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. 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 a relative sensitivity of 94.96% (95% CI: 89.90% - 97.95%) for symptomatic patient within 7 days of symptom onset (PCR Ct value≤30) and 84.62% (95% CI:65.13% - 95.64%) for asymptomatic patient (PCR Ct value≤30). The specificity is 99.53% (95% CI: 98.98% - 99.83%).

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
B.1.1.529	Omicron	South Africa

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 565 010 (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**

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