Flowflex™

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

REF L031-118M5 REF L031-118P5 REF L031-118Z5	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	20 T
Test Cassette	1	5	20
Extraction Buffer Tube	1	5	20
Disposable Swab	1	5	20
Waste Bag	1	5	20
Tube Holder	/	/	1
Package Insert	1	1	4

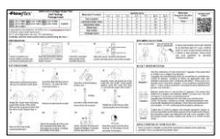
Materials Required But Not Provided
Timer

INSTRUCTION VIDEO:

PREPARATION

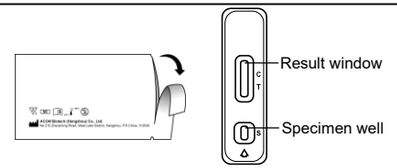
1.

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. Place the test cassette on a flat and clean surface. Check for the Result window and Specimen well on the cassette.

SPECIMEN COLLECTION

SELF COLLECTION

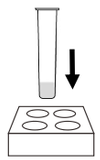
COLLECTION BY AN ADULT CAREGIVER

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. Not to be used on children under 2 years of age.

TEST PROCEDURE

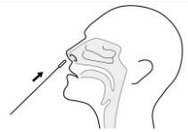
1.

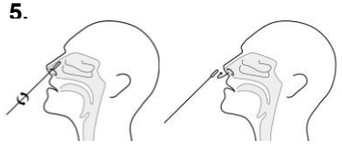
Carefully remove the aluminum foil from the top of extraction buffer tube, avoid spilling.

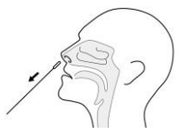
2.

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

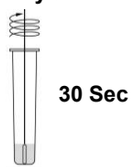
3.

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

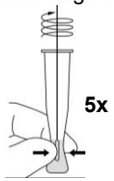
4.

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.


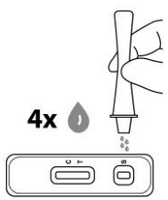
Rotate the swab 5 times while squeezing the side of the tube.

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.

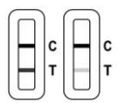
12.


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

RESULT INTERPRETATION

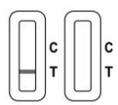
Negative

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 State or Territory Coronavirus testing services to get a laboratory PCR test immediately.** Follow the local guidelines for self-isolation.



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 State or Territory Coronavirus testing services.

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.

Orvato Healthcare Helpline: +61 02 9641 2829 (9am – 7pm | 7 Days per week)

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. 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.
Negative results from individuals with symptoms beyond seven days should be treated as likely negative. Confirm with a PCR test. 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 colored 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.

PRECAUTIONS

- Read the SARS-CoV-2 Antigen Rapid Test Package Insert carefully before performing a test. Failure to follow directions may produce inaccurate test results.
- 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 nasal sprays for at least 30 minutes before collecting a nasal sample.
- Do not use the test if the pouch is damaged.
- Each test cassette, extraction buffer tube and swab can only be used once, do not reuse.
- 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.
- If the extraction buffer contacts the skin or eyes accidentally, flush with large amounts of water and seek medical attention if necessary.
- 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.
- Testing should be performed immediately after specimen collection, or at most within one (1) hour after specimen collection, if stored at room temperature (15-30°C).

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 colored 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. A positive test result cannot necessarily determine whether a person is infectious.
5. A positive test result does not rule out co-infections with other pathogens.
6. A positive test result does not differentiate between SARS-CoV and SARS-CoV-2.
7. A negative test result does not rule out other viral or bacterial infections.
8. A negative result, from an individual having symptoms beyond seven days, should be treated as likely negative and confirmed with a PCR test.
9. The test is less reliable in the later phase of infection and in asymptomatic individuals.
10. The test should not be used on children under 2 years of age.

CONTACT INFORMATION AND ONLINE SUPPORT

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).

State Government Covid Support Line:

State Authority	COVID-19 Helpline	Operational Hours	Website
NSW	1800 020 080	Mon – Fri (8am – 5pm)	https://www.health.nsw.gov.au/
VIC	1800 675 398	Mon – Fri (8:30am – 5pm)	https://www.dhhs.vic.gov.au/
QLD	13 42 68	Mon – Fri (8am – 5pm)	https://www.health.qld.gov.au/
NT	1800 490 484	Mon – Fri (8am – 5pm)	https://health.nt.gov.au/
SA	1800 253 787	Mon – Fri (8am – 5pm)	https://www.sahealth.sa.gov.au/
TAS	1800 020 080	Mon – Fri (8am – 5pm)	https://www.tas.gov.au/
WA	1800 595 206	Mon – Fri (8am – 5pm)	https://ww2.health.wa.gov.au/
ACT	1800 022 222	Mon – Fri (8am – 6pm) Weekends & Public Holidays (9am – 5pm)	https://www.health.act.gov.au/

Contact local sponsor for support services:

Company Name: Orvato Healthcare
Phone Number: +61 02 9641 2829
Email Address: sales.au@orvatohealthcare.com

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 Sensitivity is 97.1% (165/170), Specificity is 99.5% (433/435) and an Overall Accuracy is 98.8% (598/605).

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.

Limit of Detection (LOD)

The LOD of SARS-CoV-2 Antigen Rapid Test is 160 $TCID_{50}$/mL.

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

Different variants were evaluated. The performance of SARS-CoV-2 Antigen Rapid Test is not impacted by these new virus variant(s) including: Alpha, Beta, Gamma, Delta, Kappa, Eta, Mu, Epsilon, Iota, Lambda, Zeta, Theta, B.1.616, B.1.617, B.1.617.3, B.1.618, A.23.1 etc.

Cross-Reactivity (Analytical Specificity) and Microbial Interference

Cross-reactivity was evaluated. 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		

Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated. Each substance was tested in the absence or presence of SARS-CoV-2 virus at low positive level. The substances tested are listed below and were found not to affect test performance.

Endogenous	NeilMed NasoGel for Dry Noses
Afrin Original Nasal Spray	Throat Lozenge (Dyclonine Hydrochloride)
ALKALOL Allergy Relief Nasal Spray	Zicam Cold Remedy
Chloraseptic Max Sore Throat Lozenges	Antibiotic (Mupirocin)
CVS Health Fluticasone Propionate Nasal Spray	Tamiflu
Equate Fast-Acting Nasal Spray	Antibiotic (bramycin)
Equate Sore Throat Phenol Oral Anesthetic Spray	Mometasone Furoate Nasal Spray
Original Extra Strong Menthol Cough Lozenges	Physiological Seawater Nasal Cleaner
NasalCrom Nasal Spray	

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		

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