COVID-19 Antigen Rapid Test

English

CE 1434

REF ISCOVu002-B025

For self-testing

Please read this instructions for use before using the 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 swab from individuals with symptoms or other epidemiological reasons to suspect COVID-19 infection. This test is intended for self-use by individuals aged 15 years or older and, as applicable for an adult lay user testing another person under 15 years of age. Individuals over 65 years of age should seek assistance in performing test.

The test provides only a preliminary screening test result for the SARS-CoV-2 virus. Confirmation of positive results is required using a laboratory PCR test. Persons who test negative and continue to experience COVID-19 like symptoms should seek follow up care with a doctor.

[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]

- For *in vitro* diagnostic use only.
- Do not use this test as the only guide to manage your illness. Please consult a healthcare professional if your symptoms are persisting or worsening, or if you are concerned at any time.
- Negative results may occur if testing is not performed within the first 7 days of symptom onset.
- If the test is to be used on a person under 15 years of age, the test must be undertaken by an adult.
- Keep out of reach of children to reduce the risk of accidentally drinking the extraction reagent or swallowing small parts.
- Do not use this product after the expiration date.
- Only use the test once and only with the provided parts.
- Do not undertake testing in direct sunlight.
- Avoid contact with Extraction Reagent. If the extraction reagent is inhaled, swallowed, or exposed to skin or eye, take the first aid measures according to the safety data sheet (SDS) immediately. The SDS can be obtained from scanning the QR code on the box.
- 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. This is particularly important if you do not have symptoms.
- The test cassette should remain in the sealed pouch until use.
- Wash hands thoroughly before and after testing.

[What is included in the test kit]

Components	ISCOVu002-B025
1. Test Cassette	25x
2. Extraction Reagent Tube	25x
3. Swab	25x
4. Waste Bag	25x
5. Instructions for Use	1x
6.Work Station	1x

Materials required but not provided:

- clock, timer or stopwatch

[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]

- The test is for in vitro diagnostic use only and 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.
- Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
- 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.
- Negative results may occur if the level of antigen in a sample 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.
- Negative results do not rule out SARS-CoV-2 infection, if you are experiencing COVID-19 like symptoms, you must immediately seek further laboratory PCR testing.
- Positive test results do not rule out co-infections with other pathogens.
- A Positive result cannot determine whether a person is infectious.

[Frequently asked questions (FAQ)]

How does the COVID-19 Antigen Rapid Test work?

The 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 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 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 doctor whether an additional molecular test would help with your care, and when you should discontinue home isolation.

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 COVID-19 Antigen Rapid Test for professional testing was established in prospective studies with nasal swabs collected from 560 individuals. For comparison, to each of the subjects, an RT-PCR testing was performed by professional sampling with nasopharyngeal swab. The test correctly identified 95.5% (105 out of 110) SARS-CoV-2 positive samples with a confidence interval of 89.8% to 98.0% (known as sensitivity). The test correctly identified >99% (450 out of 450) of SARS-CoV-2 negative samples with a confidence interval of 99.2% to 100% (known as specificity).

In a non-supervised clinical evaluation with 90 self-test users, the COVID-19 Antigen Rapid Test correctly identified 93.3% (28 out of 30) of SARS-CoV-2 positive samples with a confidence interval of 78.7% to 98.2%, and >99% (60 out of 60) of SARS-CoV-2 negative samples with a confidence interval of 94.0% to 100%.

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 1.0×10^6 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.

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		

Hangzhou Clongene Biotech Co., Ltd.
No.1 Yichuang Road, Yuhang Sub-district, Yuhang District,
311121 Hangzhou, China

EC REP Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, D-20537 Hamburg, Germany

Index of Symbol

	Do not reuse	IVD	For *in vitro* diagnostic use only
4℃ 30℃	Store between 4-30 ℃		Consult instructions for use
LOT	Lot number	Σ	Contains sufficient for <n> tests
	Use by		Keep away from sunlight
	Keep dry		Do not use if package is damaged
REF	Catalogue number		Caution
	Biological risks	EC REP	Authorized representative in the European Community
	Manufacturer		

Version No: 4.2
Effective Date: December 16, 2021

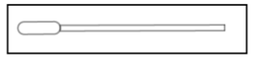
Turn pages

[Preparing to do the test]

- **Ensure that all test components are kept at room temperature (15–30 ℃).**
- Keep a clock, timer or stopwatch at hand.
- Ensure that the packaging is intact. Do not use the test if there is visible damage of the foil packaging.
- **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.**
- Wash your hands in soapy water and dry thoroughly.

[What you see when you open the kit]

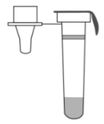
Instructions for Use



Swab

Work Station

Test Cassette



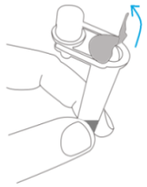
Extraction Reagent Tube

Waste bag

[Step-By-Step Instructions]

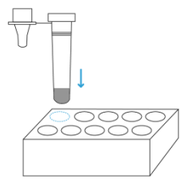
1. Open Extraction Reagent Tube

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



2. Put the Extraction Reagent Tube on the Work Station

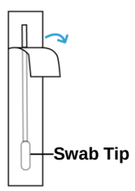
Put the work station, and insert the tube into it.



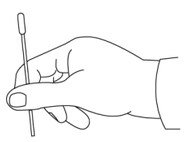
3. Open Swab

a. Open swab package at stick end.

Note: Keep fingers away from swab tip.

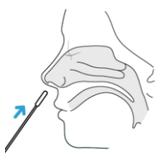


b. Take swab out.

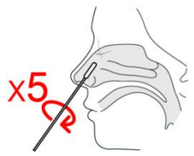


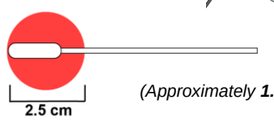
4. Swab Left Nostril

a. Gently insert the entire swab tip about **2.5cm (1 inch)** into left nostril.



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

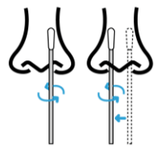




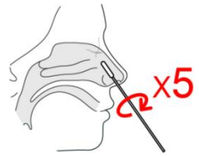
*(Approximately **1.5 times** the length of the swab tip)*

5. Swab Right Nostril

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



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

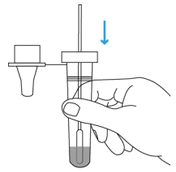


CHECK!
You should swab both nostrils.

***Note:** False negative results may occur if the nasal swab is not properly collected.*

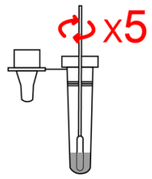
6. Insert Swab into Tube

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



7. Rotate Swab 5 Times

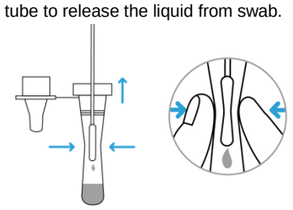
a. Rotate swab at least **5 times** while pressing swab tip against the bottom and side of tube.



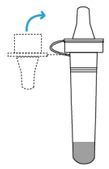
b. Leave swab in the extraction reagent for **1 minute**.

8. Remove Swab

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

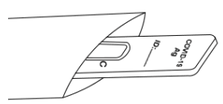


b. Cover the tube with the provided cap tightly, and insert the tube into box back.

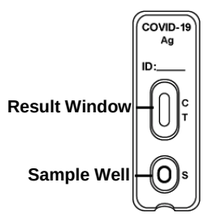


9. Open Test Cassette

Open the sealed pouch and take out the test cassette.

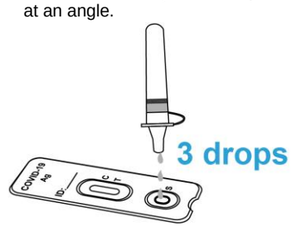


***Note**: Test cassette must stay **FLAT** on table during the entire testing.*



10. Add Sample to Sample Well

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



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

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

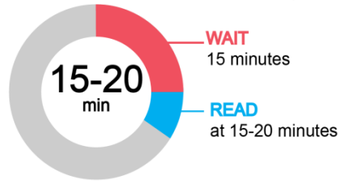
***Note 2:** The result will be not affected if 1-2 more drops of sample are accidently added – as long as you can read a C-line (see Read result below).*

11. Timing

Start the clock / stopwatch or timer.

12. Wait 15 Minutes

Read test result at **15-20** minutes, **DO NOT** read more than 20 minutes.



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

[Read result]

Positive Result

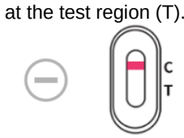
Positive Result: **Two lines appear.** One colored line appears at the control region (C), and another appears at the test region (T) .

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. You must get a laboratory PCR test as soon as possible to confirm you have COVID-19, and follow local guidelines for self-isolation to avoid spreading the virus to others.

Negative Result

Negative Result: One colored 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.

Even if you get a negative result, you still need to follow all public health advice on limiting the spread of COVID-19.

Please seek a laboratory PCR test if you develop symptoms or symptoms 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 an infection.

Invalid Result

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 or contact your doctor.

[Dispose the used test kit]

Collect parts of the kit and swab specimens in a waste bag and dispose of them with household waste.

Wash your hands thoroughly after handling.