InnoScreen™ COVID-19 Antigen Rapid Test Device (Self-Test)

REF SCOV-23/H002
SCOV-23/H020

InnovationScientific

INSTRUCTIONS FOR USE

You must follow the test instructions carefully to get an accurate result. Rapid antigen test is less reliabe than PCR when testing an asymptomatic patient or testing patient after 7 days of symptom onset as it may produce false negative result. Do not use the test for child under 2 years old. For children 2-15 years old, the test should be performed by an adult. **For in vitro diagnostic use only.**

IMPORTANT: Swabbing the nostrils is critical. If you do not swab your nose, the device will produce a false negative result.

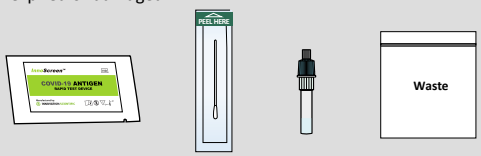
Scan QR code to access online tutorial
For Customer Support
Call 1300 165 061 (9am - 7pm AEST/ 9am - 8pm AEDT, 7 days per week)

HOW TO PERFORM THE TEST - Follow each step in numbered order

Materials provided:
- Single use swab
- Test cassette
- Extraction tube
- Waste bag

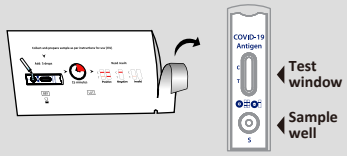
You will also need:
- Tissues
- Timer/watch

1 Unpack the test components.DO NOT DISCARD the box. Ensure you have all components required. DO NOT USE if they are expired or damaged.



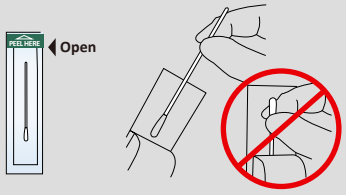
2 Gently blow your nose into a tissue to remove excess mucus. Wash your hands with soap and water for at least 20 seconds or use hand sanitiser.

3 Remove the test cassette from the pouch and place it on a flat, clean surface.DO NOT TOUCH the test window.

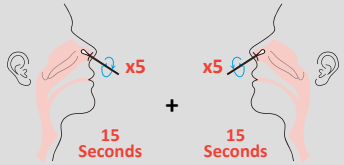


4 Insert the extration tube into the hole on the box. Unscrew the blue cap. Keep the cap aside, DO NOT DISCARD.

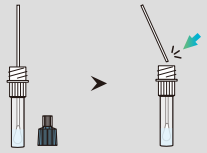
5 Open the swab from the end marked"PEEL HERE" and remove swab. DO NOT TOUCH the swab tip.



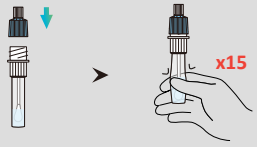
6 Gently insert the swab about 1-2cm into RIGHT nostril, rubbing against the nasal wall in a circular motion for at least 5 times for total of 15 seconds. Remove the swab then repeat the process with LEFT nostril.



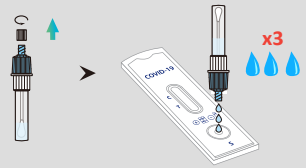
7 Place the swab into the extration tube. Break off the swab handle at the break point. Discard the break off handle.



8 Replace the blue cap on the tube. Squeeze the lower part of the tube against the swab tip inside the tube 15 times.



9 Unscrew the white cap of the tube. Invert the tube then gently squeeze the tube to add 3 full drops of solution to the sample well marked "S" on the cassette.



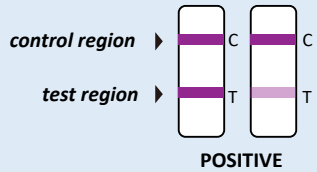
DO NOT MOVE the cassette when the test is in process.

10 Start timer and read results at 15 minutes as per INTERPRETING THE RESULTS section on this page. Results should not be read after 20 minutes.

11 After reading the result, place all the used components in the plastic bag provided and dispose into a general waste bin.

INTERPRETING THE RESULTS

POSITIVE *(Two coloured lines apperar in control region and test region)*



One purple line next to "**C**" and one purple line next to "**T**" Indicates COVID-19 positive

The color intensity in the test region "T" may be faint. Any pink/purple line visible next to "T" is positive. A positive results should be confirmed by a PCR test for follow-up clincal care.

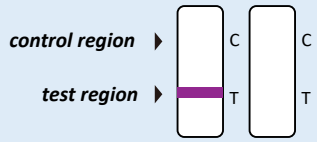
A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 were detected, and the patient is very likely to be infected with the virus and presumed to be contagious. Test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicentre locations) in making a final diagnosis and patient management decisions. Patient management should follow current Department of Health's guidelines.

NEGATIVE *(Only one coloured line appears in the control region)*

Only one purple line only next to "**C**" indicates negative

A negative test result for this test means that antigens from SARS-CoV-2 were not present in the specimen above the limit of detection. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19 particularly if the test is not performed within 7 days of symptom onset. This means that you could possibly still have COVID-19 even though the test is negative. If you test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider. In case of suspicion and you do not have symptom, repeat the tests after 1-2 days, as the coronavirus cannot be accurately detected in all phases of an infection.

INVALID TEST *(No coloured line appears in the control region)*



No purple line next to "**C**" indicates invalid

An invalid result is likely caused by user not following the procedure properly. Read instruction for use carefully before restart with a new test device. If the problem persists, contact technical support.

For local support from state and territory health department, see details in assistance section at back >>>

INTENDED USE

The InnoScreen™ COVID-19 Antigen Rapid Test Device (Self-test) is a rapid lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens from individuals with or without symptoms suspecting a COVID-19 infection. This test is authorized for non-prescription home use on individuals aged 2 years or older suspected of COVID-19 by their healthcare provider in a non-laboratory setting. If the test is being used for testing individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection, testing should be scheduled twice over two (or three) days with at least 24 hours (and no more than 36 hours) between tests.

INTRODUCTION

COVID-19 is the disease associated with SARS-CoV-2, which was first identified in China at the end of 2019. The virus is transmitted mainly via respiratory droplets that people sneeze, cough, or exhale. The incubation period for COVID-19 is currently estimated at between 2 and 14 days. Common symptoms of COVID-19 infection include fever, cough and respiratory symptoms such as shortness of breath and breathing difficulties. More serious cases develop severe pneumonia, acute respiratory distress syndrome, sepsis and septic shock that can lead to the death of the patient. People with existing chronic conditions seem to be more vulnerable to severe illness.

PRINCIPLE

The InnoScreen™ COVID-19 Antigen Rapid Test Device is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect SARS-CoV-2 viral nucleoprotein antigens in nasal swabs.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Read the Package Insert prior to use. Directions should be read and followed carefully.
- Children or teenagers aged 2 to 15 years old should have their samples collected and tested by an adult. Do not use the tests for anyone under 2 years of age.
- Do not use on anyone who is prone to nosebleeds or has had facial or head injury/surgery in the last 6 months.
- Wear a safety mask or other face-covering when collecting anterior nasal swab specimen from a child or another individual.
- Keep testing kit and kit components away from children and pets before and after use.
- Do not use kit or components beyond the expiration date.
- Do not operate your test outside of storage conditions.
- Test devices are packaged in foil pouches that exclude moisture during storage. Leave the test device in the sealed pouch until just before use. Do not use the test device if pouch is damaged or open.
- All kit components are single use items. Do not use with multiple specimens. Do not reuse the used kit components.
- Do not mix components from different kit lots.
- Do not touch swab tip when handling the swab sample.
- Perform the test immediately after collecting the sample.
- Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false-positive result. Avoid touching any bleeding areas of the nasal cavity when collecting specimens.
- When collecting a nasal swab sample, use only the Nasal Swab provided in the kit.
- Keep foreign substances and household cleaning products away from the test during the testing process. Contact with foreign substances and household cleaning products may result in an incorrect test result.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
- Handle all specimens as though they contain infectious agents.
- Do not use the Extraction buffer if it is discolored or turbid.
- Avoid skin contact with buffer as it contains trace amount of sodium azide. Buffer solution should not be ingested.
- Keep the test device on a flat surface during the testing.
- Do not interpret the test result before 15 minutes and after 20 minutes of starting the test.
- Dispose of used kit components and patient samples in household trash.
- INVALID RESULTS can occur when an insufficient volume of extraction reagent is added to the test card. To ensure delivery of adequate volume, hold vial vertically, 1 cm above the sample well, and add drops slowly.

STORAGE AND STABILITY

- Store the InnoScreen™ COVID-19 Antigen Rapid Test Device at 2-30°C.
- **DO NOT FREEZE**.
- Kit contents are stable until the expiration dates marked on their outer packaging and containers. Once opened the device should be used immediately.

HAZARDOUS INGREDIENTS FOR LIQUID REAGENT

Chemical Name/CAS	GHS Code for each ingredient	Concentration
Sodium azide/ 26628-22-8	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310	<0.02 %

LIMITATIONS OF THE TEST

1. Negative results do not rule out SARS-CoV-2 and / or other types of virus infection, particularly in those who have been in contact with the virus or have symptoms. Follow-up testing with a confirmatory tests eg. PCR should be considered to rule out infection in these individuals.
2. The InnoScreen™ COVID-19 Antigen Rapid Test Device is for in vitro diagnostic use and should only be used for the qualitative detection of SARS-CoV-2 antigen. The intensity of color in a positive band should not be evaluated as "quantitative or semi-quantitative". The test is for presumptive screening only. Consult a medical practitioner for confirmatory testing of positive results by a laboratory PCR test and follow-up clinical care should be always considered.
3. Both viable and nonviable SARS-CoV-2 viruses are detectable with the COVID-19 antigen Rapid Test Device. Test performance depends on antigen load in the specimen and may not correlate with cell culture performed on the same specimen.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test but should only be made by the physician after all clinical and laboratory findings have been evaluated.
5. Failure to follow the TEST PROCEDURE and RESULT INTERPRETATION may adversely affect test performance and/or invalidate the test result.
6. A negative result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor-quality specimen is collected. Improper transport or storage of sample may also lead to false negative results.
7. A positive result can not necessarily determine whether a person is infectious. Confirmatory testing with a laboratory PCR test should be considered to confirm infection in these individuals for follow up clinical care.
8. Results obtained with this assay, particularly in case of weak test lines that are difficult to interpret, should be used in conjunction with other clinical information available to the physician.
9. The use of rapid antigen tests in screening asymptomatic individuals or on patients in late stage of infection (>7 days of onset of symptom) may produce false negative results due to low level of antigen presented in these samples. Please refer to clinical evaluation for details.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

Clinical study was conducted to compare the results obtained on InnoScreen™ COVID-19 Antigen Rapid Test Device verses RT-PCR. Self-collected nasal swabs from 1486 participants with or without symptom were tested. InnoScreen™ COVID-19 Antigen Rapid Test Device has an overall sensitivity of 89.47% for symptomatic patient (within 7 days of symptom onset) and 68.75% for asymptomatic patient. The specificity is 99.53%.

Usability Study

A usability study was conducted for lay person. 224 enrolled participants were provided a kit and instruction for use to test themselves without any other assistance. The relative sensitivity was 92.31% (24/26) and relative specificity was 100% (198/198) when compared to RT-PCR. The results indicate the test is easy to understand and perform by a lay person.

Limit of detection

The limit of detection for InnoScreen™ COVID-19 Antigen Rapid Test Device was determined to be 126 $TCID_{50}$/mL using inactivated SARS-CoV-2 Virus.

$TCID_{50}$ (Median Tissue Culture Infectious Dose) is a method used by virologist to verify the viral titer of a testing virus.

SARS-CoV-2 variants

The following SARS-CoV-2 variants were tested on InnoScreen™ COVID-19 Antigen Rapid Test Device. All the variants can be detected at above mentioned limit of detection level.

SARS-CoV-2 Variants of Concern tested		
B.1.1.7	Alpha	United Kingdom
B.1.351	Beta	South Africa
B.1.427/B.1.429	Epsilon	United States
B.1.617.2	Delta	India
P.1	Gamma	Japan/Brazil

Cross Reactivity

The following commensal and pathogenic microorganisms that may be present in the nasal cavity were tested on InnoScreen™ COVID-19 Antigen Rapid Test Device for cross reactivity and potential interference. Cross-reactivity or interference caused by these microorganisms is unlikely to occur.

Microorganisms tested	
HCoV-HKU1	Parainfluenza 1/2/3 virus
HCoV-OC43	Human metapneumovirus
HCoV-NL63	Rhinovirus
HCoV-229E	Coxsackie virus A16
Measles virus	Haemophilus influenzae
Streptococcus pneumoniae	Candida albicans
Epstein-Barr virus	Mycobacterium tuberculosis
Bordetella parapertussis	Norovirus
Bordetella pertussis	Mump virus
Influenza A (H1N1)pdm09	Legionella pneumophila
Influenza A (H3N2)	Mycoplasma pneumoniae
Influenza A (H5N1)	Chlamydia pneumoniae
Influenza A (H7N9)	Streptococcus pyogenes
Influenza A (H7N7)	Streptococcus agalactiae
Influenza B Victoria lineage	Group C Streptococcus
Influenza B Yamagata lineage	Staphylococcus aureus
Respiratory syncytial virus	Pooled human nasal wash
Adenovirus	

Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the respiratory tract, were tested on InnoScreen™ COVID-19 Antigen Rapid Test Device. There is no interference were found to affect the test performance.

Substances tested	
3 OTC nasal sprays	Guaiacol glyceryl ether
3 OTC mouthwashes	Mucin
3 OTC throat drops	Mupirocin
4-acetamidophenol	Oxymetazoline
Acetylsalicylic acid	Phenylephrine
Albuterol	Phenylpropanolamine
Chlorpheniramine	Relenza (zanamivir)
Dexamethasone	Rimantadine
Dextromethorphan	Tamiflu (oseltamivir)
Diphenhydramine	Tobramycin
Doxylamine succinate	Triamcinolone
Flunisolide	

ASSISTANCE

State and territory contact details

Australian Capital Territory Coronavirus Helpline	02 6207 7244 https://health.act.gov.au/
New South Wales Coronavirus Helpline (Service NSW)	137 788 https://www.health.nsw.gov.au/
Northern Territory Coronavirus National Hotline	1800 020 080 https://health.nt.gov.au/
Queensland Coronavirus Helpline	134 268 https://www.health.qld.gov.au/
South Australia Coronavirus Helpline	1800 253 787 https://www.sahealth.sa.gov.au/
Tasmanian Public Health Hotline	1800 671 738 https://www.health.tas.gov.au/
Victoria Coronavirus Hotline	1800 675 398 https://www.dhhs.vic.gov.au/
Western Australia Coronavirus Hotline	1800 595 206 https://www.healthywa.wa.gov.au/

Technical support

If you have any questions regarding the use of this product, please call Innovation Scientific self-test product support 1300 165 061 (9am to 7pm AEST/9am to 8pm AEDT) or email covid19support@innovationsci.com.au. Test system problems may also be reported to the TGA through the Users Medical Device Incident Report program (email iris@tga.gov.au or call 1800 809 361).

GLOSSARY OF SYMBOLS

IVD ***In vitro* diagnostic**	**Caution**
Instructions for use	**Use by date**
Manufacturer	LOT **Batch code**
Do not re-use	REF **Catalog number**
Temperature limit	**Number of tests**

Manufactured by:
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