InnoScreen™

Flu A/B, RSV & COVID-19
Antigen Combo Test Device
(Self-Test)

REF SCFR-44/H005

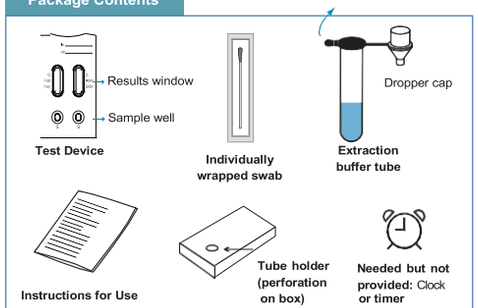
INSTRUCTIONS FOR USE

The Flu A/B, RSV & COVID-19 Antigen Combo Test Device is a rapid visual immunoassay for the direct and qualitative detection of SARS-CoV-2, influenza A, influenza B and respiratory syncytial viral antigens from nasal secretions. The test is designed for self-testing use.

Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.

Scan QR code to access online tutorial For Customer Support Call 1300 565 010 (9am - 7pm AEST/ 9am - 8pm AEDT, 7 days per week)

Package Contents



Storage and Stability

Store the kit at 2-30°C / 36-86°F and protect from direct sunlight. The expiration date of the materials is indicated on the external packaging. Do not freeze the kit.

Prepare for the Test

1. Check expiration date printed on test.
2. Wash your hands thoroughly.
3. Open the pouch and place the test cassette on a flat surface.
4. Peel off the aluminum foil cover of the extraction buffer.
5. Insert the extraction buffer into the tube holder by punching through the perforation on the box.

Test Procedure

1. Open the swab packaging. Remove the swab using the stem.

Be careful not to touch the soft, fabric tip of the swab.

2. Insert the swab about ½ to ¾ inch into the nostril. (Collect the anterior nasal swab specimen).
3. Circle the swab against the nasal wall **5 times**.

Do not just spin the swab.

4. Pull the swab out of the nose while rubbing it against the walls and repeat the process with the same swab in the other nostril.

WARNING: Inaccurate test results may occur if the nasal swab specimen is not properly collected. Collect specimen and immediately perform test according to instructions.

Note: With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need a second person to hold the child's head while swabbing.

5. Place swab into the tube that you previously placed in the tube holder.
6. Remove the tube from the tube holder. Rotate the swab while squeezing the lower part of the tube 10-15 times so that a slight pressure is exerted on the tip of the swab.

WARNING: Failure to rotate the swab 10-15 times may lead to incorrect results.

WARNING: Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.

7. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
8. Secure the dropper cap onto the buffer tube.
9. Invert the tube and add 3 drops of the solution to sample well by gently squeezing the tube.

WARNING: Do not hold the dropper tube more than ¼ inch above sample well.

WARNING: Adding other than the recommended number of drops may result in inaccurate results.

10. Set a timer and read the results at 15 minutes.

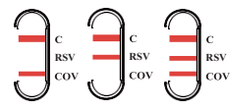
15 Minutes

WARNING: Do not read the result before 15 minutes or after 30 minutes.

Dispose of used kit components and patient samples in household trash.

Read and Interpret Your Results

For COVID-19&RSV Test -Positive



COVID-19 positive: Two coloured lines appear on the membrane. One line appears in the control region (C) and the other line appears in the COV region (COV).
RSV positive: Two coloured lines appear on the membrane. One line appears in the control region (C) and the other line appears in the RSV region (RSV).
COVID-19+RSV positive: One coloured band appears in the control region (C), and two other coloured bands appear in both COV region (COV) and RSV region (RSV).

A COVID-19 positive test result means it is very likely patients currently have COVID-19 disease. If you have a COVID-19 POSITIVE result, staying at home protects the people in your community and you should not visit high-risk settings like hospitals and aged and disability care settings. A RSV positive test result means that the virus that causes RSV was detected in the patients' sample, and it is very likely that the patient has RSV. If you have a RSV positive result, please consult a medical practitioner for clinical care.
NOTE: There is a very small chance that this test can give a result that is incorrect (a false positive). A positive result does not rule out co-infections with other pathogens.

Read and Interpret Your Results

For COVID-19&RSV Test-Negative

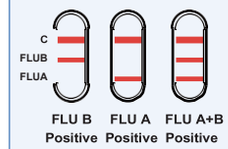
Negative: Only one coloured band appears in the control region (C), and band appears neither in the COV region (COV) nor RSV region (RSV).

A negative result for COVID-19 does not mean a person does not have COVID-19. If a person has symptoms, they should follow the guidance from the local state or territory health departments, and if unwell seek medical assistance.
A negative result does not mean a person is not infectious or does not have RSV. If you are unwell, please consult a medical practitioner for follow up care and continue to follow all public health advice on limiting the spread of RSV.
NOTE: Negative results are presumptive and may need to be confirmed with a molecular assay. If symptoms continue or suspected infection, you should be tested again with at least 24 hours and no more than 48 hours between tests as SARS-Cov-2 antigen cannot be precisely detected in all phases of an infection.

For COVID-19&RSV Test-Invalid

Invalid: No coloured band appears in the control region (C), whether a test band(s) is present or not.
Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

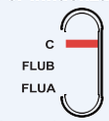
For Influenza A&B Test-Positive



Influenza A Positive: One coloured band appears in the control region (C), and another coloured band in the FLUA region (FLUA).
Influenza B Positive: One coloured band appears in the control region (C), and another coloured band in the FLUB region (FLUB).
Influenza A+B Positive: One coloured band appears in the control region (C), and two other coloured bands appear in both FLUA region (FLUA) and FLUB region (FLUB).

Co-infection with influenza A and B is rare. The positive results for both A and B should be considered an invalid result, and another test should be performed. If the test is again positive for both influenza A and B, the specimen should be re-tested by another method prior to reporting of results.
A positive test result means that the virus that causes influenza A or influenza B was detected in your sample, and it is very likely that you have influenza A or influenza B. You should adhere to the local epidemic prevention guidelines.
NOTE: There is a very small chance that this test can give a result that is incorrect (a false positive). A positive result does not rule out co-infections with other pathogens.

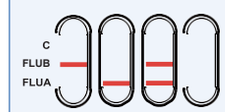
For Influenza A&B Test-Negative



Negative: Only one coloured band appears in the control region (C), and band appears neither in the FLUA region (FLUA) nor FLUB region (FLUB).

A negative test result means it is unlikely patients have influenza A/B disease. Please continue to observe local hygiene and safety measures.
NOTE: A negative result does not mean a person does not have influenza, and if symptoms persist, the person should seek medical attention and further testing if required.

For Influenza A&B Test-Invalid



Invalid: No coloured band appears in the control region (C), whether a test band(s) is present or not.
Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

INTENDED USE

The Flu A/B, RSV & COVID-19 Antigen Combo Test Device is a rapid, visual immunoassay intended for the direct and qualitative detection of nucleoprotein antigens of SARS-CoV-2 (COVID-19), Influenza A, Influenza B, and fusion protein antigen of Respiratory Syncytial Virus (RSV) in nasal swab specimens collected from individuals with respiratory infection symptoms. The test is most effective for detecting SARS-CoV-2 within the first 7 days of symptom onset, and Influenza A/B and RSV within the first 4 days of symptom onset. This test is designed for self-testing purposes. Children aged below 18 years old must be supervised or tested by an adult when carrying out the test. The assay provides a preliminary result that aids in the diagnosis of COVID-19, Influenza A/B, and/or RSV. This test has not been validated for use in asymptomatic individuals.

INTRODUCTION

The novel coronavirus (SARS-CoV-2) belongs to the β-coronavirus genus and causes COVID-19, an acute respiratory infectious disease to which the general population is susceptible. The primary sources of infection are symptomatic patients, but asymptomatic carriers can also transmit the virus. Current epidemiological studies indicate an incubation period of 1 to 14 days, with most cases manifesting within 3 to 7 days. Common symptoms include fever, fatigue, and dry cough; other symptoms such as nasal congestion, runny nose, sore throat, myalgia, and diarrhea are less frequent.

Influenza is a highly contagious acute viral respiratory infection, often causing widespread epidemics and pandemics. It is caused by viruses from the Orthomyxoviridae family, classified into three types: A, B, and C, based on the antigenic properties of their nucleoprotein and matrix proteins. Antigenic shifts in hemagglutinin and neuraminidase are responsible for the emergence of new strains in types A and B, while type C remains antigenically stable. Type A influenza is typically more prevalent and associated with the most severe epidemics. In contrast, type B infections are generally less severe, and type C infections are rare.

Respiratory Syncytial Virus (RSV) is a negative-sense, single-stranded RNA virus of the Paramyxoviridae family, causing highly contagious acute respiratory tract infections. Globally, RSV is responsible for up to one million deaths annually among infants and children under five years old and is a leading cause of nosocomial infections in hospitalized children. The mortality rate for children hospitalized with RSV infection ranges from 0.3% to 1.0% and increases to 2.5% to 4.0% in those with underlying cardiac or pulmonary conditions. RSV infection confers limited immunity, allowing for recurrent infections and the potential for severe disease throughout a person's lifetime.

RSV has a single serotype but is divided into two antigenic subgroups, A and B, which co-circulate in the community. Subgroup B is often associated with asymptomatic or mild infections, while more severe clinical outcomes are typically linked to subgroup A, which predominates in most outbreaks. RSV infections often coincide with the winter flu season, which can aid in diagnosis.

PRINCIPLE

The Flu A/B, RSV & COVID-19 Antigen Combo Test Device is designed for the qualitative detection of SARS-CoV-2, Influenza A, Influenza B, and RSV viral antigens through the visual interpretation of colour development on four individual test strips.

COVID-19 Test: Anti-SARS-CoV-2 antibodies are immobilised on the designated COV test region of the nitrocellulose membrane. During the testing process, if SARS-CoV-2 antigens are present in the specimen, they will bind to the anti-SARS-CoV-2 antibodies conjugated with coloured particles on the label pad. As the sample migrates along the strip via capillary action, the antigen-antibody complex will be captured by the immobilised anti-SARS-CoV-2 antibodies at the corresponding detection zone.

Influenza A/B Test: Anti-Influenza A and anti-Influenza B antibodies are immobilised on the respective FLUA and FLUB test regions of the nitrocellulose membrane. If the specimen contains Influenza A and/or B antigens, these will bind to the corresponding antibodies conjugated with coloured particles on the label pad. As the specimen migrates along the strip, the resulting complex will be captured by the immobilised anti-Influenza A or anti-Influenza B antibodies at the appropriate detection zones.

RSV Test: Anti-RSV antibodies are immobilised on the RSV test region of the nitrocellulose membrane. If RSV antigens are present in the specimen, they will bind to the anti-RSV antibodies conjugated with coloured particles on the label pad. As the specimen migrates along the strip, the antigen-antibody complex will be captured by the immobilised anti-RSV antibodies at the detection zone.

Excess coloured particles will be captured at the internal control zone. The appearance of coloured band(s) in the test region indicates a positive result for the corresponding viral antigens, while the absence of coloured bands indicates a negative result. The presence of a coloured band in the control region of each test strip serves as an internal procedural control, confirming that an adequate volume of specimen has been applied and that proper membrane wicking has occurred.

QUALITY CONTROL

Internal Procedural Controls

The Flu A/B, RSV & COVID-19 Antigen Combo Test Device includes built-in procedural controls to verify the proper functioning of the test. Each test strip has an internal control region to ensure the correct flow of the sample through the device. The presence of a coloured band at the "C" (control) line indicates that the test has been performed correctly and the sample has flowed as expected. The user should confirm the appearance of this red control line before interpreting the test results.

SAFETY PRECAUTIONS AND WARNINGS

- For in vitro diagnostic use only.
- Read the instructions for use thoroughly before use. Follow the directions carefully.
- This test is intended for single use only. Do not reuse any components.
- Use only the provided components from the same kit and do not mix with components from different lots.
- Children aged below 18 years old must be supervised or tested by an adult when carrying out the test.
- Do not use the test on individuals prone to nosebleeds or those who have had facial or head injuries/surgery in the past 6 months.
- Avoid contact of the swab tip with any surface before use and do not touch the swab tip during the collection process.
- Perform the test immediately after collecting the sample. Place the swab into the extraction buffer right after sample collection.
- Do not use the test kit or components if they are expired, damaged, or if the extraction buffer is discoloured or cloudy. This could indicate contamination.
- Wear a safety mask or face-covering when collecting samples from a child or another individual.
- Avoid contact with the extraction buffer, which contains trace amounts of sodium azide. If skin contact occurs, rinse with plenty of water.
- Keep the test and its components out of the reach of children and pets, both before and after use.
- Dispose of used kit components and patient samples in household trash.
- To avoid incorrect test results, keep foreign substances and household cleaning products away from the test during the testing process.
- Do not interpret the test result before 15 minutes or after 30 minutes of starting the test.
- Ensure adequate volume of extraction reagent is added to the test card by holding the tube vertically, no more than 1 inch above the sample well, and adding drops slowly.

STORAGE AND STABILITY

- Store the Flu A/B, RSV & COVID-19 Antigen Combo Test Device at 2-30°C/ 36-86°F.
- **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.

LIMITATIONS OF THE TEST

1. The Flu A/B, RSV & COVID-19 Antigen Combo Test Device is intended for self-testing and in vitro diagnostic use only. It is designed for the qualitative detection of viral antigens specific to SARS-CoV-2, Influenza A virus, Influenza B virus, and Respiratory Syncytial Virus (RSV). The intensity of the colour in the positive bands should not be interpreted as quantitative or semi-quantitative.
2. The test can detect both viable and non-viable viruses.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based solely on the results of a single test. Diagnosis should be confirmed by a healthcare professional after considering all clinical and laboratory findings.
4. Failure to adhere to the test procedure and result interpretation guidelines may negatively impact test performance and/or invalidate the results.
5. Negative results do not rule out the possibility of viral infection and should be confirmed with a molecular assay if clinically indicated.
6. A positive test result does not necessarily indicate that an individual is infectious.
7. The reliability of the test decreases in the later stages of infection and in asymptomatic individuals.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

The results of all clinical data are summarized in following tables:

COVID-19 antigen test vs. RT-PCR

Method		PCR+	PCR -	Total
Flu A/B, RSV & COVID-19 Antigen Combo Test	Positive	94	3	97
	Negative	5	415	420
	Total	99	418	517

Positive agreement: 94.9% (88.7% ~ 97.8%)*
Negative agreement: 99.3% (97.9% ~ 99.8%)*
Total agreement: 98.5% (97.0% ~ 99.2%)*
*95% Confidence Interval

Influenza A antigen test vs. RT-PCR

Method		PCR+	PCR -	Total
Flu A/B, RSV & COVID-19 Antigen Combo Test	Positive	46	1	47
	Negative	4	466	470
	Total	50	467	517

Positive agreement: 92.0% (81.2% ~ 96.8%)*
Negative agreement: 99.8% (98.8% ~ 100.0%)*
Total agreement: 99.0% (97.8% ~ 99.6%)*
*95% Confidence Interval

Influenza B antigen test vs. RT-PCR

Method		PCR+	PCR -	Total
Flu A/B, RSV & COVID-19 Antigen Combo Test	Positive	28	1	29
	Negative	3	485	488
	Total	31	486	517

Positive agreement: 90.3% (75.1% ~ 96.7%)*
Negative agreement: 99.8% (98.8% ~ 100.0%)*
Total agreement: 99.2% (98.0% ~ 99.7%)*
*95% Confidence Interval

RSV antigen test vs. RT-PCR

Method		PCR+	PCR -	Total
Flu A/B, RSV & COVID-19 Antigen Combo Test	Positive	28	1	29
	Negative	2	486	488
	Total	30	487	517

Positive agreement: 93.3% (78.7% ~ 98.2%)*
Negative agreement: 99.8% (98.8% ~100.0%)*
Total agreement: 99.4% (98.3% ~ 99.8%)*
*95% Confidence Interval

Usability Study

A layperson study was evaluated with 196 laypersons from different ages and different education to establish the performance and usability of Flu A/B, RSV & COVID-19 Antigen Combo Test for self-testing in a self-testing environment.

COVID-19 test by layman Vs. PCR

Method		PCR+	PCR -	Total
Self-test results	Positive	37	0	37
	Negative	2	157	159
	Total	39	157	196

Positive agreement: 94.9% (83.1%~98.6%) *
Negative agreement: 100.0% (97.6%~100.0%) *
Total agreement: 99.0% (96.4%~99.7%) *
*95% Confidence Interval

Influenza A test by layman Vs. PCR

Method		PCR+	PCR -	Total
Self-test results	Positive	29	0	29
	Negative	3	164	167
	Total	32	164	196

Positive agreement: 90.6% (75.8%~96.8%) *
Negative agreement: 100.0% (97.7%~100.0%) *
Total agreement: 98.5% (95.6%~99.5%) *
*95% Confidence Interval

Influenza B test by layman Vs. PCR

Method		PCR+	PCR -	Total
Self-test results	Positive	29	0	29
	Negative	3	164	167
	Total	32	164	196

Positive agreement: 90.6% (75.8%~96.8%) *
Negative agreement: 100.0% (97.7%~100.0%) *
Total agreement: 98.5% (95.6%~99.5%) *
*95% Confidence Interval

RSV test by layman Vs. PCR

Method		PCR+	PCR -	Total
Self-test results	Positive	29	0	29
	Negative	2	165	167
	Total	31	165	196

Positive agreement: 93.5% (79.3%~98.2%) *
Negative agreement: 100.0% (97.7%~100.0%) *
Total agreement: 99.0% (96.4%~99.7%) *
*95% Confidence Interval

Analytical Sensitivity

The limit of detection (LOD) of the Flu A/B, RSV & COVID-19 Antigen Combo Test for Self-testing is defined as the concentration of SARS-CoV-2, Influenza A/B, and/or RSV virus that yields positive test results approximately 95% of the time. The LOD was determined by evaluating various concentrations of SARS-CoV-2, Influenza A, Influenza B, and RSV using the Flu A/B, RSV & COVID-19 Antigen Combo Test.

The LOD values for different SARS-CoV-2 variants in the COVID-19 Test are summarized in the table below:

Viral Culture		Inactivated virus LOD concentration (TCID50/mL)
SARS-CoV-2	Wild type	$1.0\times10^{2.4}$
	B.1.1.7 (Alpha)	$1.0\times10^{2.5}$
	B.1.351 (Beta)	$1.8\times10^{2.2}$
	B.1.617.2 (Delta)	$5.0\times10^{1.5}$
	BA.1 (Omicron)	$1.0\times10^{2.25}$
	BA.2 (Omicron)	1.0×10^{2}
	BA.4 (Omicron)	1.19×10^{2}
	BA.5 (Omicron)	1.40×10^{2}
	BA.2.76 (Omicron)	1.88×10^{2}

The LOD on different influenza viral strains for Influenza A/B Test were summarized in the table below:

Viral Culture		Inactivated virus LOD concentration (TCID50/mL)	Live virus LOD concentration (TCID50/mL)
Influenza A virus (H1N1)	A/Michigan/45/2015	1.0×10^{4}	10
	A/California/07/2009	1.65×10^{4}	15.3
	A/Brisbane/02/2018	1.2×10^{4}	26
	A/Victoria/2570/2019	9.0×10^{3}	13
	A/Wisconsin/588/2019	1.48×10^{4}	21
	A/Sydney/5/2021	1.4×10^{4}	22.5
	A/Singapore/INFIMH-16-0019/2016	1.78×10^{4}	28
	A/Hong Kong/4801/2014	4.3×10^{4}	41
Influenza A virus (H3N2)	A/Hong Kong/2671/2019	9.8×10^{3}	26.5
	A/Hong Kong/45/2019	1.73×10^{4}	16
	A/Switzerland/9715293/2013	1.63×10^{4}	22
	A/Darwin/6/2021	1.05×10^{4}	8
	A/Darwin/9/2021	9.13×10^{3}	23
Influenza B virus	B/Massachusetts/2/2012	7.63×10^{4}	39
	B/Phuket/3073/2013	2.5×10^{5}	135
	B/Austria/1359417/2021	4.13×10^{4}	25
	B/Colorado/06/2017	2.2×10^{5}	100
	B/Brisbane/60/2008	5.5×10^{4}	19.5
	B/Washington/02/2019	8.0×10^{4}	35

The LOD on respiratory syncytial virus strains for RSV Test were summarized in the table below:

Viral Culture		Inactivated virus LOD concentration (TCID50/mL)
Respiratory syncytial virus	Type A	9.0×10^{3}
	Type B	2.4×10^{3}

Cross Reactivity

The Flu A/B, RSV & COVID-19 Antigen Combo Test Device demonstrated no cross-reactivity with the microorganisms listed below at the specified concentrations. Potential cross-reacting microorganisms that may be present in nasal samples have been evaluated. Only SARS-CoV showed false positive results with the SARS-CoV-2 test, which is expected due to the high genetic homology between SARS-CoV and SARS-CoV-2. Therefore, this potential cross-reactivity risk cannot be completely excluded.

Adenovirus 1	Parainfluenza virus 3
Adenovirus 2	Parainfluenza virus 4
Adenovirus 3	Rhinovirus A30
Adenovirus 4	Rhinovirus B52
Adenovirus 5	MERS-Cov
Adenovirus 7	Bordetella parapertussis
Adenovirus 55	Bordetella pertussis
Epstein-Barr virus	Candida albicans
Enterovirus EV70	Chlamydia pneumoniae
Enterovirus EV71	Group C Streptococcus
Enterovirus A16	Haemophilus influenzae
Enterovirus A24	Legionella pneumophila
Echovirus 6	Mycoplasma pneumoniae
Human coronavirus 229E	Mycobacterium tuberculosis
Human coronavirus OC43	Staphylococcus aureus
Human coronavirus NL63	Staphylococcus epidermidis
Human Metapneumovirus	Streptococcus agalactiae
Norovirus	Streptococcus pneumoniae
Parainfluenza virus 1	Streptococcus pyogenes
Parainfluenza virus 2	/

Note:

1. For SARS-CoV-2 Detection: The SARS-CoV-2 detection in the COV test shows no cross-reactivity with Influenza A virus, Influenza B virus, or Respiratory Syncytial Virus (RSV).
2. For Influenza Detection: The FLUA test for Influenza A shows no cross-reactivity with Influenza B virus, Respiratory Syncytial Virus (RSV), or SARS-CoV-2. Similarly, the FLUB test for Influenza B shows no cross-reactivity with Influenza A virus, Respiratory Syncytial Virus (RSV), or SARS-CoV-2.
3. For RSV Detection: The RSV test shows no cross-reactivity with Influenza A virus, Influenza B virus, or SARS-CoV-2.

Interfering Substances

The following substances, which may be naturally present in respiratory specimens or artificially introduced into the respiratory tract, were evaluated at the concentrations listed below. None of these substances were found to interfere with the performance of the test device.

3 OTC nasal sprays	Guaiacol glyceryl ether
3 OTC mouth washes	Mucin
3 OTC throat drops	Whole blood
4-acetamidophenol	Mupirocin
Acetylsalicylic acid	Oxymetazoline
Albuterol	Phenylephrine
Chlorpheniramine	Phenylpropanolamine
Dexamethasone	Zanamivir
Dextromethorphan	Adamantanamine
Diphenhydramine	Oseltamivir phosphate
Doxylamine succinate	Tobramycin
Flunisolide	Triamcinolone

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7. Thompson W. et al. Mortality Associated With Influenza and Respiratory Syncytial Virus in the United States. JAMA, January 8, 2003 – Vol 289, No. 2.
8. Moler F.W. et al. Respiratory syncytial virus morbidity and mortality estimates in congenital heart disease patients: a recent experience. Crit Care Med. 1992 Oct; 20(10):1406-13.
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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**
	Instructions for use
	Manufacturer
	Do not re-use
	Temperature limit
	Caution
	Use by date
LOT	**Batch code**
REF	**Catalog number**
	Number of tests

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