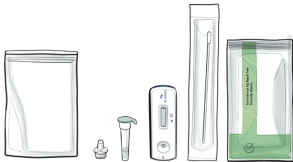


Your step-by-step guide to the Orient Gene Rapid Covid-19 (Antigen) Self-Test

Read this whole guide carefully before you start the test.

This test may be different to the one you have used before.



This instructions for use, relates to the Orient Gene Rapid Covid-19 (Antigen) Self-Test only.

This guide explains how to test yourself or another person for coronavirus (Covid-19), and report the results to the relevant local departments.

Note: The manufacturer will add/update an EXTRA CONTACT INFORMATION associated with local authority in EU if requested when the Rapid COVID-19 (Antigen) Self-Test is introduced to the member state in EU.

What you need to do

Your step-by-step guide

Read through the instructions and follow the steps in the correct order. Each test takes about 15 minutes to set up and results will be ready within a further 15 minutes.

1 Prepare your test area and check your test kit contents	page 6
2 Set up your test	page 8
3 Take your swab sample	page 10
4 Process the swab sample	page 12
5 Read your result	page 14
6 Report your result	page 15
7 What your results mean	page 16
8 Safely dispose of your test kit	page 17

15 minutes set up

Around 1 in 3 people with Covid-19 do not know they have it.

How often to test

How often you should test may vary depending on your circumstances and current national or local guidelines.

About this test

Why you should self-test

This Rapid Covid-19 (Antigen) Self-Test is a swab test for the nose to check if you are infectious. It can be used for people who have no symptoms. You should follow national guidelines to check what type of test is right for you.

If you test positive for Covid-19 you can:

- Report your result so the relevant local departments can monitor the spread of the virus, support communities across the country, combat the virus and save lives.
- Advise those you have been in close contact with, or locations you have visited in the last 14 days, to test for possible Covid-19 infection.

If you test negative for Covid-19

It is likely that you were not infectious at the time the test was taken. A negative test result, however, is not a guarantee that you do not have coronavirus.

This test is suitable for the following people:

Adults aged 18+:

Self-test and report, with assistance if needed.

Adolescents 12–17:

Self-test and report with adult supervision. The adult may conduct the test if necessary.

Children under 12:

Children under 12 years of age should be tested by an adult. Do not conduct the test if you do not feel confident testing a child. Do not continue the test if the child feels pain.

For more information on testing children see page 11.

This test is not suitable for people:

- Who are prone to nosebleeds.
- Who have had facial or head injury surgery in the last 6 months.

If any of these conditions apply to you, please contact your doctor to arrange an alternative test.

General guidance and warnings

- Store test kits away from children.
- Ensure that all steps are followed in the instructions for use. If you do not follow the instructions you may get an incorrect result and will have to do the test again.
- Leave the test cassette sealed in their foil pouches until just before use. Do not use a test cassette where the foil seal has been damaged.
- All kit components are single use items except for the extraction tube holder. **Do not reuse** any used kit components such as swabs or extraction tubes, except for the extraction tube holder.
- **Do not** mix components from different kit boxes. Only use the kit components provided in this kit.
- **Do not** use the test cassette if it has been exposed to household cleaning products (especially bleach) as this may lead to an incorrect result.
- **Do not** perform the test in direct sunlight as this may lead to an incorrect result.
- These kits are only designed for human use.
- **Do not** discard the extraction tube holder, this is reused for all tests.

1. Prepare test area & Setup

It's very important that you read the instructions and follow the steps in the correct order.

Each test will take about 15 minutes and the result will be ready after a further 15 minutes.

You will need: a timer (a watch or clock), tissues, a mirror, surface cleaner and gloves (if testing someone outside your household bubble).



- 1 **Immediately** before performing the test, clear, clean and dry a flat surface to place the home test kit on. This is to avoid contaminating the test.



- 2 **Wash your hands thoroughly** for 20 seconds, using soap and water, or hand sanitiser. This is to avoid contaminating the test.
- If doing more than one test, clean the surface and rewash your hands between each test.

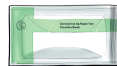
20 seconds

Check Test kit contents

- 3 In your test box you should have:



Swab inside sealed wrapper (x1/2/3/5)



Test cassette in sealed pouch (x1/2/3/5)



Plastic waste bag (x1/2/3/5)



Extraction tube with bu er (x1/2/3/5)



Nozzle cap (x1/2/3/5)

ADVICE

What to do if something is damaged, broken or missing

If you notice anything damaged, broken or missing, please **do not use the test kit**.

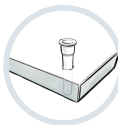
2. Prepare test area & Setup

Do not bite the seal film of the extraction tube. Avoid the extraction buffer making contact with your skin.

The extraction buffer contains preservatives which may cause an allergic reaction in some people. If the solution makes contact with the skin or eye, wash with lots of water. If skin irritation occurs get medical attention.



- 4 Keeping the tube away from your face, gently peel off the sealing film on the extraction tube to avoid spilling any fluid.



- 5 Insert the extraction tube containing the buffer into the **dotted hole** on the backside of the kit to avoid spilling it while you use the swab.



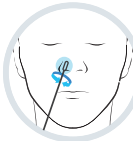
- 6 **Gently blow your nose** into a tissue and throw it away in your general household waste. This is so that you get rid of excess mucus.
- If you are testing a child/dependent help them to blow their nose, as required.

3. Take swab sample

If testing a child under 12, or a person who requires assistance, follow the alternative steps for 10 and 11 in the "Testing a child or someone else" section on page 11.

Please ensure all nose piercings or similar jewellery are removed prior to swabbing.

Testing yourself

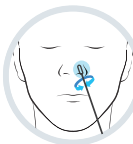


- 10 **First nostril**
- Place the fabric tip of the swab just inside one nostril (approximately 2.5cm), ensure that the fabric tip of the swab is placed 2.5 cm inside the first nostril.

x5

Gently wipe the swab around the inside of your nostril in a **circular motion 5 times**. Ensure there is good contact between the fabric tip of the swab and the inside of the nostril.

No force is needed and you do not have to push far into your nostril.



- 11 **Second nostril**
- Use the same swab, place the fabric tip of the swab just inside the other nostril (approximately 2.5cm), ensure that the fabric tip of the swab is placed 2.5 cm inside the second nostril.

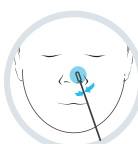
x5

Gently wipe the swab around the inside of your nostril in a **circular motion 5 times**. Ensure there is good contact between the fabric tip of the swab and the inside of the nostril.

If you experience a nose bleed during the swabbing, please stop swabbing. The swab can not be tested. It is recommended to consult your doctor if bleeding persists.

Testing child or someone else

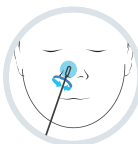
You should wear gloves when handling samples of those you are helping, if they are outside your bubble. If gloves are not available, wash your hands thoroughly to prevent any sample contamination.



- 10 **First nostril**
- Place the fabric tip of the swab just inside one nostril of the child/person you are testing.

x5

Gently wipe the swab around the inside of their nostril in a **circular motion 5 times**. No force is needed and you do not have to push far into the nostril, make sure there is good contact between the fabric tip of the swab and the inside of the first nostril.



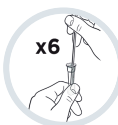
- 11 **Second nostril**
- Use the same swab, place the fabric tip of the swab just inside the other nostril of the child/person you are testing.

x5

Gently wipe the swab around the inside of their nostril in a **circular motion 5 times**, make sure there is good contact between the fabric tip of the swab and the inside of the second nostril.

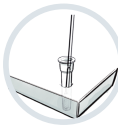
If the person you are swabbing experiences a nose bleed, please stop swabbing. The swab can not be tested. It is recommended to consult their doctor if bleeding persists.

4. Process swab sample

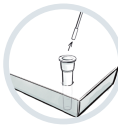


- 12 Place the fabric tip of the swab into the extraction tube fluid.

Press the tip against the edge of the extraction tube with force, while rotating it around the tube **at least 6 times**.



- 13 Leave the swab in the extraction tube, **set a timer** and leave for **1 minute**.



- 14 Withdraw swab from the extraction tube.



- 15 Place the swab into the plastic waste bag.
- If wearing gloves, remove and place into the plastic waste bag.



16 Push the nozzle cap tightly on to the extraction tube to avoid any leaks.
Place the extraction tube back in the extraction tube holder.



17 Check the expiry date (EXP) on the sealed pouch. Take the test cassette out of the sealed pouch and place it onto the cleaned flat surface.
A test cassette that has been outside of the sealed pouch for more than 30 minutes should be discarded. Safely throw away the inner desiccant bag and pouch into the plastic waste bag.

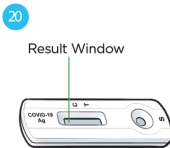


18 Gently squeeze the extraction tube to place **4 drops** of liquid onto the sample well (marked **S**) on the test cassette.
Make sure you place the test cassette on a flat and level surface . Do not move the test cassette during the test. Slowly add drops to the sample. Do not overfill.



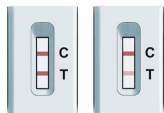
15 Minutes
19 Set a timer. Wait 15 minutes to read your result.
Do not leave the test to develop for longer than 20 minutes as this will void the test. If the test is left longer than 20 minutes, please conduct the test again.

5. Read results

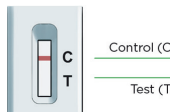


20 Result Window

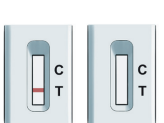
IMPORTANT
If you test positive, you and your household must self-isolate following government guidelines.



+ Positive result
The presence of two lines, a control line (C) and a test line (T), **even a faint line**, within the result window indicates the test is positive.



- Negative result
The presence of only a control line (C) within the result window indicates the test is negative.



Void result
If the control line (C) is not visible within the result window after performing the test, the result is considered void. If you get a void result, you must perform a new test.

6. Report your result

You should report your negative, positive and void results to the relevant local departments.
Report your result so the relevant local departments can monitor the spread of the virus, support communities across the country, combat the virus and save lives. You can also find out more about the result and what you need to do.
Report your result as soon as possible and within 24 hours.

7. What your results mean

You've only completed your test when you've reported your result

+ Positive result
If you get a positive result **it is likely you are infected with coronavirus** and risk infecting others. When you report your result, you will be provided with further information on the next steps to take.

WARNING
You, anyone who lives with you, and anyone in your support bubble, must self-isolate in accordance with current national and local guidance.

- Negative Result
If you get a negative result, it is likely that you were not infectious at the time the test was taken. A negative test result, however, **is not a guarantee that you do not have coronavirus**.

ADVICE
If you test negative, you must continue to follow national and local rules and guidelines including regular handwashing, social distancing and wearing face coverings, where required.

- If you get a void result, this means that the test has not run correctly. You need to take another test. Use a new test kit, but **do not reuse any of the components from the test you have just done.**

ADVICE
If the problem persists, discontinue using the test kits immediately. Order a new pack of test kits.

Make a note of your test results

Who took the test	Date	Time	Test result

Your kit contains the following materials

Items	Pack
Instructions for use (this document)	1
Swab inside sealed wrapper	x1/2/3/5
Test cassette in sealed pouch	x1/2/3/5
Extraction tube with buffer	x1/2/3/5
Nozzle cap	x1/2/3/5
Plastic waste bag	x1/2/3/5
QC certificate	1

Principle of the Test
The Rapid Covid-19 (Antigen) Self-Test is a lateral flow test that detects the nucleocapsid protein antigen of the coronavirus that causes Covid-19 from direct nasal swab. When added to the sample well, the prepared sample flows laterally on the test device. The test reaction will take 15 minutes. If the test detects the relevant coronavirus protein, a line will appear in the test line region (T) indicating a positive test result. Absence of the test line (T) suggests a negative test result. A line will always appear in the control line region (C) if the test has been performed correctly.

Summary and Explanation
Coronavirus can cause an acute respiratory infectious disease known as Covid-19. Currently, people infected with coronavirus are the main source of infection; infected people can be a source of infection even if they do not show symptoms. Based on the current epidemiologic survey, the time between infection and disease onset is 1 to 14 days, most commonly 3 to 7 days. The main signs of infection include:

- a high temperature – this means you feel hot to touch on your chest or back (you do not need to measure your temperature)
- a new, continuous cough – this means coughing a lot for more than an hour, or 3 or more coughing episodes in 24 hours (if you usually have a cough, it may be worse than usual)
- a loss or change to your sense of smell or taste – this means you've noticed you cannot smell or taste anything, or things smell or taste different to normal

8. Dispose of the test kit



21 Place the **test cassette** into the plastic waste bag along with the extraction tube, swab and any remaining packaging waste except for the extraction tube holder.



22 Place the plastic waste bag into your general household waste.

- Storage and Handling**
- Close the kit box and secure its contents when not in use.
 - The kit can be stored at room temperature or refrigerated **2-30°C**.
 - Do not** freeze any of the test kit components.
 - Do not** use the test device and buffer after expiration date. The expiration information is printed on the pouch and kit-box after the “ EXP”.
 - Discard** a test cassette that has been outside the sealed pouch for more than 30 minutes.
 - Ensure your test is at room temperature **15-30°C** prior to testing.
 - Keep out of reach of children.** The test contains small parts that may present a choking hazard.

The rapid Covid-19 (Antigen) self test is for detection of nucleocapsid protein antigen of coronavirus.
The antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Rapid diagnosis of coronavirus infection and subsequent care and treatment by healthcare professionals will help control the spread of coronavirus more efficiently and effectively.
The amount of antigen in a specimen may decrease as the disease duration progresses. Therefore, specimens collected more than 10 days after covid-19 infection may have low antigen levels that are below the minimum detection level of the test.

Performance characteristics
The Rapid COVID-19 (Antigen) Self-Test identified 97.25% of COVID-19 positive samples and 100% of COVID-19 negative samples. The overall accuracy of the Rapid COVID-19 Antigen Self-Test is 98.73%. The samples used to determine the performance of this test were collected during a clinical study conducted in the USA. The samples were confirmed positive and negative by a USFDA emergency use authorized PCR test.

Literature References

- Julien Favresse, Constant Gillot, Maxime Oliveira, Julie Cadrobbi, Marc Elsen, Christine Eucher, Kim Laffineur, Catherine Rosseels, Sandrine Van Eeckhoudt, Jean-Baptiste Nicolas, Laure Morimont, Jean-Michel Dogné and Jonathan Douxfils. Head-to-Head Comparison of Rapid and Automated Antigen Detection Tests for the Diagnosis of SARS-CoV-2 infection J. Vlin Med. 2021, 10, 265.
- Ignacio Torres, Sandrine Poujois, Eliseo Albert, Gabriela Alvarez, Javier Colomina and David Navarro. Point-of-care evaluation of a rapid antigen test (CLINITEST Rapid Covid-19 Antigen Test) for diagnosis of SARS-CoV 2 infection in symptomatic and asymptomatic individuals February 11, 2021.
- Public Health England. SARS-CoV 2 lateral flow antigen tests: evaluation of VOC1 (Kent, UK) and VOC2 (South Africa) Published 12 February 2021.
- UK Service Evaluation Study, Orient Gene, 2020, UK DHSC

Does this test detect all the virus variants?
All viruses can change, and the virus which causes Covid-19 is known to have a number of these changed versions, called variants. The rapid Covid-19 antigen Self-Test detects a part of the virus which is known to be less likely to change over time; the nucleocapsid protein, which is a small piece of SARS-CoV-2. The variants seen primarily impact another part of the SARS-CoV-2 virus, the spike protein. However, if you test negative but are still unwell, your symptoms become worse, or you develop new symptoms, it is important that you seek a healthcare professional right away.



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Obere Seepasse 34/2, 69124 Heidelberg, Germany
Email-info@lins-service.com

Symbols used



Store at 2-30°C



Sterilized using ethylene oxide



Manufacturer



Don't use the product when the package is damaged



Lot number



Expiry date



In vitro diagnostic medical device



Keep away from sunlight



Date of manufacture



Do not re-use



Warning, please refer to the instruction



Keep dry



Consult instructions for use



Number of units in pack



Latex free



Catalog number



Do not re-sterilise



European authorised representative



GCCOV-502a-H10GE/GCCOV-502a-H20GE/GCCOV-502a-H30GE/GCCOV-502a-H50GE

Revision date: 2021-06-21
B22207-01

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