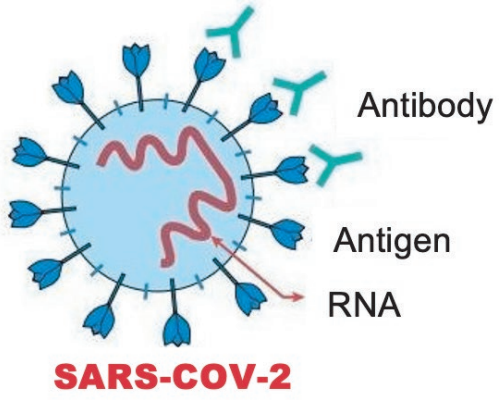
MOST COMMON SYMPTOMS:

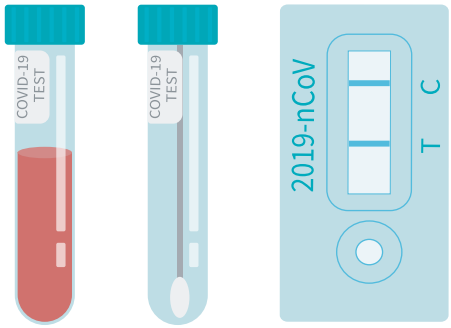
- Fever
- Dry cough
- Tiredness

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

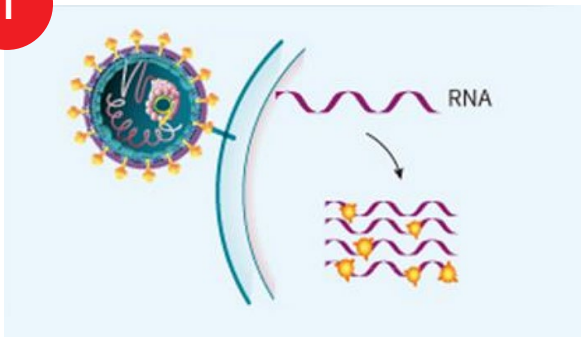
TEST METHOD	PCR	IgM / IgG ANTIBODY RAPID TEST	ANTIGEN RAPID TEST (LATEX)
ENVIRONMENTAL REQUIREMENTS	High requirements for laboratory environment	Low environmental requirements, not necessarily performed in the laboratory	Low environmental requirements, not necessarily performed in the laboratory
OPERATIONAL 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.

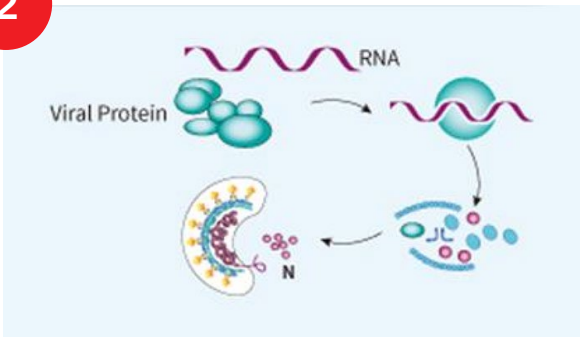
1



REPLICATION

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

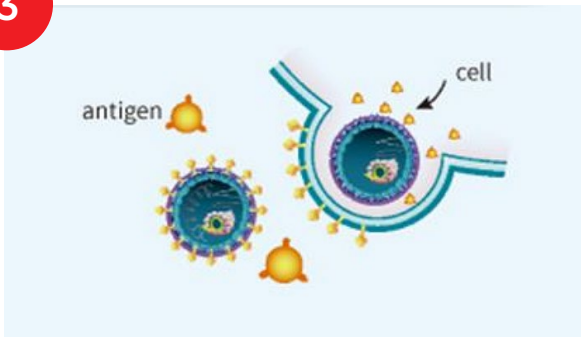
2



COMPOSITION

Successfully replicated RNA + viral protein

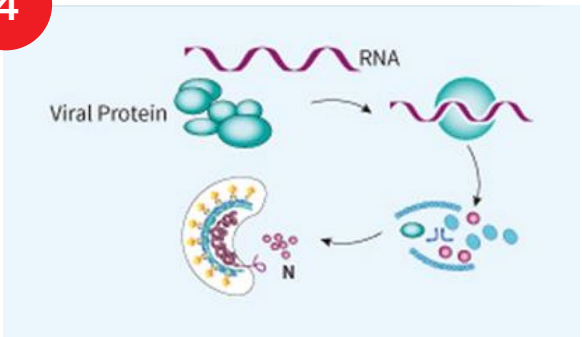
3



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

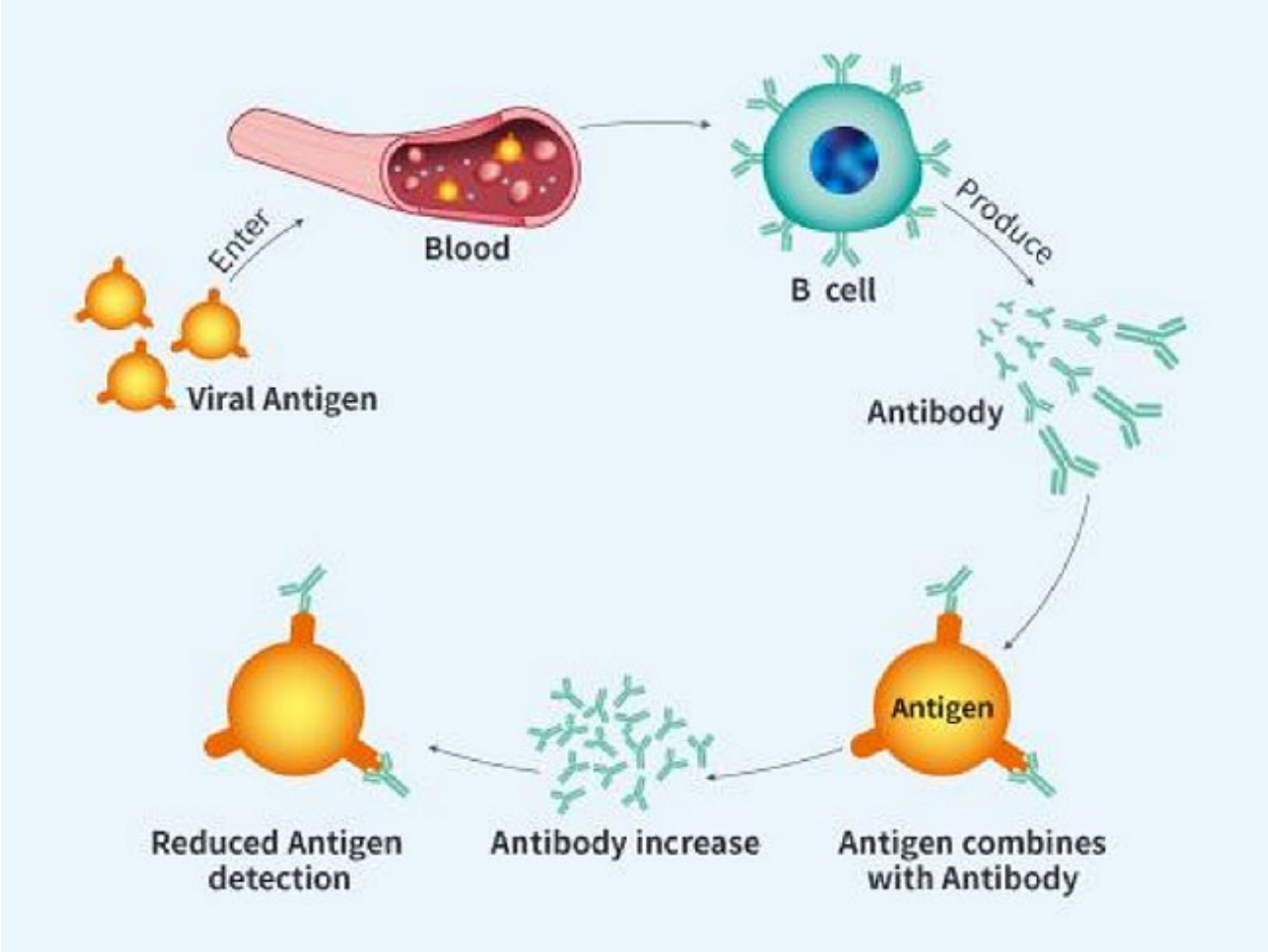
COVID-19 ANTIGEN TEST

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)

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.

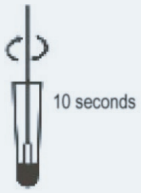
3

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.

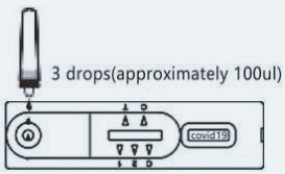
6

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

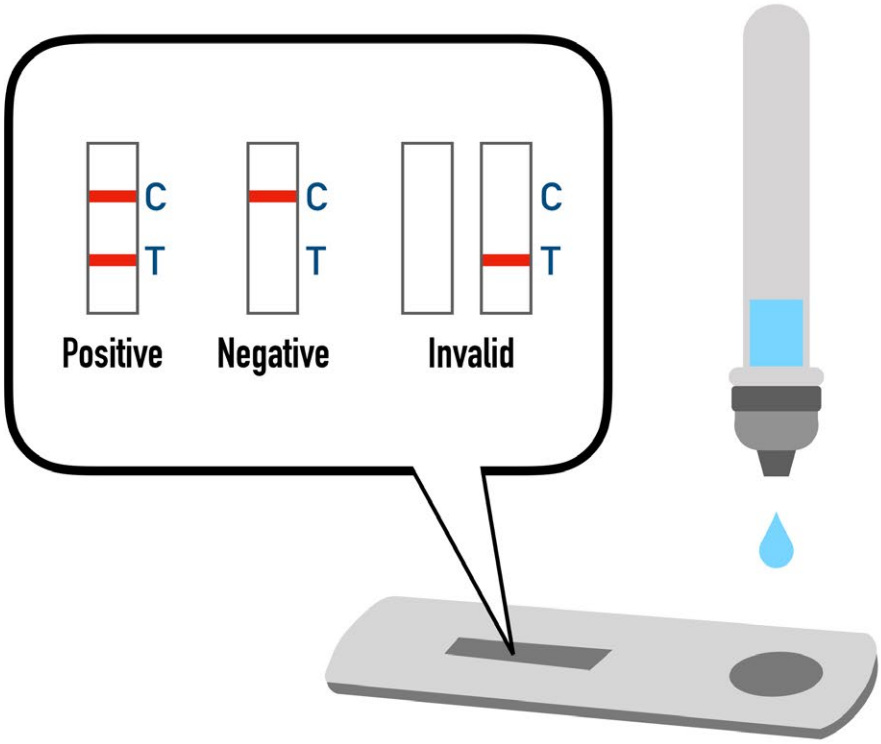


Transfer 3 drops (approx. 100UL) to the sample window of the test cassette.

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%

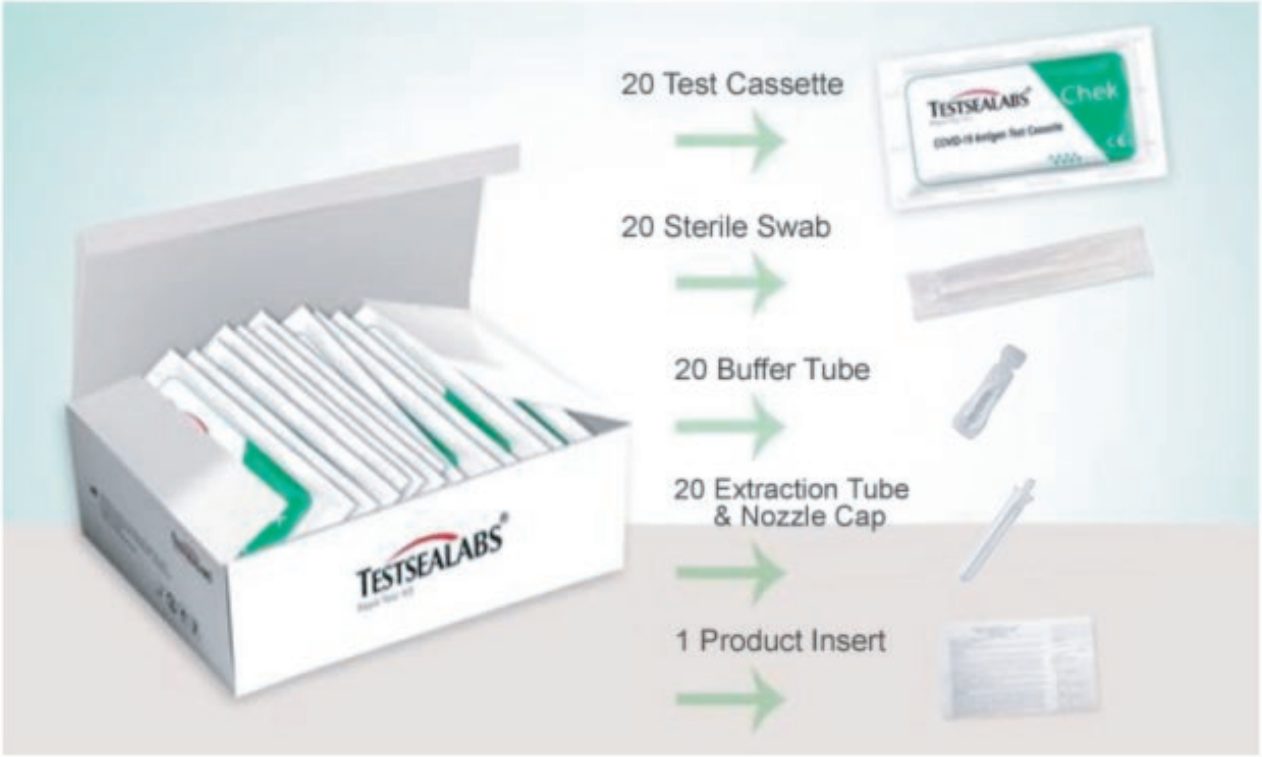
The test results meet the recommended performance standards as listed by the World Health Organisation.

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:

- Rapid Antigen Test
- Instant results in 15 mins
- Easy to use
- High sensitivity
- High specificity
- No equipment required

CERTIFICATIONS:

- TGA
- CE
- ISO

CASE SPECIFICATIONS:

- 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

FREQUENTLY ASKED QUESTIONS

WHY HAS THE TGA IMPOSED CONDITIONS ON SUPPLY FOR RAPID ANTIGEN TESTS?

The TGA has approved a significant number of rapid antigen tests.

So that they are appropriately used, and the results interpreted correctly, they can currently only be legally supplied under specific conditions. These include for use by trained health practitioners, and trained staff under their supervision, to ensure a suitable health practitioner is available to provide immediate clinical advice and treatment if required.

The conditions were recently updated to clarify:

- in what circumstances the tests can be supplied
- who can perform the test; and
- the requirements for supervision of testing.

These conditions reflect the importance of correct interpretation of results, advice and treatment being available at the time of testing. The requirement for healthcare professional involvement and the prohibition on self-testing reflect the critical importance of immediate notification of positive cases to state and territory health authorities so that contact tracing and processes to manage outbreaks can immediately start.

In a potential later scenario, where low level community transmission is being tolerated in a vaccinated population, it may be appropriate to review these requirements.

CAN TESTS BE PERFORMED BY PERSONS WHO ARE NOT HEALTH PRACTITIONERS?

Yes, but the testing needs to be performed under the overall supervision of a health practitioner, medical practitioner or paramedic and the person performing the test has been trained in the correct use and interpretation of the tests.

Use of the test by untrained persons and testing performed outside the supervision of a health practitioner would mean that the person or organisation could be liable if something goes wrong with the performance or interpretation of the test.

For information on relevant health practitioner see the question, ‘What is meant by health practitioner?’

WHERE OR WHO CAN THE TESTS BE SUPPLIED TO?

The tests can be supplied for use by specified health practitioners at the point of care to the following:

1. Registered medical practitioners or paramedics, or an organisation, business or institution that employs or engages a registered medical practitioner or paramedic to perform or oversee performance of the test.
2. Residential care (disability and rehabilitation facilities) and aged care facilities that employ or engage health practitioners (for example, nurses) to conduct or perform the test. If the residential care or aged care facilities provide care in the home this condition would also allow for performance of the test to be conducted by a health practitioner or paramedic.
3. Organisations, businesses, or institutions (that do not have the primary function of providing healthcare services) that employ or engage health practitioners or paramedics to conduct or oversee performance of the tests. For example, rapid antigen tests are being used in the mining sector consistent with these conditions.

The tests can also be supplied to accredited laboratories and to Commonwealth, state or territory government departments, in cooperation with their relevant health departments.

FREQUENTLY ASKED QUESTIONS

WHAT IS MEANT BY HEALTH PRACTITIONER? IS THIS THE SAME AS A HEALTHCARE PROFESSIONAL?

Health practitioner is defined in Section 3 of the *Therapeutic Goods Act 1989* (the Act) and is not necessarily the same as a healthcare professional. The conditions of inclusion on rapid antigen tests refer specifically to a health practitioner and not 'healthcare professional'.

Health Practitioner as defined by the Therapeutic Goods Act 1989 means:

a person who, under a law of a State or internal Territory, is registered or licensed to practice in any of the following health professions:

1. Aboriginal and Torres Strait Islander health practice
2. dental (not including the professions of dental therapist, dental hygienist, dental prosthetist or oral health therapist)
3. medical
4. medical radiation practice
5. nursing
6. midwifery
7. occupational therapy
8. optometry
9. pharmacy
10. physiotherapy
11. podiatry
12. psychology

The list above includes medical practitioners, pharmacists, and nurses along with others, but not for example pharmacy assistants, dental assistants, or personal care workers in aged care. Paramedics are not included in the definition of Health Practitioner in the Act but have been specified as a suitable health practitioner for the purposes of supply and use of rapid antigen tests.

The registration or licensing of a health practitioner, can be checked through the *Australian Health Practitioner Agency (AHPRA)*. For the purposes of rapid antigen testing health practitioner also includes a person registered under a law of a state or territory to practice paramedicine (as specified in the conditions of inclusion).

A health practitioner, including a medical practitioner or paramedic, who performs or supervises rapid antigen testing, takes on full responsibility for all testing conducted under their supervision including keeping records of such training. For further information see question 'What are the responsibilities of the health practitioner?'

IS IT OKAY FOR THE SAMPLE FOR TESTING TO BE SELF-COLLECTED? DOES SELF-COLLECTION OF A SPECIMEN ALSO NEED TO BE SUPERVISED?

Yes, samples may be self-collected but this must be supervised. This is an important step in the testing process.

Where a sample is self-collected by an individual, the collection must be supervised to verify patient identification and ensure an appropriate sample is collected. Poor sample collection is a common cause of error and can result in false negative results. Whoever is performing the actual rapid antigen test must also be able to verify which person the sample was collected from.

FREQUENTLY ASKED QUESTIONS

It is important to note the following if self-collection of a sample is necessary this must be conducted under the direct supervision of a person who has been trained in sample collection.

Further information on self-collection of specimens can be found in advice from members of the *Public Health Laboratory Network*.

Click here **to read the Therapeutic Good Administration's full list of Q&As regarding conditions of supply for rapid antigen tests.**

PharmaSOUL

KEEPING YOU SAFE AND PROTECTED.

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