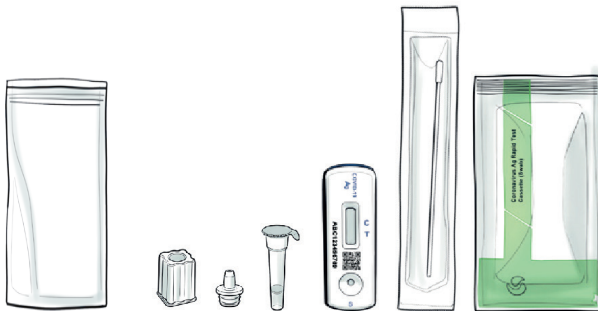# Your step-by-step guide to the Orient Gene Rapid Covid-19 (Antigen) Self-Test

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: GCCOV-502a-H7OG.

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

Alternative language versions and video demonstrations are available on **gov.uk/covid19-self-test-help.**

Report all your test results to the NHS

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.

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.

Where to find extra support

Get more self-test information at: **gov.uk/covid19-self-test-help**

About this test

Orient Gene Rapid Covid-19 (Antigen) Self-Test
GCCOV-502a-H7OG

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 NHS can monitor the spread of the virus, support communities across the UK, 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.

ADVICE

Do not delay getting help if you are worried. Trust your instincts.
If you have Covid-19 symptoms or have contracted Covid-19, please follow NHS guidance: **nhs.uk/conditions/coronavirus-covid-19**

If you have Covid-19 symptoms and your condition worsens, or you do not get better after seven days, use the NHS 111 online coronavirus service **111.nhs.uk**

If you do not have internet access, call **NHS 111**.
For a medical emergency dial **999.**

You can get more advice about Covid-19 symptoms in children at: **nhs.uk/conditions/coronavirus-Covid-19/symptoms/coronavirus-in-children/**

Once you have your test result, the fastest way to report is online.
If you live in England, Wales or Northern Ireland visit **gov.uk/report-covid19-result**
If you live in Scotland visit **covidtest.scot**

Or report by telephone; Call 119, lines open every day, 7am to 11pm, (free from mobiles and landlines)

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.
- Who are visually impaired.

If any of these conditions apply to you, please contact **119** or 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.
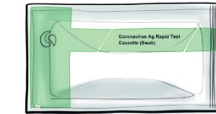
20 seconds

Check Test kit contents

Orient Gene Rapid Covid-19 (Antigen) Self-Test
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3 In your test box you should have:

Sterile swab in sealed wrapper (x7)

Test cassette in sealed pouch (x7)

Waste bag (x7)

Extraction tube with buffer (x7)

Nozzle cap (x7)

Extraction tube holder (x1 reusable) (Do not discard)

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**. You can give feedback by calling the customer contact centre. Lines open every day, 7am to 11pm.

Call: **119** (free from mobiles and landlines).
We offer support in 200 languages as well as British Sign Language.

If you are harmed by a device you can report this to the MHRA by going to:
coronavirus-yellowcard.mhra.gov.uk

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.

⚠️ If you are assisting a child/dependent and are **not part of their household or support bubble**, you should wear gloves after washing your hands.

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

**5** Place the extraction tube containing the buffer into the extraction tube holder.

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.

20 seconds

7 **Wash your hands** thoroughly for 20 seconds **after blowing nose**, using soap and water, or hand sanitiser. This is to avoid contaminating the test.

If you help a child/dependent blow their nose, **both of you must wash your hands** thoroughly for 20 seconds, or use hand sanitiser.

8 Handle of swab
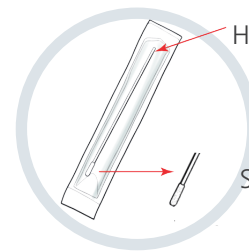
Find the sterile swab in the sealed wrapper. Identify the soft, fabric tip of the swab.

Swab tip
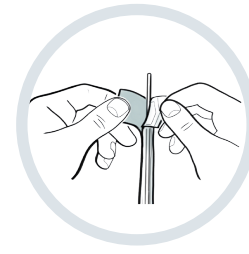
9 Peel open the swab package and gently take out the swab.
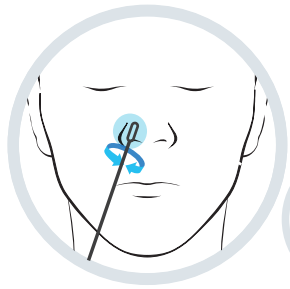
⚠️ Never touch the fabric tip of the swab with your hands or touch any surfaces.

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.

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.

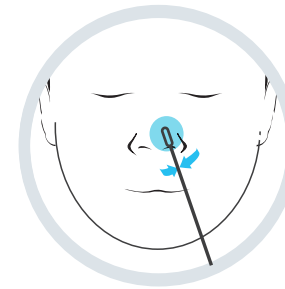No force is needed and you do not have to push far into your nostril.
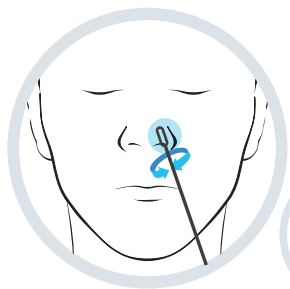
x5

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.

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.

x5

⚠️ 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.

Report all your test results to the NHS

Testing child or someone else

Orient Gene Rapid Covid-19 (Antigen) Self-Test
GCCOV-502a-H7OG

⚠️ 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.

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.
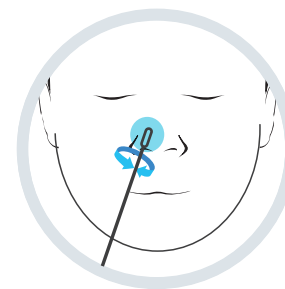
x5

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.

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.

x5

⚠️ 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.
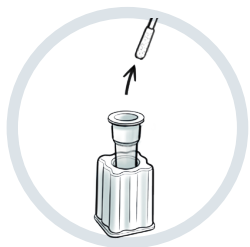
Report all your test results to the NHS
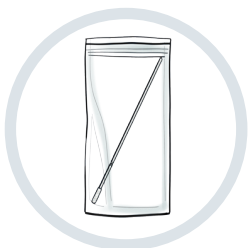
4. Process swab sample

x6
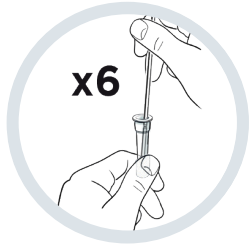
12 Place the fabric tip of the swab into the extraction tube fluid.

Press the tip against the edge of the extraction tube with force, while rotating it around the tube **at least 6 times.**
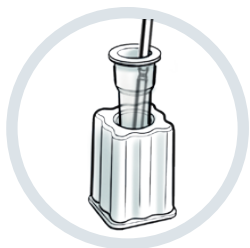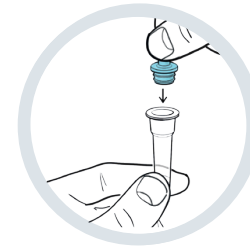
13 Leave the swab in the extraction tube, **set a timer** and leave for **1 minute.**

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.

x4

⚠️ 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.

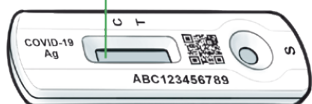**15 Minutes**

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.
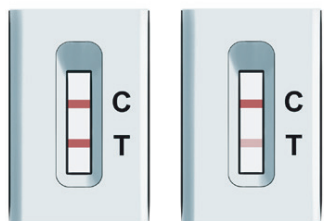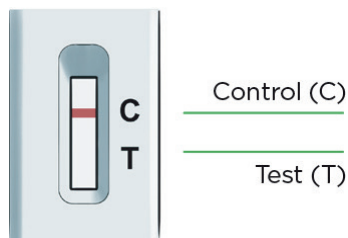
5. Read results

Result Window

IMPORTANT

If you test positive, you and your household must self-isolate following government guidelines **nhs.uk/conditions/coronavirus-covid-19/self-isolation-and-treatment/**
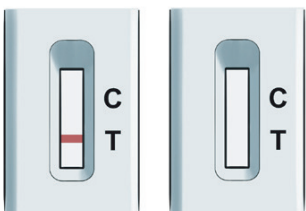
Positive result

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.

Control (C)

Test (T)

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 NHS.

Report your result so the NHS can monitor the spread of the virus, support communities across the UK, 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.
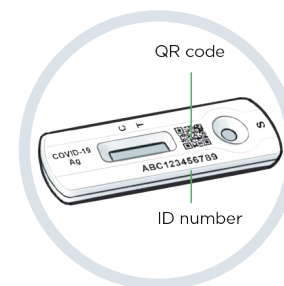
QR code

ID number

To report your results you need:

* QR code (scan with your phone)

or

* ID Number

Report online (fastest).
If you live in England, Wales or Northern Ireland visit **gov.uk/report-covid19-result**
If you live in Scotland visit **covidtest.scot**

Or report by telephone.

Please call **119** (free from mobiles and landlines).

Lines are open every day. 7am to 11pm.

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, which can be found at: **nhs.uk/conditions/coronavirus-covid-19/self-isolation-and-treatment/**

⊖ 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.

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.

Make a note of your test results

This is for your own records. You must still report your result to the NHS (see page 15 for information).
Visit: **gov.uk/report-covid19-result**

If you live in Scotland visit **covidtest.scot**

Or report by telephone; Call 119, lines open every day, 7am to 11pm, (free from mobiles and landlines)

Who took the test	Date	Time	

Your kit contains the following materials

Items	7-Pack
Instructions for use (this document)	1
Sterile swab in sealed wrapper	7
Test cassette in sealed pouch	7
Extraction tube with buffer	7
Nozzle cap	7
Waste bag	7
Extraction tube holder	1
QC certificate	1

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.

Supply of this device is only permitted as part of the DHSC deployment under the NHS Test and Trace programme.

Zhejiang Orient Gene Biotech Co.,Ltd
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Tel: +86-572-5226111 Fax: +86-572-5226222
Website: www.orientgene.com
quality@orientgene.com

UK RP SENSUS GROUP LTD
Address: The Barn, Tednambury Farm, Tednambury, Spellbrook,Herts, CM23 4BD United Kingdom

Swab information:
Jiangsu ChangFeng Medical Industry Co., LTD
Address: Touqiao Town, Guangling DISTRICT, Yangzhou, Jiangsu 225109 China   CE 0197

EC REP Llins Service & Consulting GmbH
Obere Seegasse 34/2, 69124 Heidelberg, Germany
Email-info@llins-service.com

Symbols used

🌡30°C 2°C	Store at 2 – 30°C	STERILE EO	Sterilized using ethylene oxide	▲ Manufacturer	Don't use the product when the package is damaged
LOT	Lot number	⧗	Expiry date	IVD	In vitro diagnostic medical device
☀	Keep away from sunlight	�	Date of manufacture	⊗	Do not re-use	⚠ Warning, please refer to the instruction
☂	Keep dry	[i]	Consult instructions for use	Σ/7	Number of units in pack (7)
UK RP	UK Responsible Person	LATEX	Latex free	REF	Catalog number	STERILIZE 2 Do not resterilise
EC REP	European authorised representative				

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