SARS-CoV-2 Antigen Rapid Test (Self-Testing)

Package Insert

REF L031-118M5 REF L031-118P5 REF L031-118R5	English

A rapid test for the detection of SARS-CoV-2 nucleocapsid antigens in anterior nasal swab specimens.
For in vitro diagnostic use only. For self-testing.

Carefully read the instructions before performing the test.

Materials Provided	Quantity (pcs)		
	1 T	5 T	25 T
Test Cassette	1	5	25
Extraction Buffer Tube	1	5	25
Disposable Swab	1	5	25
Waste Bag	1	5	25
Tube Holder	/	/	1
Package Insert	1	1	1

Materials Required But Not Provided	Timer

Scan the QR code in the guide or the packaging to access the guide in multiple languages and the test video on AusDiagnostics.care.

Other languages:

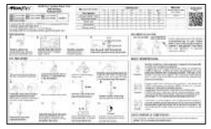
- Chinese
- Arabic
- Vietnamese
- Italian
- Greek
- Spanish
- Punjabi
- Persian
- Dari
- Korean

PREPARATION

1.

Wash or sanitize your hands. Make sure they are dry before starting the test.

2.

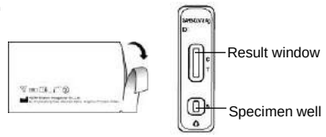


Read the instructions before using SARS-CoV-2 Antigen Rapid Test kit.

3.

Check the expiration date printed on the cassette foil pouch.

4.



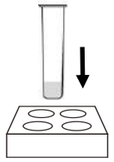
Open the pouch. Check for the Result window and Specimen well on the cassette.

TEST PROCEDURE

1.

Carefully remove the aluminum foil from the top of extraction buffer tube, avoid spilling.

2.

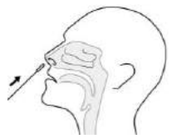


Insert the tube into the hole on the kit box. (Or place the tube in the tube holder.)

3.

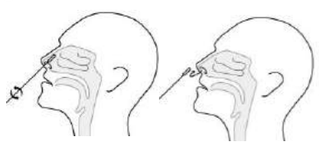
Open the swab packaging at stick end. ***Caution*:** Do not touch the absorbent tip of the swab with your hands.

4.



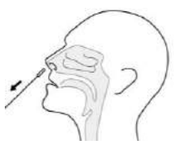
Insert the entire absorbent tip of the swab into one nostril. Using gentle rotation, push the swab less than 2.5 cm from the edge of the nostril.

5.



Rotate the swab 5 times brushing against the inside of the nostril. Remove the swab and insert it into the other nostril. Repeat step 4.

6.

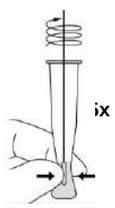


Remove swab from the nostril.

7.

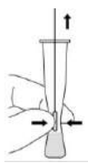
Insert the swab into the tube and swirl for 30 seconds.

8.



Rotate the swab 5 times while squeezing the side of the tube.

9.

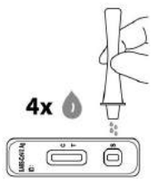


Remove the swab while squeezing the tube.

10.

Attach the dropper tip firmly onto the extraction buffer tube. Mix thoroughly by swirling or flicking the bottom of the tube.

11.



Gently squeeze the tube and dispense **4 drops** of solution into the Specimen well.

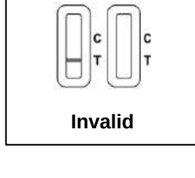
12.

15-30 min.

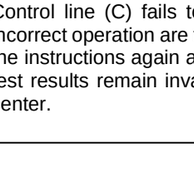
Read the result when the timer reaches 15-30 minutes. Do not read after 30 minutes.

SPECIMEN COLLECTION

SELF COLLECTION



COLLECTION BY AN ADULT CAREGIVER

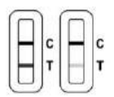


A nasal swab sample can be self-collected by an individual aged 18+ years. Children under 18 years of age should be performed by a parent or legal guardian. Please follow your local guidelines for specimen collection by children.

RESULT INTERPRETATION

Negative

Only the control line (C) and no test line (T) appears. This means that no SARS-CoV-2 antigen was detected.
A negative test result indicates that you are unlikely to currently have COVID-19 disease. Continue to follow all applicable rules and protective measures when contacting with others. There may be an infection even if the test is negative. If it is suspected, repeat the test after 1 - 2 days, as the coronavirus cannot be precisely detected in all phases of an infection.



Positive

Both the control line (C) and test line (T) appears. This means that SARS-CoV-2 antigen was detected. ***NOTE:*** *Any faint line in the test line region (T) should be considered positive.*
A positive test result means it is very likely you currently have COVID-19 disease. Contact your doctor / general practitioner or the local health department immediately. Follow the local guidelines for self-isolation. A PCR confirmation test should be carried out.

Invalid

Control line (C) fails to appear. Not enough specimen volume or incorrect operation are the likely reasons for an invalid result. Review the instructions again and repeat the test with a new cassette. If the test results remain invalid, contact your doctor or a COVID-19 test center.

SAFELY DISPOSE OF YOUR TEST KIT

Once your test is complete, put all of the used test kit contents in the waste bag provided. Put in your general household waste.

INTENDED USE

The SARS-CoV-2 Antigen Rapid Test is a lateral flow test for the qualitative detection of the nucleocapsid antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals suspected of COVID-19 within the first seven days of the onset of symptoms. The test can also test specimens from individuals without symptoms. It does not differentiate between SARS-CoV and SARS-CoV-2.
Results are for the identification of SARS-CoV-2 antigen. This antigen is generally found in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but individual 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 exact cause of disease.
The SARS-CoV-2 Antigen Rapid Test is for presumptive screening only. Consult a medical practitioner for confirmatory testing of positive results by a laboratory test and for follow-up clinical care.
Negative results do not rule out SARS-CoV-2 infection. SARS-CoV-2 Antigen Rapid Test is intended to be used to help the diagnosis of SARS-CoV-2 infection.
The usability of self-testing by an individual aged under 18 years has not been determined. It is suggested that individual under 18 years of age should be tested by an adult.

SUMMARY

The new coronaviruses belong to the beta genus. COVID-19 is an acute respiratory infectious disease. Currently, patients infected by the new coronavirus are the main source of infection; infected people without symptoms can also infect others. Based on the current knowledge, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main symptoms include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are found in a few cases.

PRINCIPLE

The SARS-CoV-2 Antigen Rapid Test is a test for the detection of the nucleocapsid antigen from SARS-CoV-2 in human anterior nasal swab specimens. Test results are read visually at 15-30 minutes based on the presence or absence of coloured lines.

To serve as a procedural control, a colored line will always appear in the control line region indicating that sufficient specimen volume was added and membrane absorption has occurred.

REAGENTS

The test cassette contains anti-SARS-CoV-2 antibodies and goat anti mouse IgG. The extraction buffer tube contains detergent and tris buffer.

WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

- Read the SARS-CoV-2 Antigen Rapid Test Package Insert 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 COVID-19 infection. Please consult a healthcare professional to discuss your results and if any additional testing is required.
- Do not use on anyone under two 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 reuse any kit components. Do not use with multiple specimens.
- Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
- Remove any piercing(s) from the nose before starting the test.
- Inadequate or improper nasal swab sample collection may yield false-negative test results.
- Do not touch the swab head when handling the swab.
- The likelihood of false-negative would increase after 7 days from the onset of symptoms. If you test negative and continue to experience symptoms or symptoms become more severe, please consult your healthcare provider. It is important that you work with your healthcare provider to help you understand the next steps you should take.
- The viral load declines in the later stage of infection and the viral load is considered to be low in asymptomatic individuals. The test could be less sensitive in these scenarios.
- Repeat testing within 1-2 days if there is an ongoing suspicion of infection, you are exposed to a high-risk setting, or if it is an occupation requirement.
- Do not use the test after the expiration date shown on the pouch.
- Do not eat, drink, or smoke before and during the test.
- Do not use the test if the pouch is damaged or unsealed.
- All used tests, specimens and potentially contaminated materials should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- The test line for a high viral load sample may become visible within 15 minutes, or as soon as the sample passes the test line region.
- The test line for a low viral load sample may become visible within 30 minutes.
- Do not collect the nasal swab specimen when nosebleed happens.
- Wash hands thoroughly after use.
- Keep the test kit away from children and animals.
- The extraction buffer can inactivate the virus which can minimize the risk for microbiological hazards. It's still necessary to handle and dispose of the used swab and other test kit contents with caution as if they contained infectious agents to reduce the spread of SARS-CoV-2 to the general population.
- If the extraction buffer comes in contact with the skin or eyes, flush with plenty of water. If irritation persists, seek medical advice from a doctor or contact First Aid poisons information center (In Australia call 13 11 26 and In New Zealand call 0800 764 766).

STORAGE AND STABILITY

- The kit can be stored at temperatures between 2 - 30 °C.
- The test is stable until the expiration date printed on the sealed pouch. Do not use after the expiration date.
- The test must remain in the sealed pouch until use.
- DO NOT FREEZE.

QUALITY CONTROL

Internal procedural controls are included in the test. A coloured line appearing in the control line region (C) is an internal procedural control. It confirms that enough specimen volume was added, and the correct procedure was carried out.

LIMITATIONS

1. The SARS-CoV-2 Antigen Rapid Test is for self-testing use only. The test should only be used for the detection of SARS-CoV-2 antigens in nasal swab specimens. The intensity of the test line does not necessarily relate to the SARS-CoV-2 viral load in the specimen.
2. A false-negative test may result if the level of antigen in a sample is below the detection limit of the test or if the sample was collected incorrectly.
3. Test results should be looked at with other clinical data available to the doctor.
4. Test is for presumptive screening only. A Consult a medical practitioner for confirmatory testing of a positive result by a laboratory test and for follow-up clinical care.
5. A positive test result cannot necessarily determine whether a person is infectious.
6. A positive test result does not rule out co-infections with other pathogens.
7. A positive test result does not differentiate between SARS-CoV and SARS-CoV-2.
8. A negative test result does not rule out other viral or bacterial infections.
9. A negative result, from an individual having symptoms beyond seven days, should be treated as likely negative and confirmed with a PCR test, if necessary.
10. The test is less reliable in the later phase of infection and in asymptomatic individuals.

CONTACT INFORMATION AND ONLINE SUPPORT

National Coronavirus Helpline
For general information about coronavirus, or if you are experiencing symptoms, call the National Coronavirus Helpline on 1800 020 080 (24 hours, 7 days) for advice on what to do next. If you require translating or interpreting services, call 131 450.

State Government Covid Support Line:

State Authority	COVID-19 Helpline	Hours
ACT Government	(02) 6207 7244	8am - 8pm , 7 days
Service NSW	13 77 88	24 hours, 7days
NT Government	1800 490 484	8am - 4:30pm , 7 days
QLD Health	13 42 68	24 hours, 7days
SA Government	1800 253787	9am - 5pm , 7 days
TAS Government	1800 020 080	Weekday 8am - 8pm ; Weekend 8am - 4pm
VIC DHHS	1800 490 484	24 hours, 7days
WA Health	13 26 843	8am - 6pm , 7 days

Product Support Line

Contact Australian Sponsor for support services:
AusDiagnostics
Website: Ausdiagnostics.care
For test kit related queries; Call: 1800 951 381 (24 hours, 7days)

Therapeutic Goods Australia

Contact the TGA to report poor performance or usability issues in the self-test environment (report an issue via the Users Medical Device Incident Report, email iris@tga.gov.au or call 1800 809 361)

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

Performance of the SARS-CoV-2 Antigen Rapid Test was established with 605 nasal swabs collected from individuals who were suspected of COVID-19. The results show that the relative sensitivity and the relative specificity are as follows:

Clinical Performance for SARS-CoV-2 Antigen Rapid Test

Method		RT-PCR (Nasopharyngeal Swab Specimens)		Total Results
SARS-CoV-2 Antigen Rapid Test (Nasal Swab Specimens)	Results	Negative	Positive	
	Negative	433	5	438
	Positive	2	165	167
Total Results		435	170	605

Relative Sensitivity: 97.1% (93.1%-98.9%)* Relative Specificity: 99.5% (98.2%-99.9%)*
Accuracy: 98.8% (97.6%-99.5%)* *95% Confidence Intervals
Stratification of the positive samples post onset of symptoms between 0-3 days has a positive percent agreement (PPA) of 98.8% (n=81) and 4-7 days has a PPA of 96.8% (n=62).
Stratification of the negative samples post onset of symptoms between 0-3 days has a positive percent agreement (NPA) of 98.7% (n=156) and 4-7 days has a PPA of 100% (n=180).
Positive samples with Ct value ⩽33 have a higher positive percent agreement (PPA) of 98.7% (n=153).

Asymptomatic Screening

Performance in asymptomatic individuals of the SARS-CoV-2 Antigen Rapid Test was established with 146 nasal swabs collected from individuals who were asymptomatic. The results show that the relative sensitivity and the relative specificity are as follows:

Method		RT-PCR (Nasopharyngeal Swab Specimens)		Total Results
SARS-CoV-2 Antigen Rapid Test (Nasal Swab Specimens)	Results	Negative	Positive	
	Negative	120	1*	121
	Positive	0	25	25
Total Results		120	26	146

Relative Sensitivity: 96.2% (80%-99.9%)* Relative Specificity: 100% (96.3%-100%)*
Accuracy: 99.3% (95.8%-99.9%)* *95% Confidence Intervals

Limit of Detection (LOD)

The LOD of SARS-CoV-2 Antigen Rapid Test was established using limiting dilutions of an inactivated viral sample. The viral sample was spiked with negative human nasal sample pool into a series of concentrations. Each level was tested for 30 replicates. The results show that the LOD is $1.6*10^2$ $TCID_{50}$/mL.

Information on what variants of COVID-19 the test can detect

SARS-CoV-2 variants were evaluated by testing different variants that are of concern in the world. Each variant was tested with recombinant nucleocapsid antigen at low positive level. No interference was observed with the following variants:

Alpha (B.1.1.7)	Epsilon (B.1.427/B.1.429)
Beta (B.1.351) / Mu (B.1.621)	Zeta (P.2)
Gamma (P.1)	Eta (B.1.525)
B.1.617	Theta (P.3)
Kappa (B.1.617.1)	Iota (B.1.526)
Delta (B.1.617.2)	B.1.616
B.1.617.3	A.23.1
B.1.618	Lambda (C.37)

Cross-Reactivity (Analytical Specificity) and Microbial Interference

Cross-reactivity was evaluated by testing a panel of related pathogens and microorganisms that are likely to be present in the nasal cavity. Each organism and virus were tested in the absence or presence of heat-inactivated SARS-CoV-2 virus at low positive level.
No cross-reactivity or interference was observed with the following microorganisms:

Adenovirus	Enterovirus	Human coronavirus 229E
Human coronavirus OC43	Human coronavirus NL63	Human Metapneumovirus
MERS-coronavirus	Influenza A	Influenza B
Parainfluenza virus 1	Parainfluenza virus 2	Parainfluenza virus 3
Parainfluenza virus 4	Respiratory syncytial virus	Rhinovirus
Human coronavirus- HKU1	Bordetella pertussis	Chlamydia trachomatis
Haemophilus influenza	Legionella pneumophila	Mycobacterium tuberculosis
Mycoplasma pneumoniae	Staphylococcus aureus	Staphylococcus epidermidis
Streptococcus pneumoniae	Streptococcus pyogenes	Pneumocystis jirovecii-S. cerevisiae
Pseudomonas aeruginosa	Chlamydia pneumoniae	Candida albicans
Pooled human nasal wash		

USABILITY STUDY

A usability study was conducted with a pool of 136 lay persons in the self-testing environment. The sensitivity is confirmed as 93.9% and specificity is confirmed as 100% in the hands of the lay person, comparing with professional RT-PCR testing.

The lay person questionnaire together with the observation recorded by a HCP 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.

FREQUENTLY ASKED QUESTIONS

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 AND PCR TEST?
A: There are different kinds of tests for COVID-19. PCR tests detect genetic material from the virus. Antigen tests, such as the Flow*flex* SARS-CoV-2 Antigen Rapid Test (Self-Testing) detect proteins from the virus. Antigen tests are very specific for the COVID-19 virus but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test is necessary and if you should continue isolating at home.

Q: WHAT IF YOU TEST POSITIVE?
A: A positive test result means that antigens from 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: A negative test result indicates no antigens for COVID-19 were detected. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19, and negative results are presumptive and may need to be confirmed with a PCR test. This means that you could possibly still have COVID-19 even though the test is negative. If you test negative and continue to experience symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider immediately. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. If you are concerned about your COVID-19 infection status after testing or think you may need follow up testing, please contact your healthcare provider.

BIBLIOGRAPHY

1. Shuo Su, Gary Wong, Weifeng Shi, et al. Epidemiology, Genetic recombination, and pathogenesis of coronaviruses. Trends in Microbiology, June 2016, vol. 24, No. 6: 490-502
2. Susan R. Weiss, Julian L. Leibowitz, Coronavirus Pathogenesis, Advances in Virus Research, Volume 81: 85-164

Index of Symbols

	Manufacturer		Contains sufficient for <*n*> tests		Temperature limit
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
	Consult instructions for use	LOT	Batch code	REF	Catalogue number
	Date of manufacture		Biological risks		

***ACON* Biotech (Hangzhou) Co., Ltd.**
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