# LUNGENE COVID-19 Antigen Rapid Test (For Self-Testing) Instructions

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

| REF | Σ |
|---|---|
| ISCOVu002-B001<br>ISCOVu002-B003<br>ISCOVu002-B005 | 1<br>3<br>5 |



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For additional language instructions please visit
**https://apacsecurity.com/covid-19-antigen-testresources/**

**Please read these instructions for use before undertaking a test.**

**Contents** [ **hide** ]

## [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 seeking assistance in performing the test.

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

Confirmation of positive results is required by contacting your State or Territory of Coronavirus testing services to get a laboratory PCR test. A negative result does not mean a  person does not have COVID-19. If you have symptoms, you should have a laboratory PCR test and follow medical advice.

## [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.
✓ If you are concerned that you have been exposed to COVID-19.
**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 managing your illness. Please contact your State or Territory Coronavirus testing services to get a laboratory PCR test if your symptoms are persisting or worsening, or if you are concerned at any time.

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. 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.
11. 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 webbing may lead to an inaccurate test result.
12. The test cassette should remain in the sealed pouch until use.
13.  Wash hands thoroughly before and after testing.
14. Dispose all parts of the used test kit into the waste bag, then discard the waste bag in the general waste.

## [What is included in the test kit]

| Components | ISCOVu002-B001 | ISCOVu002-B003 | ISCOVu002-B005 |
|---|---|---|---|
| 1. Test Cassette | 1x | 3x | 5x |
| 2. Extraction Reagent Tube | 1x | 3x | 5x |
| 3. Swab | 1x | 3x | 5x |
| 4. Waste Bag | 1x | 3x | 5x |
| 5. Instructions for Use | 1x | 1x | 1x |

## [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 the 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 get a positive result, you must immediately seek a laboratory PCR test and follow-up clinical care.
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 must immediately seek further laboratory PCR testing.
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, and confirmation

with PCR testing should be considered.

## [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 the 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 positive result is highly accurate, but 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 the 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 was conducted by participants using the COVID-19 Antigen Rapid Test. For comparison, of each of the participants, RT-PCR testing was performed by professional sampling with a 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 TCID50/mL.
### Variants
The performance of the COVID-19 Antigen Rapid Test is not affected by Alpha, Beta, Gamma, or Delta variants.
### Cross-Reactivity (Analytical Specificity)

Cross-reactivity was evaluated by testing 32 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 $1.0 \times 10^6$ 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 $1.0 \times 10^7$

CFU/mL: Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumophila, Haemophilus influenzae, Streptococcus pyogenes (group A), Streptococcus pneumonia, Candida albicans, Staphylococcus aureus.

**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 pg/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]**

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

**AU REP**
APAC Security Pty Ltd
Unit 28, 19 Narabang Way, Belrose, NSW, 2085, Australia
Tech support: +61 2 9986 2252, hours: 9am-7pm (AEST), 7 days per week
Email: **support@apacsecurity.com**
**https://www.apacsecurity.com**

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@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://** |
| New South Wales Department of Health | General inquiries: 1300 066 055 Coronavirus hotline (Service NSW, 24/7): 137 788 **https://www** |
| Northern Territory Department of Health | General inquiries: 08 8922 8044 Coronavirus hotline (National helpline): 1800 020 080 **https://h** |
| Queensland Department of Health | 13HEALTH: 13 432 584 Coronavirus hotline: 134COVID, 134 268 **https://www.health.c** |
| South Australian Department of Health | General inquiries: 1300 232 272 Coronavirus hotline (9am to 5pm daily): 1800 253 787 **https://v** |
| Tasmanian Department of Health | General inquiries: 1300 135 513 Public Health Hotline (coronavirus): 1800 671 738 **https://www** |
| Victorian Department of Health | Department of Health and Human Services: 1300 650 172 Victorian coronavirus hotline (24/7): 1800 675 398 **https://www** |
| Western Australian Department of Health | General inquiries: 08 9222 4222 Coronavirus hotline: 13COVID (8am to 6pm, Mon–Fri), 1800 59 |

**Index of Symbol**

| | |
|---|---|
|  | Do not reuse |
|  | Store between 4-30 ℃ |
| REF | Catalog number |
|  | Do not use it if the package is damaged |
| IVD | For in vitro diagnostic use only |
|  | Consult instructions for use |
|  | Contains sufficient for <n> tests |
| LOT | Lot number |
|  | Keep away from sunlight |
|  | Keep dry |
|  | Use by |
|  | Caution |
|  | Manufacturer |

Version No.: 2.2
Effective Date: January 05, 2022



**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 °C).

3. Ensure that the packaging is intact; Do not use the test if there is visible damage to the foil packaging.

4. Open the box and you will get the components shown below:



**Instructions for Use**          **Swab**          **Extraction Reagent Tube**          **Waste bag**
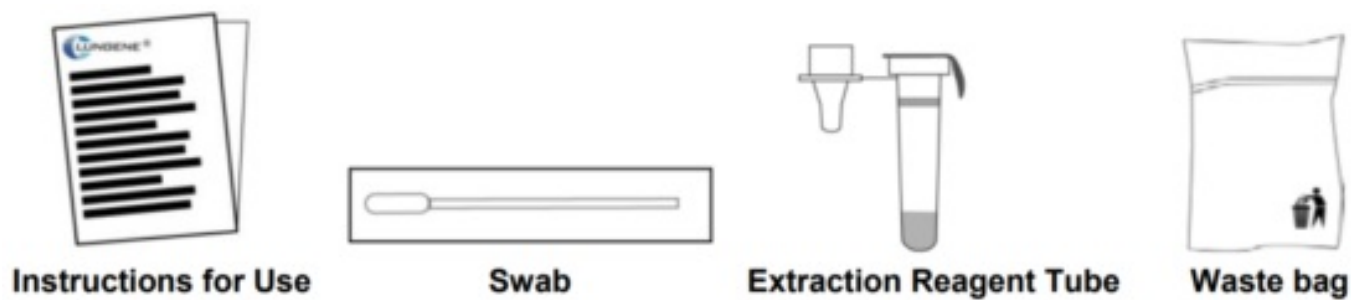


**Note:** Only open the foil packaging of the test cassette when you are ready to carry out the test. Use the test cassette within one hour after opening.

## [Before starting]

Wash your hands in soapy water and dry thoroughly.
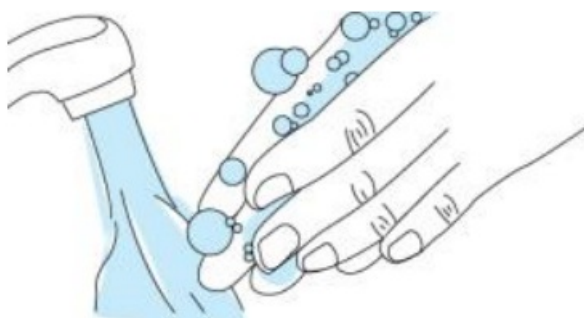


## [Step-By-Step Instructions]

1. **Open Extraction Reagent Tube**

   Carefully tear off the sealed foil film on the extraction reagent tube.
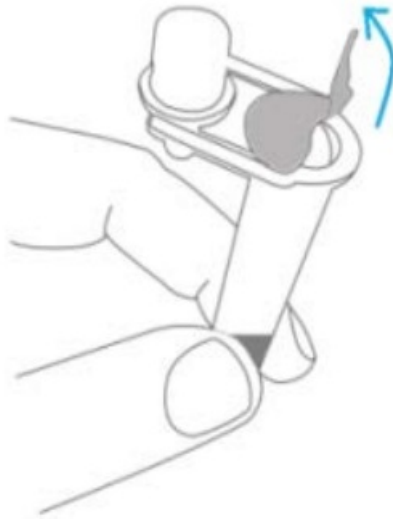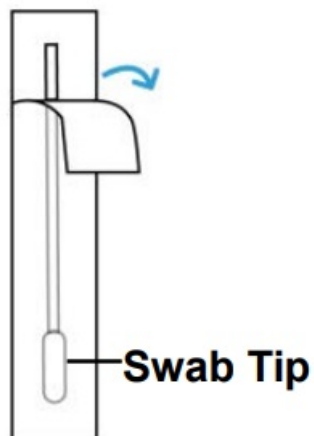
2. **Insert Tube into Box**

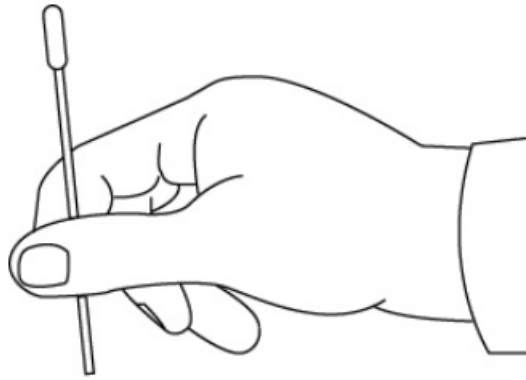Gently press the tube through the perforated hole in the box.
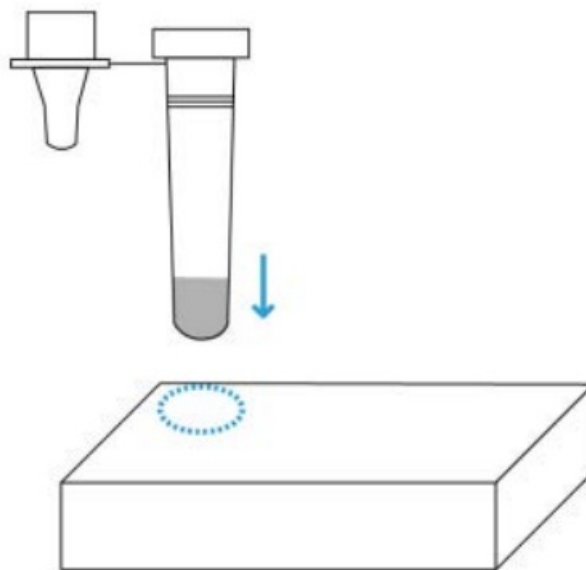
3. **Remove the Swab**

a. Open the swab package at the stick end.

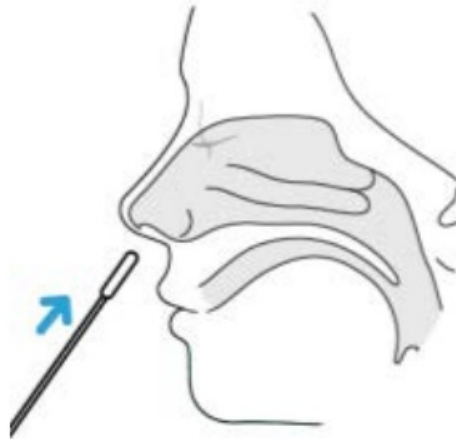**Note:** Keep fingers away from the swab tip.

Swab Tip

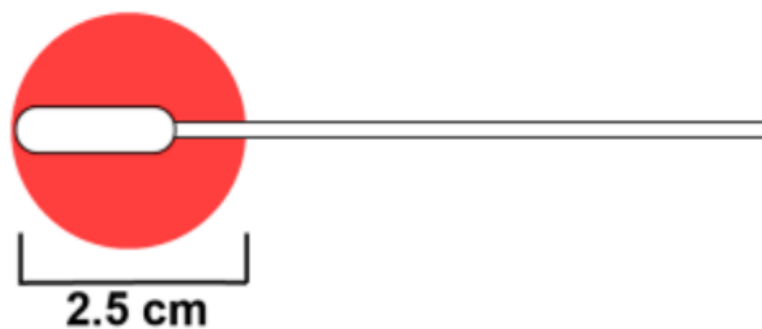b. **Take out the swab.**

4. **Swab the Left Nostril**

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



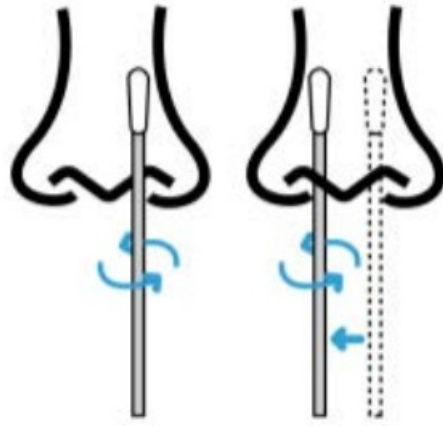   b. Firmly brush the swab against the inside of the nostril in a circular motion **5 times** or more.



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



   2.5 cm

5. **Swab the Right Nostril**

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



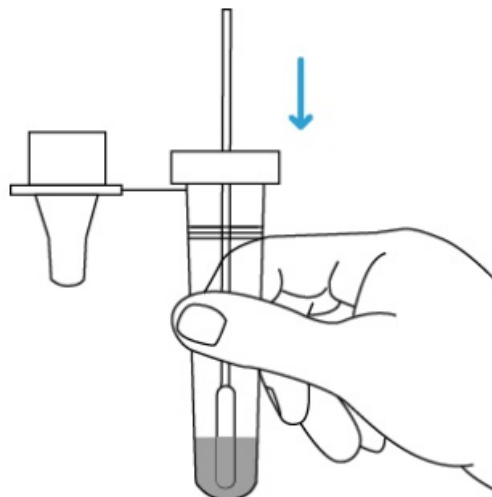b. Firmly brush the swab against the inside of the nostril in a circular motion **5 times** or more.



⚠️**CHECK!**

You should swab both nostrils.

**Note:** A false-negative result may occur if sample collection is not thoroughly undertaken.
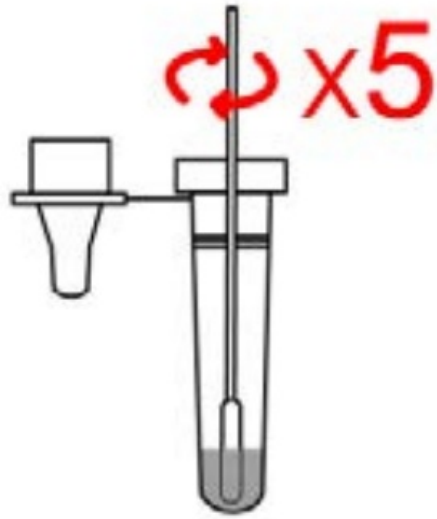
6. **Insert the Swab into the Tube**

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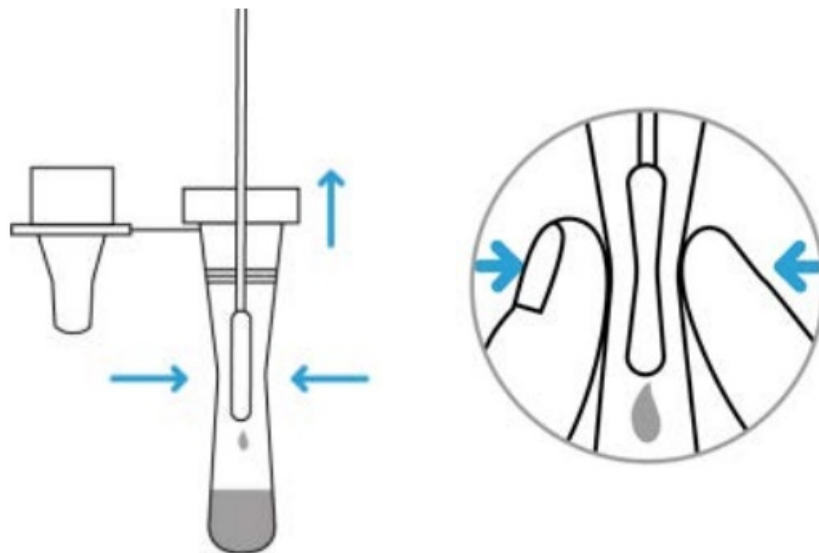
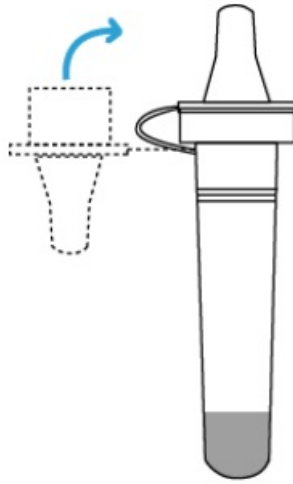b. Let the tip of the swab soak in the tube for **1 minute.**



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.
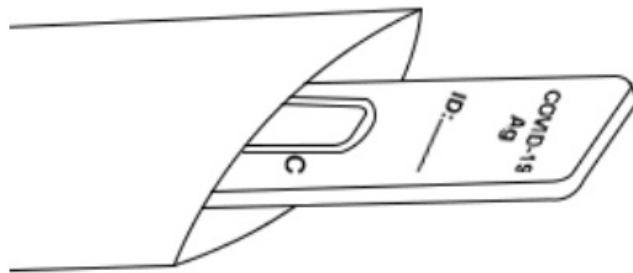


b. Cover the tube with the provided cap tightly and insert the tube back into the box.
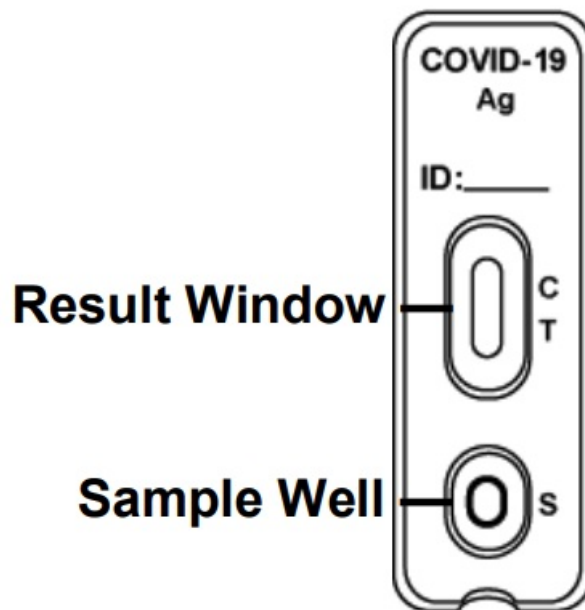
9. **Take out the Test Cassette from the pouch**

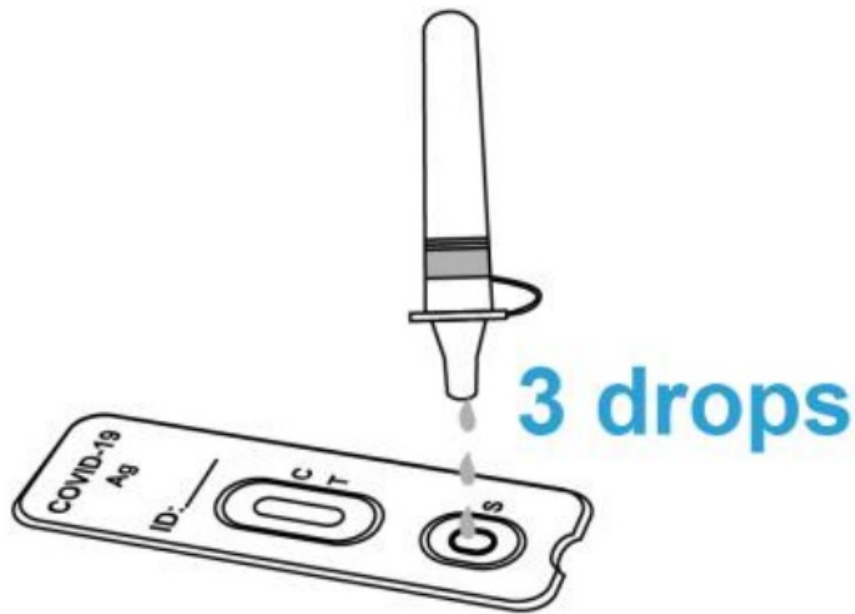   Open the sealed pouch and take out the test cassette.



   **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 the sample are used.

**Note** 2: The result will not be affected if 1-2 more drops of the sample are accidentally 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 for **15-20** minutes, **DO NOT** read the result after 20 minutes.
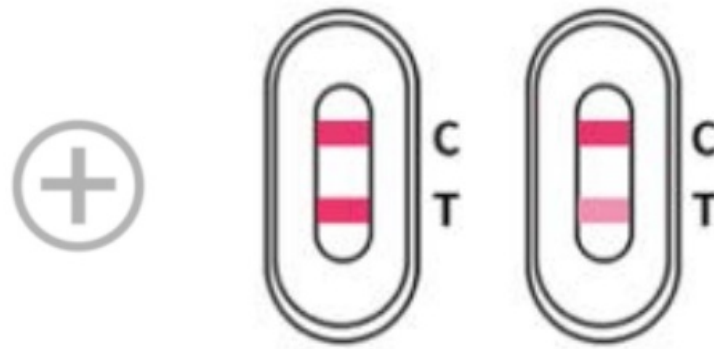


⚠ **Note:** False results can occur if the test results are read before 15 minutes or after 20 minutes.

**[Read result]**

**Positive Result**
**Two lines appear.** One colored line appears in the control region (C), and another appears in 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. Contact your State or Territory of Coronavirus testing services to **get a laboratory PCR test** as soon as possible, and follow local guidelines for self-isolation to avoid spreading the virus to others.

**Negative Result**
One colored line appears in the control region (C), and no line appears in the test region (T).
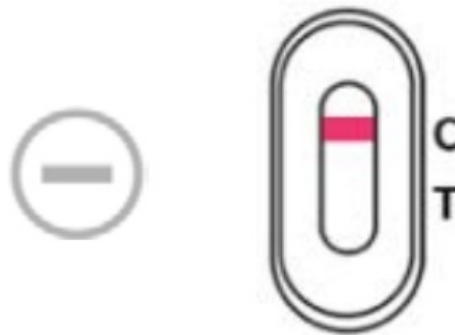


A negative test result indicates that you are unlikely to carry the COVID-19 disease.
Even if you get a negative result, you still need to follow all public health advice on limiting the spread of COVID-19.
Please contact your State or Territory Coronavirus testing services to get a laboratory PCR test if you develop symptoms or symptoms that are persisting. 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 infection.
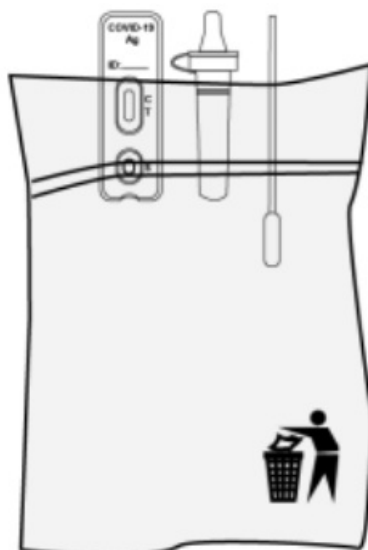
**Invalid Result**
The control (C) line fails to appear.
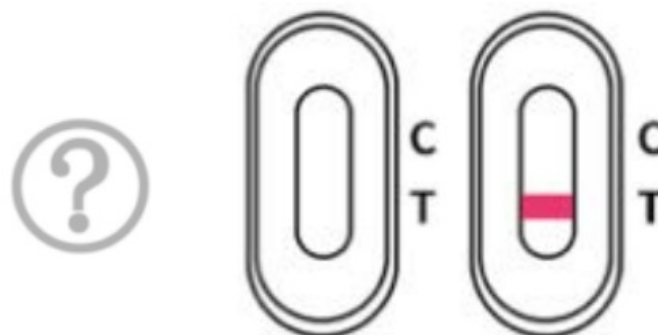


**Note:** If a C-line does not appear, the test result is invalid regardless of the appearance of a T-line or not.
If a C-line does not appear, you need to retest with a new test cassette or contact your State or Territory Coronavirus testing services to get a laboratory PCR test.

**[Dispose of the used test kit]**



Collect all parts of the test kit and place them 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://apacsecurity.com/covid-19-antigen-test-resources/**
For further support call +61 2 9986 2252, hours: 9 am-7 pm (AEST), 7 days per week.

## Documents / Resources



**LUNGENE COVID-19 Antigen Rapid Test (For Self-Testing)** [pdf] Instructions
COVID-19 Antigen Rapid Test For Self-Testing

## References

- ⋀ **COVID-19 Antigen test resources - APAC Security**
- ⋀ **COVID-19 Antigen test resources - APAC Security**
- ᵀᴳᴬ **Medical Device Incident Reports**
- **Welcome-Hangzhou Clongene Biotech Co., Ltd**
- **| Health**

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