2SAN
Better care. Better life.

COVID-19 & Influenza A/B & RSV Antigen Nasal Test Kit

Package Insert - For Self-testing

REF CFR007AU | English

Instructions for Use

COVID-19 & Influenza A/B & RSV Antigen Nasal Test Kit

Quick Reference Instructions

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

Scan the QR code or visit our website for video instructions www.2san.com/ifu-australia or call our helpline on: 1800 630 750 (9 AM to 7 PM AEST 7 days/week).

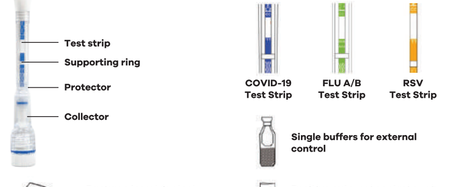
Scan for more information

SCAN ME

INTENDED USE

The COVID-19 & Influenza A/B & RSV Antigen Nasal Test Kit for Self-testing is an *in-vitro* immunoassay. The assay is intended for home testing (or self-testing). Children aged between 2 and 18 years old must be supervised or tested by an adult when carrying out the test. The assay is an *in-vitro* immunochromatographic assay for the qualitative detection of nucleoprotein antigens of SARS-CoV-2 (COVID-19), Influenza A, and Influenza B, and fusion protein antigen of Respiratory Syncytial Virus (RSV) in nasal swab specimens collected from patients against the respiratory infection for COVID-19 (within the first 7 days of the onset of symptoms) and influenza A/B and RSV (within the first 4 days of the onset of symptoms). The assay obtains a preliminary result only, aiding in the diagnosis of COVID-19, Influenza A/B and/or RSV. This test has not been cleared for use in asymptomatic individuals.

PACKAGE CONTENTS



Single buffers for external control


Package Insert for test

Package insert for external controls


Positive external control swab

Negative external control swab


Needed but not provided: **Clock**

Components	1 Test	2 Tests	5 Tests
Test Device	1x	2x	5x
Instructions for Use	1x	1x	1x

STORAGE AND STABILITY

1. Store the COVID-19 & Influenza A/B & RSV Antigen Nasal Test Kit at 2-30°C when not in use.
2. DO NOT FREEZE.
3. Kit contents are stable until the expiration dates marked on outer packaging and container.
4. Do not use after expiry date on packaging.

BEFORE THE TEST

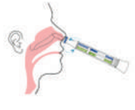
1. Bring devices, reagents and specimens to room temperature (15-30ºC) before use.
2. Remove the test device from its packing. For the best results, the assay should be performed within 2 hours.
3. Wash your hands with soap and water or use hand sanitizer for 20 seconds.

TAKE YOUR NASAL SWAB

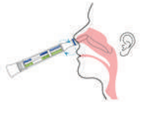
1. Take the test device out of the tube with extraction buffer.

2. Remove the protector.

3. Gently insert the sample collector until resistance is met (about 1-2 cm into the nostril). Rotate the collector five times against the nasal wall and remove from the nostril.



4. Pull the swab out of the nose while twisting it slightly.



Note!!
Caution should be taken when inserting the sample collector into the nasal cavity. With children, the maximum depth of insertion into the nostril may be less than 2cm, and you may need to have a second person to hold the child' s head while swabbing. This may feel uncomfortable. Do not insert the collector any deeper if you feel strong resistance.

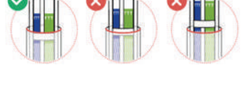
5. Repeat the sample collection procedure for the other nostril to ensure that sufficient specimen be collected from both nasal cavities.

WARNING: Inaccurate test results may occur if the nasal swab specimen is not properly collected.

PROCESS THE SWAB SAMPLE

1. Place the test device vertically into the extraction tube until the top edge of the extraction tube reach the top of the supporting ring.

WARNING: When placing the test device vertically into the extraction tube, the edge of the extraction tube must reach the top of the supporting ring. If not, this may lead to lateral flow failure, resulting in an incorrect result or invalid result.



2. Read the results at 15 minutes. Do not read the results after 30 minutes.

When the test is finished, please dispose all the components as biological waste.

READ AND INTERPRET YOUR RESULTS

Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

For COVID-19 test:

Positive: Two coloured bands appear on the membrane.
One band appears in the control region (C) and another band appears in the test region (T).

NOTE: A positive test result means it is very likely patients currently have COVID-19 disease. If you get a positive result, you should stay at home. Find out what you need to do from your state or territory health department. This includes whether you need to report your result and quarantine requirements. If you are unwell, you should seek medical assistance.

Negative: Only one coloured band appears, in the control region (C). No apparent coloured band appears in the test region (T).

NOTE: 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. If you get a negative result, it is less likely that you have COVID-19 but continue to follow all public health advice on limiting the spread of the virus. If you feel unwell or have symptoms, you should get a PCR test as soon as possible.

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. If you are unwell and have symptoms, get a PCR test at a testing site.

For Influenza A/B test:

Influenza A Positive: One coloured band appears in the control region (C), and another coloured band in the A region (A).

Influenza A Positive: One coloured band appears in the control region (C), and another coloured band in the B region (B).

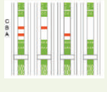
Influenza A+B Positive: One coloured band appears in the control region (C), and two other coloured bands appear in both A region (A) and B region (B).
Co-infection with influenza A and B is rare. A clinical specimen that generates positive results for both A and B should be considered an invalid result, 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 the patient's sample, and it is very likely that the patient has influenza. Please continue to observe local hygiene and safety measures.

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 or identify any specific influenza virus subtype.

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



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 RSV test:

Positive: Two coloured bands appear on the membrane.
One band appears in the control region (C) and another band appears in the test region (T).
A positive test result means that the virus that causes RSV was detected in the patient's sample, and it is very likely that the patient has RSV. Please continue to observe local hygiene and safety measures.

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 or identify any specific RSV subtype.

Negative: Only one coloured band appears, in the control region (C). No apparent coloured band appears in the test region (T).
A negative test result means it is unlikely patients have RSV disease. Please continue to observe local hygiene and safety measures.

NOTE: : A negative result does not mean a person is not infectious or does not have RSV. if symptoms persist the person should seek medical attention and further testing if required.

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.

PRINCIPLE

The COVID-19 & Influenza A/B & RSV Antigen Nasal Test Kit detects viral antigens through visual interpretation of colour development on the three internal test strips for COVID-19, FLU A/B and RSV respectively.

For COVID-19 test:

Anti-SARS-CoV-2 antibodies are immobilised at the test region of the nitrocellulose membrane. Anti-SARS-CoV-2 antibodies conjugated to coloured particles are immobilised on the conjugated pad.

The nasal secretions, collected by the intended user, are supposed to be mixed with the extraction buffer, which is individually packed in the kit.

During testing, target antigens, if present in the nasal secretions, will be released into the extraction buffer. As the specimen migrates along the strip by capillary action and then interacts with reagents on the Sample Pad, the target antigens will bind to anti-SARS-CoV-2 antibodies on the Conjugate Pad. Consequently, the antigen-antibody complex will be captured by the anti-SARS-CoV-2 antibodies immobilised at the Test Region. Excess coloured particles will be captured at the Control Region of the NC membrane.

The presence of a coloured band in the test region indicates a positive result for the SARS-CoV-2 viral antigens, while its absence indicates a negative result. A coloured band at the control region serves as a procedural control, generally indicating that a proper volume of specimen has been added and membrane wicking is working.

For Influenza A/B test:

Anti-Influenza A virus antibodies and anti-Influenza B virus antibodies are immobilised at two separate test regions of the nitrocellulose membrane. Anti-Influenza A virus antibodies and anti-Influenza B virus antibodies conjugated to coloured particles are immobilised on the conjugated pad.

The nasal secretions, collected by the intended user, are supposed to be mixed with the extraction buffer, which is individually packed in the kit.

During testing, target antigens, if present in the nasal secretions, will be released into the extraction buffer. As the specimen migrates along the strip by capillary action and then interacts with reagents on the Sample Pad, the target antigens will bind to antibodies on the Conjugate Pad. Consequently, the antigen-antibody complex will be captured by the antibodies immobilised at the two Test Regions. Excess coloured particles will be captured at the Control Region of the NC membrane.

The presence of a coloured band in the test region indicates a positive result for the Influenza A/B viral antigens, while its absence indicates a negative result. A coloured band at the control region serves as a procedural control, generally indicating that a proper volume of specimen has been added and membrane wicking is working.

For RSV test:

Anti-respiratory syncytial virus antibodies are immobilised at the test region of the nitrocellulose membrane. Anti-respiratory syncytial virus antibodies conjugated to coloured particles are immobilised on the conjugated pad.

The nasal secretions, collected by the intended user, are supposed to be mixed with the extraction buffer, which is individually packed in the kit.

During testing, target antigens, if present in the nasal secretions, will be released into the extraction buffer. As the specimen migrates along the strip by capillary action and then interacts with reagents on the Sample Pad, the target antigens will bind to anti-respiratory syncytial virus antibodies on the Conjugate Pad. Consequently, the antigen-antibody complex will be captured by the anti-respiratory syncytial virus antibodies immobilised at the Test Region. Excess coloured particles will be captured at the Control Region of the NC membrane.

The presence of a coloured band in the test region indicates a positive result for the respiratory syncytial viral antigens, while its absence indicates a negative result. A coloured band at the control region serves as a procedural control, generally indicating that a proper volume of specimen has been added and membrane wicking is working.

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PRECAUTIONS

- For *in-vitro* Diagnostic Use Only.
- Caution should be taken when inserting the sample collector into the nasal cavity.
- DO NOT ingest.
- Use a separate test for each person.
- Keep the collector clean. Do not touch the collector and make sure it does not touch any surfaces before use.
- Read the Package Insert prior to use. Directions should be read and followed carefully.
- Do not use kit or components beyond the expiration date. Do not use kit if component missing or damaged.
- The device contains material of animal origin and should be handled as a potential biohazard. Do not use if pouch is damaged or open.
- Test devices are packaged in foil pouches that exclude moisture during storage. Inspect each foil pouch before opening. Do not use devices that have holes in the foil or where the pouch has not been completely sealed. Erroneous result may occur if test reagents or components are improperly stored.
- All patient specimens should be handled and discarded as if they are biologically hazardous. All specimens must be mixed thoroughly before testing to ensure a representative sample prior to testing.
- Used or expired devices shall be disposed as biological waste.
- Failure to bring specimens and reagents to room temperature before testing may decrease assay sensitivity. Inaccurate or inappropriate specimen collection, storage, and transport may yield false negative test results.
- Avoid skin or eyes contact with buffer before, during or after testing.
- If infections with SARS-CoV-2, Influenza A virus, Influenza B virus and/or respiratory syncytial virus are suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions and sent to state or local health departments for testing.
- Do not puncture the sealing membrane in the extraction tube before testing.
- If you feel unwell or need COVID-19 advice for someone in your care, talk with your health provider, or speak to a nurse by calling the health direct helpline on 1800 022 222.
- If you develop symptoms such as severe shortness of breath or chest pain, call triple zero (000) immediately.

QUALITY CONTROL

Internal Procedural Controls

The COVID-19 & Influenza A/B & RSV Antigen Nasal Test Kit has built-in (procedural) controls. Each test has an internal standard zone to ensure proper sample flow. The user should confirm that the coloured band located at the "C" region is present before reading the result.

LIMITATIONS OF THE TEST

1. The COVID-19&Influenza A/B&RSV Antigen Nasal Test Kit is for self-testing *in-vitro* diagnostic use, and should only be used for the qualitative detection of viral antigens specific for SARS-CoV-2, Influenza A virus, Influenza B virus and respiratory syncytial virus. The intensity of colour in a positive band should not be evaluated as "quantitative or semi-quantitative".
2. Both viable and non-viable viruses are detectable with the kit.
3. 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.
4. Failure to follow the TEST PROCEDURE and RESULT INTERPRETATION may adversely affect test performance and/or invalidate the test result.
5. Negative results may not mean a person is not infectious and if symptoms are present, the person must seek immediate further testing.
6. A negative result does not rule out infection with another type of respiratory virus.
7. It is recommended to repeat testing (e.g. within 1-3 days) if ongoing suspicion of infection, high risk setting or occupational or other requirement.
8. The tests are less reliable in the later phase of infection (more than 7 days after the onset of COVID-19 symptoms or more than 4 days after the onset of Influenza A/B symptoms) and in asymptomatic individuals.
9. A positive result cannot necessarily determine whether a person is infectious.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

The LOD on different SARS-CoV-2 variants for COVID-19 Test were summarised in the table below:

COVID-19	Inactivated virus LOD concentration ($TCID_{50}$/mL)
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 summarised in the table below:

Influenza	Inactivated virus LOD concentration ($TCID_{50}$/mL)	Live virus LOD concentration ($TCID_{50}$/mL)
Influenza A (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
Influenza A (H3N2)		
A/Singapore/INFIMH-16-0019/2016	1.78×10^{4}	28
A/Hong Kong/4801/2014	4.3×10^{4}	41
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 (Yamagata lineage)		
A/Singapore/INFIMH-16-0019/2016	7.63×10^{4}	39
A/Hong Kong/4801/2014	2.5×10^{5}	135
Influenza B (Victoria lineage)		
B/Austria/1359417/2021	4.13×10^{4}	25
B/Colourado/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 summarised in the table below:

Respiratory syncytial virus	Inactivated virus LOD concentration ($TCID_{50}$/mL)
RSV Type A	9.0×10^{3}
RSV Type B	2.4×10^{3}

Clinical Evaluation

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

For COVID-19 Antigen Test

COVID-19 Antigen Test vs. RT-PCR		RT PCR		
		Positive	Negative	Total
COVID-19 & Influenza A/B & RSV Antigen Nasal Test Kit	Positive	105	3	108
	Negative	3	514	517
	Total	108	517	625

Diagnostic Sensitivity: 97.2% (92.2% ~99.1%)*
Diagnostic Specificity: 99.4% (98.3% ~99.8%)*
Overall Agreement: 99.0% (97.9% ~ 99.6%)*
*95% Confidence Interval

For Influenza A Antigen Test

Influenza A Antigen Test vs. RT-PCR		RT PCR		
		Positive	Negative	Total
COVID-19 & Influenza A/B & RSV Antigen Nasal Test Kit	Positive	66	6	72
	Negative	4	549	553
	Total	70	555	625

Diagnostic Sensitivity: 94.3% (86.2% ~97.8%)*
Diagnostic Specificity: 98.9% (97.7% ~99.5%)*
Overall Agreement: 98.4% (97.1% ~ 99.1%)*
*95% Confidence Interval

For Influenza B Antigen Test

Influenza B Antigen Test vs. RT-PCR		RT PCR		
		Positive	Negative	Total
COVID-19 & Influenza A/B & RSV Antigen Nasal Test Kit	Positive	35	5	40
	Negative	3	582	585
	Total	38	587	625

Diagnostic Sensitivity: 92.1% (79.2% ~97.3%)*
Diagnostic Specificity: 99.1% (98.0% ~99.6%)*
Overall Agreement: 98.7% (97.5% ~ 99.4%)*
*95% Confidence Interval

For RSV Antigen Test

RSV Antigen Test vs. RT-PCR		RT PCR		
		Positive	Negative	Total
COVID-19 & Influenza A/B & RSV Antigen Nasal Test Kit	Positive	42	6	48
	Negative	4	573	577
	Total	46	579	625

Diagnostic Sensitivity: 91.3% (79.7% ~96.6%)*
Diagnostic Specificity: 99.0% (97.8% ~99.5%)*
Overall Agreement: 98.4% (97.1% ~ 99.1%)*
*95% Confidence Interval

Usability Study

197 lay users took part in the usability study and were also tested with a PCR. Results are summarised below.

For COVID-19 Antigen Test

COVID-19 Antigen Test vs. RT-PCR		RT PCR		
		Positive	Negative	Total
COVID-19 & Influenza A/B & RSV Antigen Nasal Test Kit	Positive	35	0	35
	Negative	1	161	162
	Total	36	161	197

Diagnostic Sensitivity: 97.2% (85.8% ~99.5%)*
Diagnostic Specificity: 100.0% (97.7% ~100.0%)*
Overall Agreement: 99.5% (97.2% ~ 99.9%)*
*95% Confidence Interval

For Influenza A Antigen Test

Influenza A Antigen Test vs. RT-PCR		RT PCR		
		Positive	Negative	Total
COVID-19 & Influenza A/B & RSV Antigen Nasal Test Kit	Positive	30	1	31
	Negative	4	162	166
	Total	34	163	197

Diagnostic Sensitivity: 88.2% (73.4% ~95.3%)*
Diagnostic Specificity: 99.4% (96.6% ~99.9%)*
Overall Agreement: 97.5% (94.2% ~ 98.9%)*
*95% Confidence Interval

For Influenza B Antigen Test

Influenza B Antigen Test vs. RT-PCR		RT PCR		
		Positive	Negative	Total
COVID-19 & Influenza A/B & RSV Antigen Nasal Test Kit	Positive	30	0	30
	Negative	3	164	167
	Total	33	164	197

Diagnostic Sensitivity: 90.9% (76.4% ~96.9%)*
Diagnostic Specificity: 100.0% (97.7% ~100.0%)*
Overall Agreement: 98.5% (95.6% ~ 99.5%)*
*95% Confidence Interval

For RSV Antigen Test

RSV Antigen Test vs. RT-PCR		RT PCR		
		Positive	Negative	Total
COVID-19 & Influenza A/B & RSV Antigen Nasal Test Kit	Positive	30	0	30
	Negative	2	165	167
	Total	32	165	197

Diagnostic Sensitivity: 93.8% (79.9% ~98.3%)*
Diagnostic Specificity: 100.0% (97.7% ~100.0%)*
Overall Agreement: 99.0% (96.4% ~ 99.7%)*
*95% Confidence Interval

Cross Reactivity

The COVID-19 & Influenza A/B & RSV Antigen Nasal Test Kit presented no cross-reactivity with these below microorganisms at specified concentrations. Potentially cross-reacting microorganisms may be present in the nasal samples have been validated, and only SARS-CoV showed false positive results with SARS-CoV-2 test, and due to the high homology between SARS-CoV and SARS-CoV-2, this unfavorable risk cannot be ruled out.

Microorganisms	Microorganisms
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	/

Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the respiratory tract, were evaluated at the concentrations listed below. None of them were found to affect test performance of the kit.

Analytes	Analytes
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

MEDICAL DEVICE INCIDENT REPORT

You can contact the Therapeutic Goods Administration (TGA) to report poor performance or usability issues via the online Users Medical Device Incident Report, emailing iris@tga.gov.au or calling 1800 809 361 (08: 30am to 5:00pm Monday to Friday) or https://www.tga.gov.au/.

SAFETY INFORMATION

Wearing a mask can help protect you and those around you if you are in an area with community transmission and physical distancing is not possible.

Follow the directions of your local state or territory government health department to protect yourself.

Test kit solutions should only be used as directed; do not ingest; do not dip the swab into provided solution or other liquid.

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