own™
self-testing for everybody.

COVID-19 Antigen Nasal Test Kit for Self-testing

Package Insert - For Self-testing

REF COV010AU | English

Instructions for Use

COVID-19 Antigen Nasal Test Kit for Self Testing

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 (9AM to 7PM AEST, 7 days/week)

Scan for more information

INTENDED USE

The COVID-19 Antigen Nasal Test Kit for Self Testing is an in vitro immunoassay. The assay is for the direct and qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal secretions from individuals within 7 days of symptom onset or other epidemiological reasons to suspect COVID- 19 infection. The kit is in aid of diagnosis of COVID-19.

This test is authorised for home use with self-collected anterior nasal swab specimens directly from individuals aged 15 years and older or with adult-collected anterior nasal samples directly from individuals aged 2 years or older. The COVID-19 Antigen Nasal Test Kit for Self- Testing does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 viral nucleoprotein antigen. Antigen is generally detectable in nasal samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

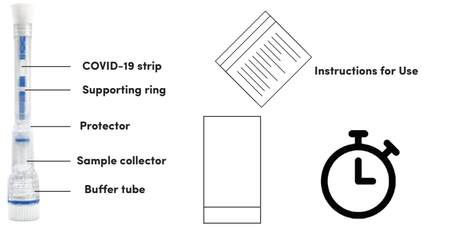
Individuals who test positive should stay at home to protect the people in your community and should not visit high-risk settings like hospitals and aged and disability care settings for at least 7 days or until symptoms have gone, unless seeking immediate medical care. To help protect those around you, we recommend to avoiding contact with people who are at higher risk of severe disease, wearing a mask outside the home, working from home where possible, avoiding going to school, public areas, or travel on public transport, in taxis or ride-share services, practicing good hygiene, and following your local health department's advice when leaving home.

Negative results are presumptive and confirmation with a molecular assay, if necessary for patient management may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

PRINCIPLE

The COVID-19 Antigen Nasal Test Kit for Self Testing detects SARS-CoV-2 viral antigens through visual interpretation of colour development. 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.
During testing, target antigens, if present in the nasal secretions, will be released into the extraction buffer. And then the specimen migrates along the strip by capillary action, the target antigens will bind to anti-SARS-CoV-2 antibodies on the conjugate pad. Consequently, and will be captured by the anti-SARS-CoV-2 antibodies immobilised at the test region.
After testing, 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.

PACKAGE CONTENTS



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

WARNINGS & PRECAUTIONS

- For *In Vitro* Diagnostic Use Only.
- 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.
- Each device is for single use only and cannot be reused.
- Caution should be taken when inserting the sample collector into the nasal cavity.
- Do not use kit or components beyond the expiration date.
- Do not puncture the membrane in the extraction tube before testing.
- Read the instructions for use before use. The instructions for use must be read carefully and followed.
- The device contains material of animal origin and should be handled as a potential biohazard.
- The test components are packed in foil pouches to protect them from moisture during storage. Check each foil pouch before opening it. Do not use any component that has holes in the film or the pouch has not been completely sealed. Improper storage of test items or components can lead to incorrect results.
- Do not use the kit when any component including test device, protector, extraction buffer, package insert is missing.
- 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.
- The buffer components include salts and surfactants, the preservative is sodium azide and water is the solvent. Avoid skin or eyes contact with buffer. In the event of contact with buffer, rinse with plenty of water.
- Do not use this test on anyone under 2 years of age.
- Keep test kit and materials out of the reach of children and pets, before and after use. Small test components can pose a choking hazard.
- Use only the supplied test components. Do not replace the buffer with any other liquid.
- Keep the collector clean. Do not touch the collector and make sure it does not touch any surfaces before use. Place the swab in the buffer immediately after collecting the sample.
- If you have a nose piercing, dab the other nostril. If pierced on both sides, remove the piercing on one side before wiping it off.
- If infection with SARS-CoV-2 is 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.
- This test is for human use only.
- There may be false negatives due to new unknown variants of SARS-Cov-2 prior to validation data available
- COVID-19 Antigen Nasal Test Kit for Self Testing could detect SARS-CoV-2 variant alpha, beta, gamma, kappa and delta.

QUALITY CONTROL

Internal Procedural Controls
COVID-19 Antigen Nasal Test Kit for Self Testing has built-in (procedural) controls. Each test device 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 Antigen Nasal Test Kit for Self Testing is for for in vitro diagnostic self-testing use, and should only be used for the qualitative detection of SARS-CoV-2 antigen. The intensity of colour in a positive band should not be evaluated as "quantitative or semi-quantitative".
2. Both viable and nonviable SARS-CoV-2 viruses are detectable with the COVID-19 Antigen Nasal Test Kit for Self Testing.
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 do not preclude SARS-CoV-2 infection and should be confirmed via molecular assay.
6. This test cannot be used to evaluate the immune response (antibodies). The immune response requires different test methods.
7. Even if the result is negative, you still need to continue observing all protective and hygienic measures.
8. Carefully follow the instructions given by the government.
9. False negative results may appear if testing is not performed within the first 7 days of symptom onset.
10. There may be false negatives due to new unknown variants of SARS-Cov-2 prior to validation data available.
11. A negative result does not rule out infection with another type of respiratory virus.
12. The COVID-19 Antigen Nasal Test Kit for Self Testing does not differentiate between SARS-CoV and SARS-CoV-2.
13. The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
14. The test is less reliable in the later phase of infection and in asymptomatic individuals.
15. Recommend repeat testing (e.g. within 1-3 days) if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or other requirement.
16. A positive result cannot necessarily determine whether a person is infectious.

STORAGE AND STABILITY

1. Store the COVID-19 Antigen Nasal Test Kit for Self Testing 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.

PERFORMANCE

Analytical Sensitivity:

The limit of detection was determined with a quantified SARS-CoV-2 virus and has been evaluated at $1\times10^{2.4}$TCID50/mL.

Clinical Evaluation:

A total of 508 clinical specimens were collected to verify the performance of COVID-19 Antigen Nasal Test Kit for Self Testing. There were 106 positive specimens from the individuals who were suspected of COVID-19 within 7 days of symptom and 402 negative clinical specimens confirmed by RT-PCR.

Usability Study:

A layperson study was evaluated with 112 laypersons from different age and different education to establish the performance and usability of COVID-19 Antigen Nasal Test Kit for Self-testing in a self-testing environment. The tests by layperson correctly identified 92.3% (36/39) of positive samples and 100.0% (73/73) of negative samples compared with RT-PCR.

Cross Reactivity:

Cross reactivity with the following organisms has been studied. Samples positive for the following organisms were found negative when tested with the COVID-19 Antigen Nasal Test Kit for Self Testing.

Adenovirus 1	HCoV-HKU1	Bordetella pertussis
Adenovirus 2	MERS-coronavirus	Candida albicans
Adenovirus 3	Influenza A (H1N1)	Chlamydia pneumoniae
Adenovirus 4	Influenza A (H3N2)	Group C Streptococcus
Adenovirus 5	Influenza B Victoria lineage	Haemophilus influenzae
Adenovirus 7	Influenza B Yamagata lineage	Legionella pneumophila
Adenovirus 55	Human metapneumovirus	Mycoplasma pneumoniae
Epstein-Barr virus	Norovirus	Mycobacterium tuberculosis
Enterovirus EV70	Parainfluenza virus 1	Staphylococcus aureus
Enterovirus EV71	Parainfluenza virus 2	Staphylococcus epidermidis
Enterovirus A16	Parainfluenza virus 3	Streptococcus agalactiae
Enterovirus A24	Parainfluenza virus 4	Streptococcus pneumoniae
Enterovirus B1	Respiratory syncytial virus A	Streptococcus pyogenes
Echovirus 6	Respiratory syncytial virus B	Pseudomonas aeruginosa
HCoV-229E	Rhinovirus A30	Staphylococcus salivarius
HCoV-OC43	Rhinovirus B52	
HCoV-NL63	Bordetella parapertussis	

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 COVID-19 Antigen Nasal Test Kit for Self Testing.

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

MEDICAL DEVICE INCIDENT REPORT

You can contact the Therapeutic Goods Administration (TGA) to report poor performance or usability issues via the Medical Device Incident Reporting, emailing iris@tga.gov.au or https://www.tga.gov.au or calling 1800 809 361 (8:30am to 5:00pm Monday to Friday).

GLOSSARY OF SYMBOLS

REF	Catalog number	2°C 30°C	Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer	Σ	Contains sufficient for <n> tests
2	Do not reuse		Do not use if package is damaged

CUSTOMER SUPPORT CONTACT

For inquiries call our helpline on 1800 630 750 (9AM to 7PM AEST, 7 Days/Week)

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Revision date: 2024-09-04

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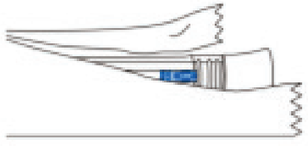
PROCEDURE

- The test should be used at room temperature (15°C to 30°C).
- If the test has been stored in a cool place (below 15°C), allow the test to stand at room temperature for 30 minutes before use.
- Do not use the test if the foil package is visibly damaged.
- Do not open the foil package until you are ready to perform the test. Use the test within 1 hour after opening.

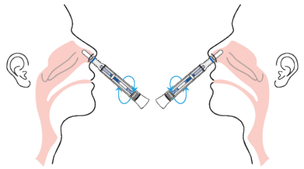
1 Wash your hands thoroughly. If you do more than one test, clean the surface and wash your hands again between each test.



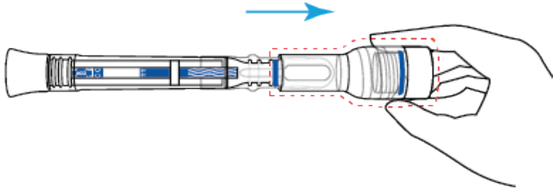
2 Remove the test device from its packing. For the best results, the assay should be performed within one hour.

NOTE:

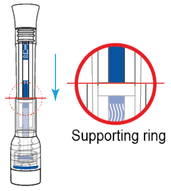
1. It is important to obtain as much secretion as possible.
2. This may feel uncomfortable. Do not insert the collector any deeper if you feel strong resistance. Children aged 2-15 years should be tested by an adult (18+ years old).



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

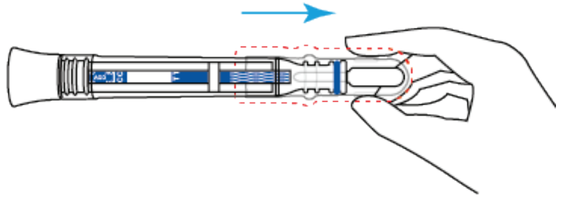


3 Take the test device out of the tube with extraction buffer.

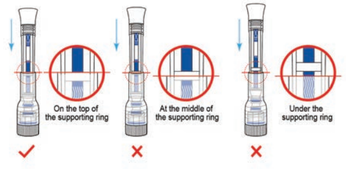


6 Take out the nasal collector from the nostril. Place the test device vertically into the extraction tube until the top edge of the extraction tube reach the top of the supporting ring.

NOTE: 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.



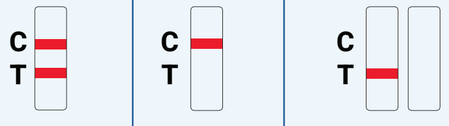
4 Remove the protector.



7 Read the results at 15 minutes. When your test is finished, put all of the contents of the test kit you used in the waste bag provided. Dispose of the closed waste bag with household waste. Do not read results after 30 minutes.

READ AND INTERPRET YOUR RESULTS

For COVID-19 Test



Positive | **Negative** | **Invalid**

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 test region (T).

The intensity of the colour in the test area (T) varies. However, any shade in the test area should be considered positive. Note that this is a qualitative test only and the virus concentration in the sample cannot be determined.

If you get a positive result, it indicates a possible SARS-CoV-2 infection.

- If you have a COVID-19 POSITIVE result, staying at home protects the people in your community.
- If you test positive, you should not visit high-risk settings like hospitals, and aged & disability care settings for at least 7days or until symptoms have gone, unless seeking immediate medical care.
- To help protect those around you, we recommend to avoiding contact with people who are at higher risk of severe disease, wearing a mask outside the home, working from home where possible, avoiding going to school, public areas, or travel on public transport, in taxis or ride-share services, practicing good hygiene, and following your local health department's advice when leaving home.
- If you have any appointments you cannot miss (visit to a doctor, family violence service or police), let them know in advance that you have COVID-19.
- 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. Tell the call handler and the paramedics on arrival if you have COVID-19.**
- Most people with COVID-19 experience only mild symptoms, or no symptoms at all (asymptomatic). You can manage these symptoms with over-the-counter medication.
- Try to get plenty of rest, drink lots of water and eat well. You can still do moderate exercise if you feel well enough, within your home and/or garden if you have one. If you are eligible, your GP can prescribe COVID-19 oral treatments to reduce your chance of severe illness or hospitalisation. Seek urgent medical attention (call 000) if you develop severe symptoms, such as difficulty breathing, an oxygen level of less than 92% when tested with a pulse oximeter, blue lips or face, pain or pressure in the chest, cold and clammy, or pale and mottled, skin, fainting or collapsing, being confused, difficultly waking up, little or no urine output, and coughing up blood.
- Severe COVID-19 in children is rare. Most children will have no, or only mild symptoms. If you are worried about your child's symptoms, contact your GP as soon as possible. A GP or nurse will treat your child based on their age, symptoms and past medical history. If they are showing severe symptoms, call 000 immediately.
- Most people who test positive for COVID-19 recover completely, but some people may develop long COVID. COVID-19 vaccinations, including boosters, reduce your risk of re-infection and gives the best protection against severe illness from COVID-19. After testing positive, you should wait 6 months before making a booster dose appointment.

COVID-19 NEGATIVE: Only one coloured line appears in the control region (C). No apparent coloured band appears in the test region (T).

Negative results do not completely rule out SARS-CoV-2 infection. Please continue to comply with all applicable rules regarding contact with others and protective measures. An infection can also be present if the test is negative. In case of suspicion, being in a high risk setting or where there is an occupational risk or other requirement, repeat the tests after 1-3 days or have a RT-PCR test, as the coronavirus cannot be accurately detected in all phases of an infection.

COVID-19 INVALID: Control band fails to appear.

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 test results remain invalid, contact a doctor or a COVID-19 test center. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

Note: Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

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