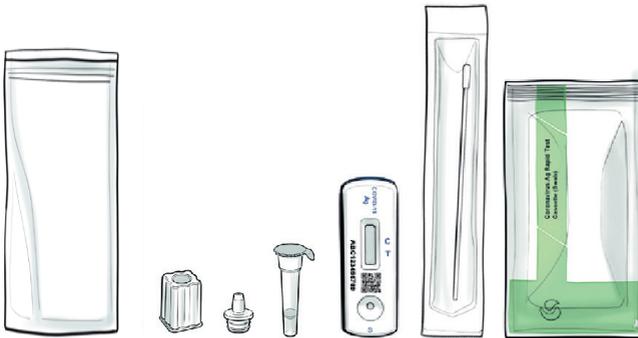


Read this whole guide carefully before you start the test.
This test may be different to the one you have used before.

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



These instructions for use relate to Orient Gene's Rapid Covid-19 (Antigen) Self-Test (GCCOV-502a-H7OGE) only.

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

Alternative language versions including Welsh and video demonstrations are available on [gov.uk/covid19-self-test-help](https://www.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 after a further 15 minutes.



Contents of this booklet

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

With regular self-testing we can slow the spread and help protect the most vulnerable in our families and communities.

This booklet only refers to Orient Gene Rapid Covid-19 (Antigen) Self-Test: GCCOV-502a-H70GE

Advice about taking the test

There are useful tips, advice and warning boxes spread out along the guide, to help you. By following these instructions carefully step-by-step, you will have a much better chance of getting a reliable result.

General guidance and warnings

- If you experience a nose bleed during swabbing, please stop swabbing. The swab cannot be tested.
- The product has not been made with natural rubber latex however the presence or traces of natural rubber latex in the product as delivered to the end-user cannot be excluded completely.
- Keep the test kit away from children.
- 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.

Advice

- Store the test kit at normal room temperature or in a cool dry place (2°C to 30°C).
- Do not leave in direct sunlight and do not store in a freezer.
- The kit should be used at room temperature (15°C to 30°C). If the kit has been stored in an area less than 15°C, leave it at normal room temperature for 30 minutes before using.

This booklet only refers to Orient Gene Rapid Covid-19 (Antigen) Self-Test: GCCOV-502a-H70GE

About this test

Why you should self-test

This Rapid COVID-19 (Antigen) Self-Test kit is a swab test for the nose to check if you are infectious. It's for people who have symptoms as well as those with no symptoms. However you should follow national guidelines to check what type of test is right for you.

If you test positive for COVID-19 you should:

- help limit the spread of the disease, you and your household should follow current government guidelines: [nhs.uk/conditions/coronavirus-covid-19/self-isolation-and-treatment/](https://www.nhs.uk/conditions/coronavirus-covid-19/self-isolation-and-treatment/)
- advise people you have been in close contact with and locations you have visited in the last 48hrs before your symptoms started, or from the day a positive test result is shown if no symptoms are present, to test for possible COVID-19 infection. Always follow local and national guidelines.

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. You should continue to follow government guidelines.

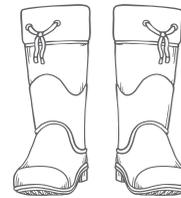
Advice

If you or your child/children have coronavirus (COVID-19) symptoms or have contracted coronavirus (COVID-19), please refer to NHS guidance online: [nhs.uk/conditions/coronavirus-COVID-19](https://www.nhs.uk/conditions/coronavirus-COVID-19)

If you or your child/children have symptoms of coronavirus (COVID-19) and the condition gets worse, or you/your child/children do not get better after 7 days, visit the NHS **111** online service: 111.nhs.uk. If you do not have internet access, call NHS **111**. For a medical emergency dial **999**.

Do not delay getting help if you are worried. Trust your instincts.

Who this test is suitable for



Adults aged 18+

Self test and report, with assistance if needed.



Adolescents aged 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.

- Visually impaired people can still use our test kits, but may need assistance.
- This test is not suitable for people who are prone to nose bleeds, or people who have had facial or head injury surgery in the last 6 months.

How often to test

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

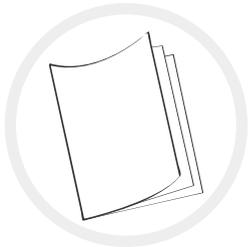
Where to find extra support

Get more self-test information at: [gov.uk/covid19-self-test-help](https://www.gov.uk/covid19-self-test-help)

1. Prepare your test area

You'll need:

- a timer such as a watch or clock
- tissues
- a mirror
- surface cleaner
- hand sanitiser or soap and access to warm water



- 1** Read this instruction guide carefully. You can also watch the swab test video online if you need more help: [gov.uk/guidance/covid-19-self-test-help](https://www.gov.uk/guidance/covid-19-self-test-help)



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



- 3** Wash your hands thoroughly for 20 seconds, using soap and warm water, or hand sanitiser. If you are testing more than one person or repeating a void test, clean the surface and rewash your hands between each test. This is to avoid contaminating the test.

Check your kit contents

- 4** In your test box you should have:



Sterile swab in sealed wrapper (x7)



Test cassette in sealed pouch (x7)



Zip-lock bag (x7)
Use as Waste bag



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

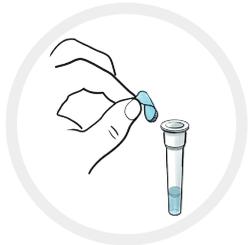
If you notice anything damaged, broken or missing, please do not use the test kit. You can give feedback by calling the customer contact centre. Lines are open every day, 7am to 11pm.

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 reporting it could help others, please go to: [coronavirus-yellowcard.mhra.gov.uk](https://www.coronavirus-yellowcard.mhra.gov.uk)

2. Set up your test



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

Warning

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

Warning

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.



- 6** Place the extraction tube containing the buffer into the extraction tube holder.

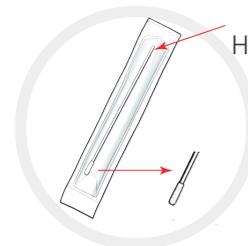


- 7** **Gently blow your nose** into a tissue and throw it away in your general household waste. This is so that you get rid of excess mucus.
If you are testing a child/dependent help them to blow their nose, as required.

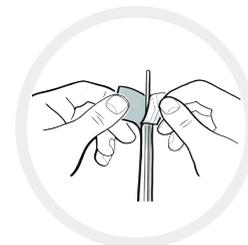


20
seconds

- 8** **Wash your hands** thoroughly for 20 seconds **after blowing your 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.



- 9** Find the sterile swab in the sealed wrapper. Identify the soft, fabric tip of the swab.



- 10** Peel open the swab package and gently take out the swab.

Warning

Never touch the fabric tip of the swab with your hands or touch any surfaces.

3. Take your swab sample

Warning

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

If testing a child under 12, or a person who requires assistance, follow the steps on page 11.

Testing yourself

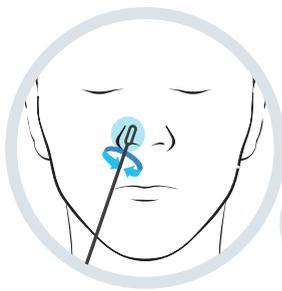
10

First nostril

Place the fabric tip of the swab just inside one nostril (approximately 2.5 cm), 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.

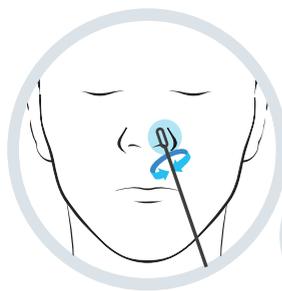


11

Second nostril

Use the same swab, place the fabric tip of the swab just inside the other nostril (approximately 2.5 cm), 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.



Warning

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.

This booklet only refers to Orient Gene Rapid Covid-19 (Antigen) Self-Test: GCCOV-502a-H70GE

Doing a test on someone else

Children under 12 should be tested by an adult. Follow the guidelines below on how to prepare and test a child or a person who requires assistance. You can watch a demonstration video at: [gov.uk/guidance/covid-19-self-test-help](https://www.gov.uk/guidance/covid-19-self-test-help)

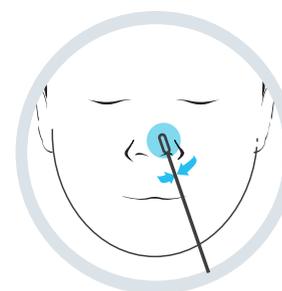
If you're testing a child, show them the test kit and talk to them about what you are going to do. If possible, sit them on someone's lap or have someone hold their hand. Ask the child to blow their nose into a tissue. Place the tissue in a closed bin.

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.

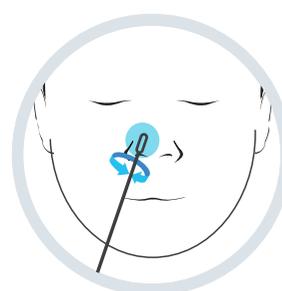


11

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.

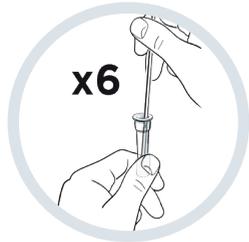


Warning

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.

This booklet only refers to Orient Gene Rapid Covid-19 (Antigen) Self-Test: GCCOV-502a-H70GE

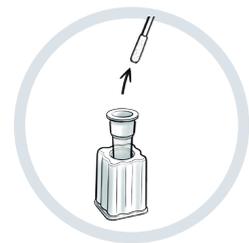
4. Process the swab sample



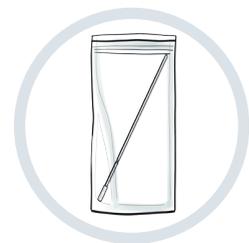
12 Place the fabric tip of the swab into the extraction tube fluid.
Press the tip against the edge of the extraction tube with force, while rotating it around the tube **at least 6 times**.



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 zip-lock bag.

Advice

The individual zip-lock bag can be used as the 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.

Warning

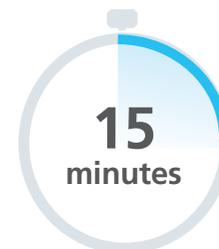
A test cassette that has been outside of the sealed pouch for more than 30 minutes should be discarded. Safely throw away the inner desiccant bag and pouch into the plastic waste bag/zip-lock bag.



18 **Gently** squeeze the extraction tube to place **4 drops** of liquid onto the sample well (marked **S**) on the test cassette.

Advice

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.



19 **Set a timer.**
Wait 15 minutes to read your result.

5. Read your result

Important

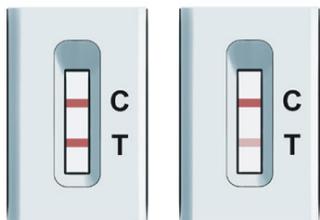
Do not leave the test to develop for longer than 20 minutes as this will make the result void.



+ Positive result

Two lines appear. One coloured line should be in the control line region (C), and another coloured line should be in the test line region (T).

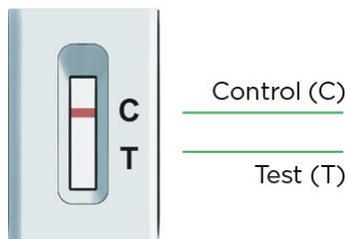
Two lines, one next to C and one next to T, even faint lines, show the test is positive.



Important

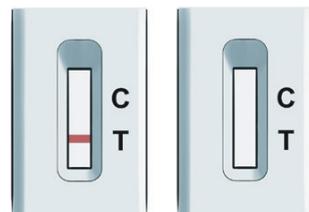
If you test positive you should self-isolate, your household should follow government guidelines on self-isolating:

[nhs.uk/conditions/coronavirus-covid-19/self-isolation-and-treatment/](https://www.nhs.uk/conditions/coronavirus-covid-19/self-isolation-and-treatment/)



- Negative result

One coloured line appears in the control line region (C). No line appears in the test line region (T).

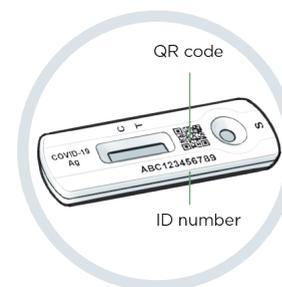


Void result

Control line (C) fails to appear.

6. Report your result

You should report your positive, negative and void results to the NHS.



Recording all test results helps scientists spot new virus outbreaks and advise how to respond. If people only report a positive result, case levels look higher than they really are.

So even if your result is negative or void, you'll make sure NHS information stays accurate.

You need the QR code, or the ID number under it to report your result.



Report online (fastest)

If you live in England, Wales or Northern Ireland visit:

[gov.uk/report-covid19-result](https://www.gov.uk/report-covid19-result)

If you live in Scotland visit:

[covidtest.scot](https://www.covidtest.scot)

Or report by telephone

Call **119**

Lines are open every day, 7am to 11pm, (free from mobiles and landlines)



7. What your results mean

You have only completed your test when you have reported your result

Positive result

If you get a positive result, it is likely you are currently infected with COVID-19 and risk infecting others. You should self-isolate. When you report your result, you will be provided with further information on the next steps to take.

Warning

You, and anyone who lives with you, should follow current national and local guidance. This can be found at:

[nhs.uk/conditions/coronavirus-COVID-19/self-isolation-and-treatment/](https://www.nhs.uk/conditions/coronavirus-COVID-19/self-isolation-and-treatment/)

Negative result

If you get a negative result, it is likely 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 COVID-19.

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

If you develop symptoms you should self-isolate and get the current recommended test at:

[gov.uk/get-coronavirus-test](https://www.gov.uk/get-coronavirus-test) or by calling the customer contact centre on **119**. Lines open every day, 7am to 11 pm. You and your household should follow national guidelines.

Void result

If you get a void result, this means it's not possible to say if you had the virus when the test was done. To check if you have coronavirus, take another test as soon as possible. Do not reuse anything from the first test, and start the test procedure from step 1.

If the problem persists

If the problem persists, discontinue using the test kits immediately.

If you do not have another test available, you may take a different type of test through the NHS COVID-19 app or by visiting:

[gov.uk/get-coronavirus-test](https://www.gov.uk/get-coronavirus-test) or by calling the customer contact centre on **119**. Lines are open every day, 7am to 11 pm.

8 Test performance

The test is more likely to give a positive result if someone has high levels of coronavirus (COVID-19).

This means that it is most likely to detect the people who are currently infectious and need to immediately self-isolate.

9 Safely dispose of your test kit



Once your test is complete, put all of the used test kit contents in the waste bag provided, except for the plastic tube holder, and put this in your general household waste.

Wash your hands thoroughly after disposal.

Advice

The individual zip-lock bag can be used as the waste bag.

Make a note of your test results

This is for your own records. You should still report your result to the NHS (see page 15 for information).

Visit: [gov.uk/report-covid19-result](https://www.gov.uk/report-covid19-result)

If you live in Scotland visit: [covidtest.scot](https://www.covidtest.scot)

QR code / ID number of the test kit	Who took the test	Date	Time	Test result

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
Zip-lock bag	7
Extraction tube holder	1
QC certificate	1

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



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 Anji 313300, Huzhou, Zhejiang, China
 Tel: +86-572-5226111 Fax: +86-572-5226222
 Website: www.orientgene.com
 quality@orientgene.com



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



Shanghai International Holding Corp. GmbH (Europe)
 Add: Eiestrasse 80, 20537 Hamburg, Germany



Swab information:

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



Llins Service & Consulting GmbH
 Obere Seegasse 34/2, 69124 Heidelberg, Germany
 Email-info@llins-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 (7)



UK Responsible
 Person



Latex free



Catalog number



Do not resterilise



European authorised
 representative

Version B22088-02 Effective date 2021/09/14

REF GCCOV-502a-H70GE

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Report all your test results to the NHS