COVID-19 Antigen Rapid Test (For Self-testing)

English

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ISCOVu002-B001	1
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Scan me for the how to use video
For further support call 02 8313 0570
For additional language instructions please visit https://thecompleteguardian.com/rapid-antigen-test-5-pack/

Please read these instructions for use before undertaking a test.

[Intended use]

The COVID-19 Antigen Rapid Test is a lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swabs from individuals suspected of being infected with COVID-19 within the first 7 days of symptom onset. This test is intended for self-use by persons aged 15 years or above and also for an adult testing another person under 15 years of age. Individuals over 65 years of age should consider to seek assistance in performing the test.

The test is an aid for diagnosis of COVID-19 and only provides a presumptive test result for the SARS-CoV-2 virus. It is intended to be used in the home or similar environment by a lay person.

A negative result does not mean a person does not have COVID-19. If you have a COVID-19 POSITIVE result, staying at home protects the people in your community and you should not visit high-risk settings like hospitals and aged and disability care settings. 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. For details, please visit https://www.health.gov.au/topics/covid-19/testing-positive.

[When to use the test kit]

Use this test:

✓ If you have COVID-like symptoms including headache, fever, a cough, sore throat, loss of sense of smell or taste, shortness of breath, etc.

Do not use this test:

X If you are prone to nosebleeds.

[Warnings and precautions]

1. For *in vitro* diagnostic use only.
2. Do not use this test as the only guide to manage your illness. If you have a COVID-19 POSITIVE result, staying at home protects the people in your community and you should not visit high-risk settings like hospitals and aged and disability care settings. 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. For details, please visit https://www.health.gov.au/topics/covid-19/testing-positive.
3. The test is less reliable in the later phase of infection and in asymptomatic individuals.
4. Negative results may occur if testing is not performed within the first 7 days of symptom onset.
5. If the test is to be used on a person under 15 years of age, the test must be undertaken by an adult.
6. Keep out of reach of children to reduce the risk of accidentally drinking the extraction reagent or swallowing small parts.
7. Do not use this product after the expiration date.
8. Only use the test once and only with the provided parts.
9. Do not undertake testing in direct sunlight.
10. The extraction reagent is a clear liquid, which is prefilled and sealed in the extraction reagent tube. Do not use the extraction reagent tube when you observe leakage, discoloration or any foreign object in the liquid. In this case, you have to discard the extraction reagent tube and replace it with a new extraction reagent tube.
11. Avoid contact with Extraction Reagent. If the extraction reagent is accidentally exposed to a person's skin or eye, rinse with plenty of running water immediately. If irritation persists, seek medical assistance.
12. This test involves taking a sample from deep inside your nose. When doing the test, pay particular attention to the instructions on how to swab your nose. Incorrect swabbing may lead to an inaccurate test result.
13. The test cassette should remain in the sealed pouch until use.
14. Wash hands thoroughly before and after testing.
15. Dispose all parts of the used test kit into the waste bag, then discard the waste bag in the general waste.
16. The test cannot differentiate SARS-CoV from SARS-CoV-2.

[What is included in the test kit]

Components	ISCOVu002-B001	ISCOVu002-B002	ISCOVu002-B005	ISCOVu002-B020
1. Test Cassette	1×	2×	5×	20×
2. Extraction Reagent Tube	1×	2×	5×	20×
3. Swab	1×	2×	5×	20×
4. Waste Bag	1×	2×	5×	20×
5. Instructions for Use	1×	1×	1×	4×
6. Work Station	/	/	/	1×

[Storage and stability]

- Store as packaged in the sealed pouch between **4–30** ℃.
- The LOT and the expiration date were printed on the foil packaging and box.

[Limitations]

1. The test should be used for the qualitative detection of SARS-CoV-2 antigens in nasal swab specimens only. The intensity of the T-line does not necessarily correlate to SARS-CoV-2 viral titer in the specimen.
2. Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
3. The test is a presumptive test only. If you have a COVID-19 POSITIVE result, staying at home protects the people in your community and you should not visit high-risk settings like hospitals and aged and disability care settings. 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. For details, please visit https://www.health.gov.au/topics/covid-19/testing-positive.
4. Negative results may occur if the level of antigen in the specimen is below the detection limit of the test. Repeat testing after 1-2 days is recommended, if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or have a known exposure to COVID-19.
5. Negative results do not rule out SARS-CoV-2 infection, if you are experiencing COVID-like symptoms, you should seek medical assistance.
6. A Negative result does not rule out infection with another type of respiratory virus.
7. A Positive result cannot determine whether a person is infectious.
8. Positive results do not rule out co-infections with other pathogens.
9. Positive results may occur, particularly in areas with low numbers of COVID-19 infections.

[Frequently asked questions (FAQ)]

How does the CLUNGENE COVID-19 Antigen Rapid Test work?

The CLUNGENE COVID-19 Antigen Rapid Test is a type of test called an antigen test. When you have COVID-19, the SARS-CoV-2 virus (the virus that causes COVID-19) can be present in your nasal secretions. The CLUNGENE COVID-19 Antigen Rapid Test can detect small parts of SARS-CoV-2 virus in your nasal secretions. These small parts of the SARS-CoV-2 virus are known as proteins or antigens.

Will this test hurt?

No, the nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable or tickly. If you feel pain, please stop the test and seek advice from a doctor.

What are the potential benefits and risks of this test?

Potential risks include:

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

Potential benefits include:

- The results, along with other information, can help your doctor make informed recommendations about your treatment/care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

What is the difference between a COVID-19 antigen, molecular, and antibody test?

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

Another type of test is an antibody test. A COVID-19 antibody test detects antibodies that have been made by your immune system in response to a previous COVID-19 infection. Antibody tests are not suitable to diagnose an active COVID-19 infection.

[Performance characteristics]

Clinical Performance

The clinical performance of CLUNGENE COVID-19 Antigen Rapid Test for self-testing was evaluated in a prospective study in Greece between June 2021 and July 2021. A total of 578 laypersons (of which, 122 within 7 days post symptom onset) were sequentially enrolled. No additional training or instructions were provided. Self-sampling with nasal swabs and self-testing were conducted by participants using the COVID-19 Antigen Rapid Test. For comparison, to each of the participants, an RT-PCR testing was performed by professional sampling with nasopharyngeal swab. The COVID-19 Antigen Rapid Test showed a sensitivity of 95.1% (95% confidence interval: 89.7%-97.7%, N=122) and a specificity of 100% (95% confidence interval: 99.2%-100%, N=456) compared to RT-PCR.

Limit of Detection (Analytical Sensitivity)

The COVID-19 Antigen Rapid Test can detect SARS-CoV-2 virus as low as 570 $TCID_{50}$/mL.

Variants

The performance of COVID-19 Antigen Rapid Test is not affected by Alpha, Beta, Gamma, Delta, Omicron variants.

Cross Reactivity (Analytical Specificity)

Cross reactivity was evaluated by testing 33 potential cross-reactive substances that may be present in the nasal cavity.

No cross-reactivity was observed with recombinant MERS-CoV nucleocapsid protein when tested at the concentration of 50 μg/mL.

No cross-reactivity was observed with the following viruses when tested at the concentration of 1.0×10^6 PFU/mL: Influenza A (H1N1), Influenza A (H1N1pdm09), Influenza A (H3N2), Influenza B (Yamagata), Influenza B (Victoria), Adenovirus (type 1, 2, 3, 5, 7, 55), Human metapneumovirus, Parainfluenza virus (type 1, 2, 3, 4), Respiratory syncytial virus, Enterovirus, Rhinovirus, Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, Human coronavirus HKU1.

No cross-reactivity was observed with the following bacteria when tested at the concentration of 1.0×10^7 CFU/mL: Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumophila, Haemophilus influenzae, Streptococcus pyogenes (group A), Streptococcus pneumoniae, Candida albicans, Staphylococcus aureus.

Cross-reactivity was observed with recombinant SARS-CoV nucleocapsid protein when tested at the concentration of 1 ng/mL or more because SARS-CoV has high homology to the SARS-CoV-2.

Interference

The following potential interference substances were evaluated with the COVID-19 Antigen Rapid Test at the concentrations listed below and were found not to affect test performance.

Substance	Concentration	Substance	Concentration
Mucin	2 mg/mL	Fluticasone propionate	5 mg/mL
Whole blood	4%	Dexamethasone	5 mg/mL
Zanamivir	5 mg/mL	Tobramycin	5 μg/mL
Ribavirin	5 mg/mL	Mupirocin	10 mg/mL
Arbidol	5 mg/mL	Triamcinolone	10 mg/mL
Oseltamivir phosphate	10 mg/mL	Histamine dihydrochloride	10 mg/mL
Saline nasal spray	15%	Benzocaine	5 mg/mL
Oxymetazoline	15%	Menthol	10 mg/mL
Phenylephrine	15 mg/mL		

[Contact information]

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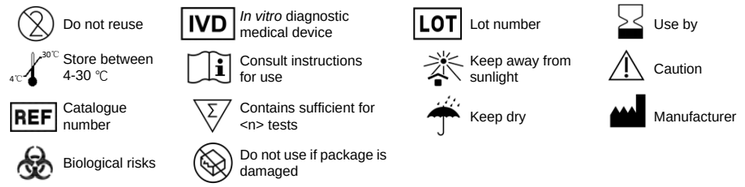
No.1 Yichuang Road, Yuhang Sub-district, Yuhang District, 311121 Hangzhou, China
https://en.clongene.com/

AU REP Powersource Group Pty Ltd
Shop 2, 371 Wattles St, Ultimo NSW 2007 Australia
Email: info@thecompleteguardian.com
Phone: 02 8313 0570
Website: https://thecompleteguardian.com/rapid-antigen-test-5-pack/

In the event you are experiencing problems with the test, please contact our authorized representative in Australia as above.

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@health.gov.au or call 1800 809 361.

Index of Symbol



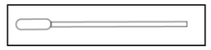
Version No.: 2.0
Effective Date: July 29, 2024

Turn page

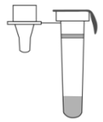
[Preparing to do the test]

1. Keep a clock, timer or stopwatch at hand.
2. **Ensure that all test components are kept at room temperature (15-30℃).**
3. Ensure that the packaging is intact; Do not use the test if there is visible damage of the foil packaging.
4. Open the box and you will get the components shown below:

Instructions for Use



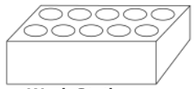
Swab



Extraction Reagent Tube

Waste bag

Test Cassette



Work Station
(For 20 Tests pack only)

Note1: *Only open the foil packaging of the test cassette when you are ready to carry out the test. Use the test cassette within one hour after opening.*
Note2: *A positive control is not provided with the device,and the exteral controls are available for separate purchase.*
Positive control: 1st WHO International Standard for SARS-CoV-2 antigen (NIBSC code: 21/368).

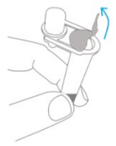
[Before starting]

Wash your hands in soapy water and dry thoroughly.

[Step-By-Step Instructions]

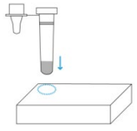
1. Open Extraction Reagent Tube

Carefully tear off the sealed foil film on the extraction reagent tube.

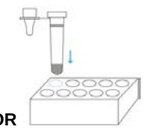


2. Insert Tube into Box

Gently press the tube through the perforated hole in the box.
OR
Place the tube in the work station.



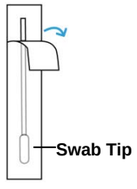
OR



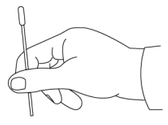
3. Remove the Swab

a. Open the swab package at the stick end.

Note: *Keep fingers away from swab tip.*

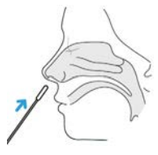


b. Take out the swab.

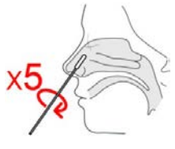


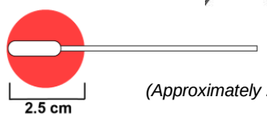
4. Swab the Left Nostril

a. Gently insert the entire tip of the swab, app. **2.5 cm** into the left nostril.



b. Firmly brush the swab against the inside of the nostril in a circular motion **5 times** or more.

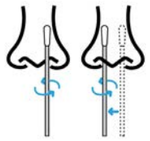




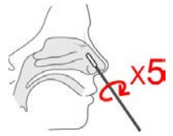
*(Approximately **1.5 times** the length of the swab tip)*

5. Swab the Right Nostril

a. Remove the swab from the left nostril and insert it into right nostril about **2.5 cm**.



b. Firmly brush the swab against the inside of the nostril in a circular motion **5 times** or more.

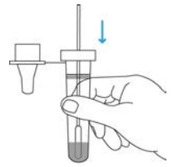


CHECK!
You should swab both nostrils.

Note: *A false negative result may occur if sample collection is not thoroughly undertaken.*

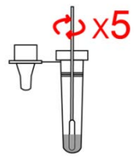
6. Insert the Swab into the Tube

Insert the nasal swab into the tube which contains the extraction reagent.



7. Rotate the Swab 5 Times

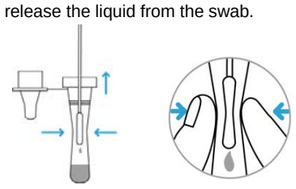
a. Rotate the swab at least **5 times** while pressing the swab tip against the bottom and the sides of the tube.



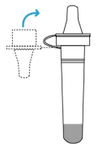
b. Let the tip of the swab soak in the tube for **1 minute**.

8. Remove the Swab

a. Remove the swab while squeezing the sides of the tube against the swab, to release the liquid from the swab.

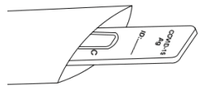


b. Cover the tube with the provided cap tightly and insert the tube back into the box.

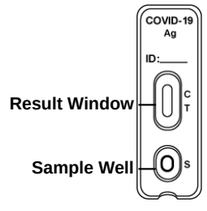


9. Take out the Test Cassette from the pouch

Open the sealed pouch and take out the test cassette.



Note*: Test cassette must lay **FLAT** on the table during the entire testing.*



10. Add Sample to the Sample Well

a. Hold the tube vertically over the Sample Well - not at an angle.

b. Add **3 drops** from the tube into the Sample Well by gently squeezing the sides of the tube.

Note 1: *A false negative result may occur if less than 3 drops of sample is used.*

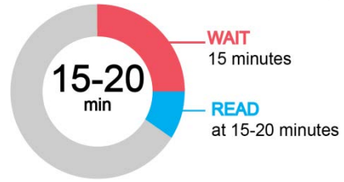
Note 2: *The result will not be affected if 1-2 more drops of sample are accidently added – as long as you can read a C-line (see Read result below).*

11. Timing

Start the clock / stopwatch or timer.

12. Wait 15 Minutes

Read the test result at **15-20** minutes, **DO NOT** read the result after 20 minutes.

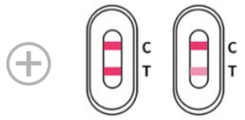


Note: *False results can occur if the test results are read before 15 minutes or after 20 minutes.*

[Read result]

Positive Result

Two lines appear. One coloured line appears at the control region (C), and another appears at the test region (T).

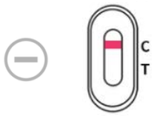


Please look very closely!
The intensity of the T-line can be very faint.

A positive test result indicates that you are likely to carry the COVID-19 disease. If you have a COVID-19 POSITIVE result, staying at home protects the people in your community and you should not visit high-risk settings like hospitals and aged and disability care settings. 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. For details, please visit https://www.health.gov.au/topics/covid-19/testing-positive.

Negative Result

One coloured line appears at the control region (C), and no line appears at the test region (T).



A negative test result indicates that you are unlikely to carry the COVID-19 disease.
If you suspect an infection, it is recommended that you repeat testing after 1–2 days, as the virus cannot be precisely detected in all phases of an infection. Please seek medical assistance if you develop symptoms or symptoms are persisting.

Invalid Result

Control (C) line fails to appear.

Note: *If a C-line does not appear, the test result is invalid regardless of the appearance of a T-line or not.*

If a C-line does not appear, you need to retest with a new test cassette and contact the sponsor.

[Dispose of the used test kit]

Collect all parts of the test kit and place in the waste bag that can be placed in the general waste.

Wash your hands thoroughly after handling.

Scan the QR code to watch how to use the device and access other resources.
For additional language instructions please visit
https://thecompleteguardian.com/rapid-antigen-test-5-pack/
For further support call 02 8313 0570 ,
hours: 9am-7pm (AEST), 7 days per week