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

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 extraction 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 extraction 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.

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 appear in control region and test region)

- **Control region**
  - C
  - C one purple line next to "C"

- **Test region**
  - T
  - T one purple line next to "T"

Indicates COVID-19 positive

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

- **Control region**
  - C
  - Only one purple line next to "C" indicates negative

- **Test region**
  - T

Indicates COVID-19 negative

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

- **Control region**
  - C
  - No purple line next to "C" indicates invalid

- **Test region**
  - T

Indicates COVID-19 invalid

For local support from state and territory health department, see details in assistance section at back...
Oxymetazoline should be scheduled twice over two (or three) days with at least 24 hours other epidemiological reasons to suspect COVID infection, test should be scheduled twice over two (or three) days with at least 24 hours.

**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 secrete, 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, apnea, 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 nucleic acid antigens in nasal swabs.

**PRECAUTIONS**

- For in-vitro diagnostic use only.
- Follow 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 under 2 years of age.
- Do not use on anyone who is prone to nosebleeds or who has had facial or head injuries/surgery in the last 6 months.
- Wear a safety mask or other face protective gear when handling the swab.
- As with all sample collection devices, 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.
- Hand all specimens as though they contain infectious agents.
- Do not use the Extraction buffer if it is discolored or turbid.

**STORAGE AND STABILITY**

Store the InnoScreen™ COVID-19 Antigen Rapid Test Device at 2-25°C.

**DO NOT FREEZE.**

- Kits 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**

<table>
<thead>
<tr>
<th>Chemical Name/CAS</th>
<th>GHS Code for each ingredient</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium azide/</td>
<td>H300</td>
<td>0.02 %</td>
</tr>
<tr>
<td>Acute Tox. 2 (Oral), H310</td>
<td>Acute Tox. 1 (Dermal), H310</td>
<td></td>
</tr>
</tbody>
</table>

**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.
2. Follow-up testing with a confirmatory test or PCR should be considered to rule out infection in these individuals.
3. 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 test and follow-up clinical care should be always considered.
4. Both viable and nonviable SARS-CoV-2 viruses are detectable in 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.
5. 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.
6. Failure to follow the TEST PROCEDURE and RESULT INTERPRETATION may adversely affect test performance and/or invalidate the test result.

**PERFORMANCE CHARACTERISTICS**

**Clinical Study**

Clinical study was conducted to compare the results obtained on InnoScreen™ COVID-19 Antigen Rapid Test Device versus RT-PCR. Self-collected nasal swabs from 1486 participants with or without symptoms were tested. InnoScreen™ COVID-19 Antigen Rapid Test Device has an overall sensitivity of 99.47% for symptomatic patient (within 5 days of symptom onset) and 68.75% for asymptomatic patient. The specificity is 99.53%.

**Uses/Effects**

A usability study was conducted for lay. 242 enrolled participants were provided a kit and instruction for use to test themselves without any other assistance. The relative specificity was 93.21% (24/26) and relative specificity was 100% (18/18) when compared to RT-PCR. The results indicate the test is easy to understand and perform by a layperson.

**Limit of detection**

The limit of detection for InnoScreen™ COVID-19 Antigen Rapid Test Device was determined to be 125 TCID50/mL using inactivated SARS-CoV-2 Virus.

**TCID50 (Median Tissue Culture Infectious Dose)** is a method used by virologists to verify the 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 as above mentioned limit of detection level.

**SARS-CoV-2 Variants of Concern tested**

<table>
<thead>
<tr>
<th>Variant</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>B.1.1.7</td>
<td>UK</td>
</tr>
<tr>
<td>B.1.351</td>
<td>South Africa</td>
</tr>
<tr>
<td>B.1.427/1.129</td>
<td>United States</td>
</tr>
<tr>
<td>B.1.617.2</td>
<td>India</td>
</tr>
<tr>
<td>B.1.617.2</td>
<td>Japan</td>
</tr>
</tbody>
</table>

**Cross Reactivity**

The following common 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**

- Parainfluenza 1/2/3 virus
- Human metapneumovirus
- Respiratory syncytial virus
- H3N2 virus
- Human rhinovirus
- Coxackie virus A16
- H1N1 virus
- H5N1 virus
- H7N9 virus
- Streptococcus pneumoniae
- Candida albicans
- Mycobacterium tuberculosis
- Neisseria
- Chlamydia pneumoniae
- Mumps virus
- Legionella pneumophila
- Mycoplasma pneumoniae
- Streptococcus pyogenes
- Streptococcus ugalae

**ASSISTANCE**

State and territory contact details

- Australian Capital Territory Coronavirus Helpline [https://health.act.gov.au/]
- New South Wales Coronavirus Helpline (Service NSW) [https://www.health.nsw.gov.au/]
- Northern Territory Coronavirus Helpline [https://nt.gov.au/heath]
- Queensland Coronavirus Helpline [https://www.health.qld.gov.au/]
- South Australia Coronavirus Helpline [https://www.sahealth.sa.gov.au/]
- Tasmania Public Health Hotline [https://www.tas.gov.au/PublicHealth]
- Victoria Coronavirus Helpline [https://www.coronavirus.vic.gov.au/]
- Western Australia Coronavirus Helpline [https://www.health.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 9pm AEDT) or email covid@support.innovationsci.com. Test system problems may also be reported to the TGA through the Users Medical Device Incident Report program (email medicaldeviceincidents@tga.gov.au or call 1800 020 080).

**GLOSSARY OF SYMBOLS**

**IVD**

- In vitro diagnostic

**Instructions for use**

**Manufacturer**

**Do not re-use**

**Temperature limit**

**Number of tests**

**Manufactured by: Innovation Scientific Pty Ltd**

1/87 Railway Road North, Mulgrave
NSW 2576 Australia
Website: www.innovationsci.com.au