Instruction manual
SARS-CoV-2 Antigen Rapid Test

Read the instructions for use completely before performing the test.
For in vitro diagnostic and for self-testing use.

Product

SARS-CoV-2 Antigen Rapid Test

Intended use

The SARS-CoV-2 Antigen Rapid Test is a lateral flow test for the qualitative detection of the SARS-CoV-2 nucleocapsid antigen extracted from anterior nasal swab specimens directly from individuals suspected of COVID-19 within the first seven days of the onset of symptoms. It is intended to be used to help the diagnosis of SARS-CoV-2 infection. It does not differentiate SARS-CoV-2 from other SARS-coronavirus.

This test is a single-use test kit intended for lay users as a self-testing. Positive test results can be used for early isolation and rapid treatment of suspected cases, but they can not serve as a basis for a definitive diagnosis of Covid-19 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. Do not use the test in children under the age of 2.

Component

Specification / Ingredients	1 test/kit	5 tests/kit	10 tests/kit	20 tests/kit	25 tests/kit
Test cassettes and desiccants in a sealed foil pouch	1	5	10	20	25
Extraction Reagent	0.5mL*1	0.5mL*5	0.5mL*10	0.5mL*20	0.5mL*25
Extraction tube	1	5	10	20	25
Swab	1	5	10	20	25
IFU	1	1	2	4	25

MATERIALS REQUIRED BUT NOT PROVIDED
Watch/Timer
Garbage bag

Safety

1. The test kits should be stored at temperatures of 4-30°C and should not be exposed to direct sunlight or moisture. DO NOT FREEZE.Before use, tests stored at low temperature should be brought to room temperature.
2. Do not use expired and damaged products. The expiry date is printed on the outer packaging.
3. Keep the test kits away from young children to reduce the risk of accidentally drinking the buffer liquid or swallowing small parts.
4. The test cassette should be used as soon as possible after removal from the foil bag to avoid prolonged exposure to moisture, as these could affect the test result.
5. Under room temperature (15-30°C) and humidity of less than 60%, the test kits must beused within half an hour after opening the packaging. If the humidity exceeds 60%, use immediately after opening the packaging.
6. The test set should be disposed after use in a lockable garbage bag in the household waste.
7. Incorrect operation may affect the accuracy of the results, such as e. g. too little effective time in the buffer solution, too little or too much buffer in the solution, insufficient sample addition, inaccurate detection time, etc.
8. False-negative results can occur when the swab is placed in a bag between sampling and evaluation.
9. Do not suck the sample with your mouth.
10. During the test, do not smoke, eat, drink alcohol, apply make-up or put in contact lenses, or take them out.
11. Disinfect spilled samples or reagents with disinfectant.
12. If the extraction reagent come into contact with the skin or eyes, wash/ rinse the affected area with plenty of water. If irritation is found, contact your doctor.
13. After the test, stow all components in a sealable plastic bag and dispose of them in household or residual waste.
14. Wash hands thoroughly after test completion.

Frequently asked questions

Q:What if you test positive?
A: A positive test result means it is very likely you currently have COVID-19 disease. Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
Q: What if you test negative?
A: 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. Infection is not guaranteed to be excluded, as a low virus load or a possible sampling error can result in a wrong result. If it is suspected, repeat the test after 1 - 2 days, as the coronavirus can not be precisely detected in all phases of an infection.
Q: What if you test invalid?
A: If no line appears on the control line (C), indicating insufficient sample volume, incorrect operation, or expired tests.
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.
Q: Will this test hurt?
A: No, the nasal swab is not sharp, and it should not hurt. Discomfort may occur if the swab is inserted beyond the recommended depth. If painful, slightly withdraw the swab to finish the sample collection process.
Q: Can I use my own swab?
A: No, you must only use the components included in the test kit.
Q: Can I re-use any of the components of the test kit?
A: No, no component can be reused and it is not recommended to mix the components of kits with different lot.
Q: Could I swab just one nostril?
A: No. Please use the swab to collect specimen from both of your nostrils to ensure sufficient sample collection to generate an accurate result.

Restrictions of the test procedure

1. The results of this product should not be considered a definitive diagnosis and are for clinical reference only. Please follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
2. If the virus antigen content in the sample is below the detection limit, the test result may be negative, false negatives are more likely to occur in the later phase of infection and in asymptomatic individuals particularly if testing is not performed within the first 7 days of symptom onset.
3. As the disease lasts, the number of antigens in the sample may decrease and the results may be negative 7 days after symptoms appeared compared to the RT-PCR test.
4. Due to the limitations of testing procedures, negative results cannot rule out the possibility of infection with SARS-CoV-2 and possibility of infection with another type of respiratory virus. Please follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
5. Due to the limitations of testing procedures, positive result should not be viewed as a definitive diagnosis, but should be assessed in the context of clinical symptoms and other diagnostic methods. A positive result cannot necessarily determine whether a person is infectious.
6. If ongoing suspicion of infection, high risk setting or other epidemiological reasons, but test result was negative, repeat the test after 1 - 2 days.
7. Please contact the TGA for locally support services or reporting poor performance and 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).

Quality

The test cassette has a test line (T) and a control line (C) on the surface of the membrane. Neither the test nor control line is visible in the results window before a sample is applied. The control line is used for procedural control and should be displayed whenever the test procedure is properly carried out and the control line reagents work.
The occurrence of the control line (C) confirms sufficient sample volume, sufficient membrane discharge and correct process technology.

Test principle

The rapid test is based on the GICA principle, whereby the nitrocellulose membrane is coated with monoclonal coronavirus (SARS-CoV-2) antibody 2 and goat-anti-mouse IgG antibody, the monoclonal coronavirus (SARS-CoV-2) antibody 1 fixed on a gold conjugate pad solid phase. When the antigen is contained in the sample, it combines with the appropriate gold-labelled monoclonal antibodies to form a complex and moving forward under the chromatography on the membrane, then combines with the coated antibody on the test line to form Au-novel coronavirus (SARS-CoV-2) monoclonal antibody 1-antigen-novel coronavirus (SARS-CoV-2) monoclonal antibody 2 complex to condenses into a red band (Test line, T).

Excess particles are intercepted at the control line (C). If a red line appears in the test line area (T), this should be considered a positive result.

If no antigen is included in the sample, no complex can form on the test line, and no red line appears, which is a negative result. The gold-labelled monoclonal antibody binds to the coated goat-anti-mouse IgG antibody on the control line to form a complex of "Au-coronavirus (SARS-CoV-2) monoclonal antibody 1-goat-anti-mouse-IgG antibody", regardless of whether the sample contains antigen, and the color is developed as a cohesion (Control line, C). If the control line is not visible, the test must be repeated with a new cassette.

Performance specification of the rapid test

1. Limit of Detection
The LOD of SARS-CoV-2 Antigen RapidTest is 8 $TCID_{50}$/mL.

2. Variant
The SARS-CoV-2 variant Alpha (UK B.1.1.7), Beta (South Africa B.1.351), Gamma (Brazil B.1.1.28) and Delta(Indian B.1.617.2)could be detected out by the SARS-CoV-2 Antigen Rapid Test at specific concentrations. But the type of the variant can not be distinguished.

3. Clinical performance
The performance of the SARS-CoV-2 antigen rapid test was evaluated in Germany with European subjects. A total of 402 frozen swab samples including 102 positive samples and 300 negative samples from the anterior nose were tested. All the swab specimens were confirmed as positive or negative and validated with Ct value by the RT-PCR as a comparator method.

SARS-CoV-2 Antigen Rapid Test	RT-PCR		Total
	Positive	Negative	
Positive	100	0	100
Negative	2	300	302
Total	102	300	402
Rate	98.04% (Sensitivity)	100.00% (Specificity)	99.50% (Reliability)

Explanation of terms:
98.04%Sensitivity: In total 102 PCR confirmed positive samples: 100 PCR confirmed positive samples were correctly detected by SARS-CoV-2 Antigen Rapid Test. There are 2 false negative cases.
100%Specificity: In total 300 PCR confirmed negative samples were all correctly detected by SARS-CoV-2 Antigen Rapid Test.
99.50%Reliability: In total 402 PCR confirmed samples:400 PCR confirmed samples were correctly detected by SARS-CoV-2 Antigen Rapid Test.

4. Usability study
A usability study was conducted with a pool of 141 lay persons in the self-testing environment. The sensitivity is confirmed as 100% and specificity is confirmed as 100% in the hands of the lay person, comparing with professional RT-PCR testing.
The lay questionnaire along with the observation recorded by healthcare professionals indicated that the package insert could be easily followed by a lay user and that the test could be easily performed by a lay user.

5.Analytical specificity
1) Interfering substances
The test showed no interference with following substances:
Mucin, Blood (human), Guaiacol glyceryl ether, Arbidol hydrochloride hydrate, Zanamivir, Meropenem, Oseltamivir, Ritonavir, Peramivir trihydrate, Ribavirin, Histamine hydrochloride, Levofloxacin, Oxymetazoline hydrochlorid, Ceftriaxone sodium, Cefradine, Cefalexin, Benzocaine, Tobramycin, Lopinavir, Azithromycin, Watermelon frost buccal tablets, Dexamethasone, Flunisolid, Beclomethasone, Sodium chloride, Alpha interferon, Phenylephrine hydrochloride, Acetaminophen, Ibuprofen, Aspirin, Acetylsalicylic acid, Hydrocortisone, Albuterol, Chlorpheniramine, Diphenhydramine, Budesonide, Mometasone, Fluticasone, NeilMed, Menthol, Quinine (malaria), Lamivudine (retroviral drug), Biotin, HAMA.
2) Cross-reactivity
The test showed no cross-reactivity with following 26 viruses and 14 other microorganisms, except for the Human SARS-coronavirus Nucleoprotein:
HCoV-NL63, HCoV-OC43, HCoV-229E, HCoV-HKU1, MERS, Adenovirus Type3, Adenovirus Type7, Adenovirus Type1, Adenovirus Type5, Adenovirus Type8, Adenovirus Type11, Adenovirus Type21, Adenovirus Type55, Echovirus, Influenza virus A (H1N1), Influenza virus A (H3N2), Influenza virus B Strain, Parainfluenza Type 1, Parainfluenza Type 2, Parainfluenza Type 3, Parainfluenza Type 4, Respiratory syncytial virus (RSV) type A, Respiratory syncytial virus (RSV) type B, Rhinovirus A16, Human Metapneumovirus (hMPV) 16 Type A1, Candida albicans, Legionella pneumophila, Streptococcus pneumoniae, Pseudomonas aeruginosa, Staphylococcus epidermidis, Staphylococcus salivarius, Mycoplaa Pneumoniae, Chlamydia Pneumoniae, Streptococcus pyogenes, Mycobacterum tuberculosis, Hemophilus influenzae, Bordetella pertussis, Pneumocystis, Pooled human nasal wash.
3) Microbial Interference Studies
By testing 10 other microorganisms, it was found that other microorganisms have no effect on the test results.
Staphylococcus aureus, Escherichia coli, Streptococcus salivarius, Proteus mirabilis, Klebsiella pneumoniae, Staphylococcus haemolyticus, Mumps Virus Ag, Avian Influenza Virus(H7N9), Measles virus, Norovirus.

Explanation of the symbols

	Consult instructions for use		Keep dry
	Temperature limit	LOT	Batch code
	Do not re-use	IVD	*In vitro* diagnostics medical device
	Manufacturer		Date of Manufacture
	Use-by date		contains sufficient for <n> tests
	Keep away from sunlight	/	/

Manufacturer information

MANUFACTURER/POST-SALESERVICEUNIT
QingdaoHightopBiotechCo., Ltd.
Add.: No.369 Hedong Road, Hi-tech Industrial Development Zone, Qingdao, Shandong,266112, China
Tel: +86-532-58710705 Fax:+86-532-58710706
Web:www. hightopbio.com E-mail: sales@hightopbio.com

Sponsor:
ALPHA-MEDICS AUSTRALIA PTY LTD
Add.: 133 Market Street, South Melbourne, VIC3205
Tel: 1800 575 090 Web:www.alpha-medics.com.au
E- mail: sales@alpha-medics.com.au

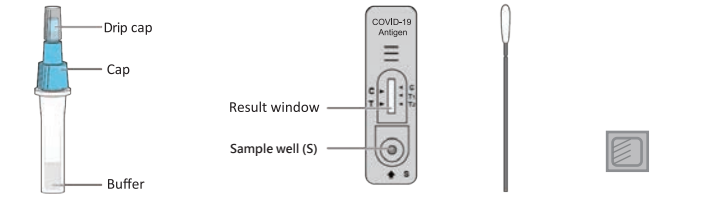
Contact information and online support

In the event you are experiencing problems with the test, please contact our Alpha-Medics Support hotline, see below.
Additionally, you may wish to report poor performance or usability issues to the Therapeutic Goods Administration (TGA) via the Users Medical Device Incident Report, email iris@tga.gov.au or call 1800 809 361.
To contact your local state/territory health department click on the following link: https://www.health.gov.au/about-us/contact-us/local-state-and-territory-health-departments
Local state and territory health departments
Contact details and websites of the local state and territory health departments.

Australian Capital Territory Department of Health	Business hours: 02 5124 9213 Coronavirus helpline (8am to 8pm daily): 02 6207 7244 https://health.act.gov.au
New South Wales Department of Health	General enquiries: 1300 066 055 Coronavirus hotline (Service NSW, 24/7): 137 788 https://www.health.nsw.gov.au
Northern Territory Department of Health	General enquiries: 08 8922 8044 Coronavirus hotline (National helpline): 1800 020 080 https://health.nt.gov.au
Queensland Department of Health	13HEALTH: 13 432 584 Coronavirus hotline: 134COVID, 134 268 https://www.health.qld.gov.au
South Australian Department of Health	General enquiries: 1300 232 272 Coronavirus hotline (9am to 5pm daily): 1800 253 787 https://www.sahealth.sa.gov.au/
Tasmanian Department of Health	General enquiries: 1300 135 513 Public Health Hotline (coronavirus): 1800 671 738 https://www.health.tas.gov.au
Victorian Department of Health	Department of Health and Human Services: 1300 650 172 Victorian coronavirus hotline (24/7): 1800 675 398 https://www.dhhs.vic.gov.au
Western Australian Department of Health	General enquiries: 08 9222 4222 Coronavirus hotline: 13COVID (8am to 6pm, Mon–Fri), 1800 595 206 https://www.healthywa.wa.gov.au

Alpha-Medics Support Hotline: +61 03 7022 6852 or 1800 575 090
Hours: 8am-7pm (AEST), 7 days per week

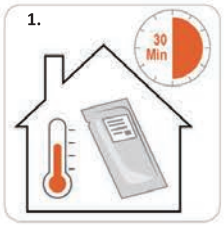
- Only use the swabs and buffer solution included in the test kit for the test.
- Process the samples exactly as described here.
  Too little sample material or improper processing can lead to incorrect results.
- Keep the test kits out of the reach of children to reduce the risk of accidentally drinking the buffer liquid or swallowing small parts.
- Do not use expired or opened test kits.
  The test cassette becomes unusable half an hour after unpacking.



Extraction Tube | Test Cassette | Swab | Desiccant (please dispose)

Note: The diagram is for reference only. See the real object for details.
The appearance of extraction tube and color of it's cap may be different from the actual product, which has no effect on normal use.

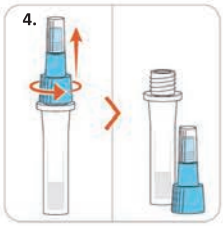
I. PREPARATION



Bring all components of the test kit to room temperature (15 to max. 30 ° C) 30 minutes before starting the test.

Wash your hands thoroughly.

Have a clock ready or use a timer.

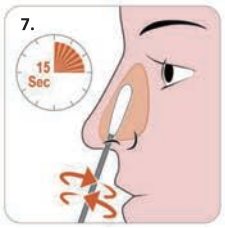


Unscrew the blue cap from the extraction tube. Don't spill the liquid.

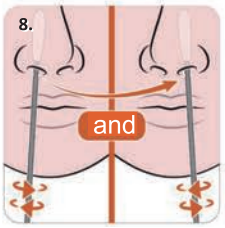
Unpack the test cassette and use this right away according to the following instructions.

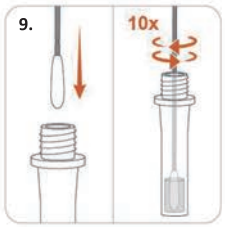
Unpack the swab.

II. SAMPLING

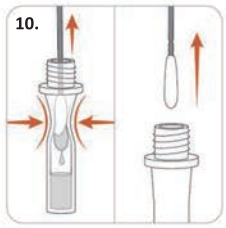


- Insert the swab approx. 2–2.5 cm deep into one nostril.
  The absorbent, the tip should be completely immersed in the nasal cover.
- Wipe the swab along the inner wall of the nose in circular movements for about 15 seconds.
- Repeat with the same swab in the other nostril.

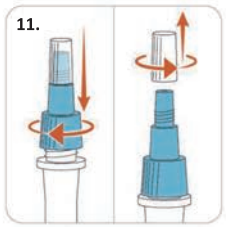




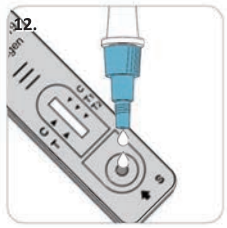
Immerse swabs in extraction tubes with buffer solution and rotate 10 times. Let it work for 1 minute.



Then squeeze out the swab using the extraction tube. Collect the liquid in the tube. Remove the swab and put it in the garbage bag.



Close the extraction tube with the cap and unscrew the drip cap.
Do not shake!



Turn the tube upside down and add 2 to a maximum of 3 drops to the sample well (s) of the test cassette.
Do not move the test cassette.

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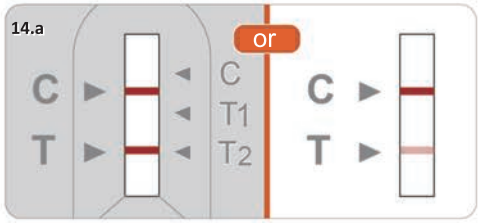
III. RESULTS INTERPRETATION

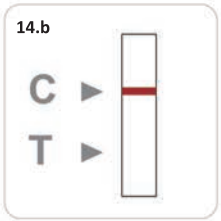
Read the result in the result window after 15minutes
Results after 20 minutes have no meaning.
C = Control line
T = Testing line



POSITIVE **POSITIVE**

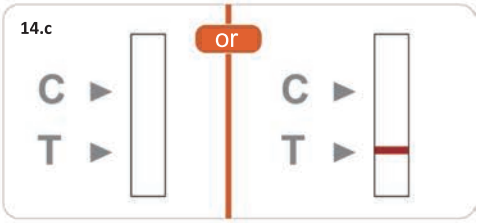
A red line appears on both the control line (C) and the test line (T)
NOTE: Any faint line in the test line region (T) should be considered positive.
A positive test result means it is very likely you currently have COVID-19 disease. Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

The lines shown can vary in intensity!



NEGATIVE

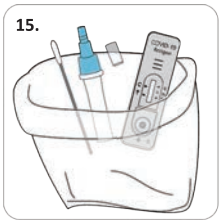
The red line appears only on the control line (C), no red line on the test line (T).
A negative test result indicates that you are unlikely to currently have COVID-19 disease. Continue to follow all applicable rules and protective measures when contacting with others. Infection is not guaranteed to be excluded, as a low virus load or a possible sampling error can result in a wrong result. **If it is suspected, repeat the test after 1 - 2 days, as the coronavirus can not be precisely detected in all phases of an infection.**



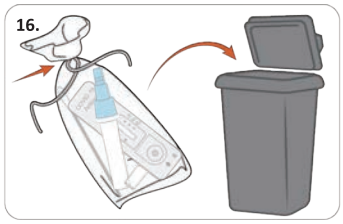
INVALID **INVALID**

If no line appears on the control line (C), indicating insufficient sample volume, incorrect operation, or expired tests.
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.

IV. DISPOSAL



After the test, stow all components in a sealable plastic bag and dispose of them in household or residual waste.



Wash your hands thoroughly.

Please scan the QR code to access instructional guides and additional information.
To generate a DIGITAL CERTIFICATE or share your test result, please download the SELF CHECK APP.

Alpha-Medics Support Hotline: +61 03 7022 6852 or 1800 575 090
Hours: 8am-7pm (AEST), 7 days per week

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