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COVID-19 Antigen Home Test

Instructions for Use – For Self-testing

REF – COV011AU | English

INTENDED USE

COVID-19 Antigen Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 virus that causes COVID-19 in nasal swab samples from individuals suspected of COVID-19 within 7 days of symptom onset.

This device is authorised for home-use in a non-laboratory setting with direct anterior nasal (nares) swab samples for:

- Unobserved self-collection for individuals aged 18 years or older
- Adult supervised self-collection for individuals for ages 14 or older
- Adult collecting from individuals aged 2 years or older

COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

The COVID-19 Antigen Home Test is intended for self-use and/or, as applicable for an adult lay user testing for another person aged 2 years or older in a non laboratory setting.

The assay obtains a preliminary result only, aiding in the diagnosis of COVID-19. This test has not been cleared for use in asymptomatic individuals.

PRINCIPLE

The COVID-19 Antigen Home Test detects SARS-CoV-2 viral nucleocapsid proteins through visual interpretation of color development on the internal strip. Anti-SARS-CoV-2 mAb is immobilized at the test region of the nitrocellulose membrane. Anti-SARS-CoV-2 mAb conjugated to colored particles are immobilized on the conjugated pad.

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 mAb on the conjugate pad. Consequently, the antigen-antibody complex will be captured by the anti-SARS-CoV-2 mAb immobilized at the test region. Excess colored particles will be captured at the control region of the NC membrane.

The presence of a colored band in the test region indicates a positive result for the SARS-CoV-2 viral, while its absence indicates a negative result. A colored 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.

WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

Read the COVID-19 Antigen Home Test instructions carefully before performing a test. Failure to follow directions may produce inaccurate test results.

- The test is intended to aid in the diagnosis of a current SARS-CoV-2 infection. Please consult a healthcare professional to discuss your results and if any additional testing is required.
- Keep test kit and materials out of the reach of children and pets before and after use.
- Do not use on anyone under 2 years of age
- Do not open the kit contents until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.
- Do not use the test if the pouch is damaged or open for an hour or longer.
- Do not reuse any kit components.
- Make sure there is sufficient light when reading the testing results.
- Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
- Remove any piercings from the nose before starting the test.
- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past 6 months.
- Inadequate or improper nasal swab sample collection may yield false negative test results
- Do not touch the swab head when handling the swab.
- The test is intended to be read at 15 minutes. If the test is read before 15 minutes or after 30 minutes, false negative or false positive results may occur, and the test should be repeated with a new test cassette.
- Do not ingest any kit components.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the extraction tube
- The chemicals in the reagent solution are hazardous to the skin and eye. Please see the below table for safety recommendations for skin and eye irritation. No personal protective equipment is recommended for use.
- In the event of spillage, ensure that it is cleaned thoroughly using a household disinfectant, like 75% alcohol.
- Use only the components provided in the test kit. Do not use other things to replace them.
- All test materials must be at room temperature before use.
- You should wear a face mask if swabbing others.
- Exposure to humidity may decrease the stability of the test. The test should be performed within an hour after removing it from the pouch.
- Collect specimen and immediately perform test according to instructions.
- This test is read visually. Individuals with impaired vision or colour-impaired vision may not be able to adequately interpret test results.
- Wash hands thoroughly or use hand sanitizer after handling. Negative test results do not exclude infection with COVID-19 (so face masks, social distancing and good hygiene practice must be maintained).
- A negative result does not rule out infection with another type of respiratory virus. Information on other limitations of the test such as a positive result cannot necessarily determine whether a person is infectious.
- Dispose of kit contents and patient samples in household trash.
- This is a qualitative test, therefore quantitative values of SARS-CoV-2 antigen concentration cannot be determined.
- The immune response cannot be evaluated using this test. Other test methods are required for that purpose.
- The test does not differentiate between SARS-CoV and SARS-CoV-2.
- Children 2 to 13 years of age should not swab themselves and should instead be swabbed by an adult.
- The control line may show up within a few minutes of starting the test. It may take up to 15 minutes for the test line to show up.
- Test devices are single use only and should be discarded after use. Do not re-use the test device.
- A negative result does not rule out infection with another type of respiratory virus. Information on other limitations of the test such as a positive result cannot necessarily determine whether a person is infectious.
- If the reagent solution contacts the skin or eye, flush with plenty of water.If irritation persists, seek medical advice.

FREQUENTLY ASKED QUESTIONS

Q: WHAT IS COVID-19?

A: COVID-19 is an acute respiratory infectious disease caused by the SARS-CoV-2 virus, a novel Betacoronavirus. SARS-CoV-2 is mostly spread person-to-person, both by individuals with symptoms of COVID-19 infection and by infected people without symptoms. Based on the current knowledge, the incubation period is 1 to 14 days, mostly 4-5 days. Symptoms include fever, fatigue, and cough.

Q: WHAT DOES AN INVALID TEST RESULT MEAN?

A: If no control line shows up on the test, the result is invalid (even if any test line shows up). An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and the test should be run again, using all new test components.

Q: WILL THIS TEST HURT?

A: No, the nasal swab is not sharp, and it should not hurt. Sometimes the swab can feel slightly uncomfortable. If you feel pain, please stop the test and seek advice from your healthcare provider.

Q: WHAT ARE THE KNOWN POTENTIAL RISKS AND BENEFITS OF THIS TEST?

A: Potential risks include:

- Possible discomfort during sample collection.
- Possible incorrect test results (see Result Interpretation section).

Potential benefits include:

- The results, along with other information, can help you and your healthcare provider make informed decisions about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN TEST AND A MOLECULAR TEST?

A: There are different kinds of tests for COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests, such as the COVID-19 Antigen Home Test detect proteins from the virus.Antigen tests are very specific for the COVID-19 virus but are not sensitive as molecular tests.This means that a positive result is highly accurate, but a negative result does not rule out infection.

Q: HOW ACCURATE IS THIS TEST?

A:The performance of the COVID-19 Antigen Home Test was established in a prospective clinical study using an EUA authorised molecular test as a comparator method (PPA (93.6%) and NPA (99.6%)). The performance of this test was not clinically validated for serial testing in patients with or without symptoms consistent with COVID-19. Serial testing recommendations are supported by the study conducted by the National Institutes for Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the US FDA.

Q: WHAT IF YOU TEST POSITIVE?

A: A positive test result means that antigens from the virus that causes COVID-19 were detected and it is very likely you currently have COVID-19 disease. There is a very small chance that this test can give a positive result that is wrong (a false positive result). If you test positive you should self-isolate at home to stop spreading the virus to others. Seek follow-up care with your healthcare provider immediately. Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical history, and your symptoms.

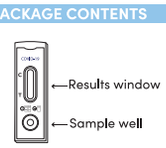
Q: WHAT IF YOU TEST NEGATIVE?

A: All COVID-19 antigen test negative results are presumptive. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19; however, you should follow-up with a healthcare provider. Symptomatic individuals who test negative should repeat testing at least twice over three days with at least 48 hours between tests and at least three times over five days with at least 48 hours between tests if they are asymptomatic.

STORAGE AND STABILITY

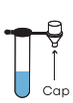
Store the kit at 2-30°C / 36-86°F and protect from direct sunlight. The expiration date of the materials is indicated on the external packaging. Do not freeze the kit.

PACKAGE CONTENTS



Test Device

Individually wrapped swab



Extraction buffer tube

Instructions for Use

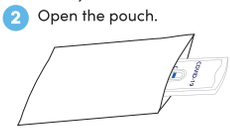
Needed but not provided: Clock

Test Device	Individually wrapped swab	Extraction buffer tube	Instructions for Use
1	1	1	1
2	2	2	1
5	5	5	1

PREPARE FOR THE TEST

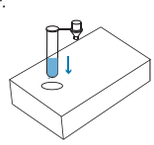
1. Wash your hands thoroughly.

2. Open the pouch.



Peel off the aluminum foil cover of the extraction buffer

Insert the extraction buffer into the tube holder.



Note: An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children age 2 to 13 years should be tested by an adult

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12/12/2025
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TAKE YOUR NASAL SWAB

1. Open the swab packaging. Remove the swab from 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. Gently twist the swab 5 times against the nasal wall. Do not just spin the swab. The swab should remain in the nostril for 15 seconds.

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

5. Repeat the process with the same swab in the other nostril, also for 15 seconds.

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

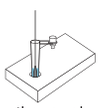
Note:

1. With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch,and you may need to have a second person to hold the child's head while swabbing.
2. For best results, the assay should be performed within one hour of sample collection.

Scan for instructional video and IFU

PROCESS THE SWAB SAMPLE

1. Place swab into the tube.



2. 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 squeeze the tube can lead to incorrect results due to excess buffer in the swab.

3. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

4. Insert the nozzle to the buffer tube.

5. Invert the tube and add 3 drops of the solution to the sample well by gently squeezing the tube. Do not add test sample to the rectangular results window.

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

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

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

After test is completed, dispose of used materials in trash.

READ AND INTERPRET YOUR RESULTS

WARNING: Do not read the result before 15 minutes or after 30 minutes. Inaccurate test interpretations may occur.

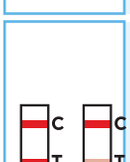
Look at the result window and locate the letters C and T on the side of the window. A pink/purple line should always appear at the C position; this is a control line and signals that the test is working properly.

Negative result

If a control line (C) is visible (regardless of how faint it is) and a test line (T) is not visible, this means that the result is negative. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If all repeat tests are negative and you are concerned you have COVID-19, you may choose to test again using an antigen test or consult with your health care provider regarding molecular testing.

Notice: To increase the chance that the negative result for COVID-19 is accurate, you should:

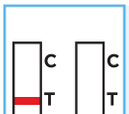
- Test again in 48 hours if you have symptoms on the first day of testing.
- Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.



Positive result

If a test line (T) is visible together with a control line (C), this means that the result is positive. Look carefully at the result: The test should be considered positive if two lines are visible - even if they are faint. A positive test result means that the virus that causes COVID-19 was detected in your sample, and it is very likely that you have COVID-19. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. Your doctor may require you to undergo a molecular PCR test to confirm the result. There is a very small chance that this test can give a result that is incorrect (a false positive).

Notice: You do not need to perform repeat testing if you have a positive result at any time.



Invalid result

If a control line (C) is not visible, even if the test line is visible, the result must be considered invalid. The test is not working correctly and you should perform another test using a different test kit. You may have performed the test incorrectly. Carefully read Instructions for Use and repeat the test. If your test result is still invalid, please contact a doctor or visit a COVID-19 test center.

PERFORMANCE

Analytical sensitivity (Limit of Detection) and inclusivity

The LOD on SARS-CoV-2 Wild type and different variants for COVID-19 Antigen Home Test were summarized in the table below:

Wild type	$2\times10^{2.4}$ $TCID_{50}$/mL
B.1.1.7 (Alpha)	$2\times10^{2.5}$ $TCID_{50}$/mL
B.1.351 (Beta)	$1.8\times10^{2.2}$ $TCID_{50}$/mL
P.1 (Gamma)	$1.6\times10^{2.4}$ $TCID_{50}$/mL
B.1.617.2 (Delta)	$1\times10^{2.5}$ $TCID_{50}$/mL
B.1.1.529.1(Omicron BA.1)	$1\times10^{2.25}$ $TCID_{50}$/mL
B.1.1.529.2(Omicron BA.2)	1×10^{2} $TCID_{50}$/mL

Usability Evaluation

A usability study was conducted with 105 lay persons in the self-testing environment. The sensitivity is confirmed as 91.4% and specificity is confirmed as 100% in the hands of the lay person, comparing with professional RT-PCR testing. The lay person questionnaires together with the observation recorded by healthcare professionals showed that the package insert can be easily followed by a lay person, and that the test can be easily operated by a lay person.

Clinical evaluation

A total of 289 clinical specimens were collected. 118 positive specimens and 171 negative specimens were confirmed by RT-PCR.

The results are shown below:

COVID-19 Antigen Home Test	RT-PCR		
	Positive	Negative	Total
RSV Positive	110	1	111
Negative	8	170	178
Total	118	171	289
	Diagnostic Sensitivity: 93.2% (87.2%-96.5%)* Diagnostic Specificity: 99.4% (96.8%-99.9%)* Overall Agreement: 96.9% (94.2%-98.4%)* *95% Confidence Interval		

Cross Reactivity

The COVID-19 Antigen Home Test presented no cross-reactivity with these below microorganisms at specified concentrations

HCoV-OC43	Adenovirus	*Mycobacterium tuberculosis*
HCoV-NL63	Parainfluenza 1 virus	*Bordetella parapertussis*
HCoV-229E	Parainfluenza 2 virus	*Bordetella pertussis*
Measles virus	Parainfluenza 3 virus	*Streptococcus pneumoniae*
Epstein-Barr virus	Parainfluenza 4 virus	*Legionella pneumophila*
Influenza A (H1N1)pdm09	Human metapneumovirus	*Mycoplasma pneumoniae*
Influenza A (H3N2)	Rhinovirus	*Chlamydia pneumoniae*
Influenza A (H5N1)	Coxsackie virus A16	*Streptococcus pyogenes*
Influenza A (H7N9)	Norovirus	*Streptococcus agalactiae*
Influenza A (H7N7)	Mump virus	*Group C Streptococcus*
Influenza B Victoria lineage	MERS-coronavirus	*Staphylococcus aureus*
Influenza B Yamagata lineage	*Haemophilus influenzae*	
Respiratory syncytial virus	Candida albicans	

Interfering Substances

The following substances, which occur naturally in respiratory samples or which can be artificially introduced into the respiratory tract, have been evaluated at listed below. None of them affect the test performance of the COVID-19 Antigen Home Test.

Analytes	Concentration
3 OTC nasal sprays	10%
3 OTC mouthwashes	10%
3 OTC throat drops	10%
4-acetamidophenol	10 mg/ml
Acetylsalicylic acid	10mg/ml
Albuterol	10mg/ml
Chlorpheniramine	5mg/ml
Dexamethasone	50µg/ml
Dextromethorphan	10µg/ml
Diphenhydramine	5mg/ml
Doxylamine succinate	1mg/ml
Flunisolide	25µg/ml
Guaiacol glyceryl ether	20mg/ml
Mucin	1%
Mupirocin	250µg/ml
Oxymetazoline	25µg/ml
Phenylephrine	10mg/ml
Phenylpropanolamine	1mg/ml
Relenza®(zanamivir)	10mg/ml
Adamantanamine	500ng/ml
Oseltamivir phosphate	10mg/ml
Tobramycin	10mg/ml
Triamcinolone	14 mg/ml

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 (8:30 am to 5:00 pm Monday to Friday).

INDEX OF SYMBOLS

REF	Catalogue number		Temperature Limitation
	Consult instructions for use	LOT	Batch Code
IVD	*In vitro* diagnostic		Use by date
	Manufacturer		Do not reuse

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12/12/2025
100312-AU-10