

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

Your step-by-step guide to the SureScreen SARS-CoV-2 Antigen Rapid Test Cassette (Nasal Swab) (Gold)



These instructions are for the SureScreen Diagnostics SARS-CoV-2 Antigen Rapid Test Cassette (Nasal Swab) (Gold), Product Code: COVID19AGVCGS7.

The guide explains how to test yourself, your child or another person for COVID-19, and how to report your results.

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

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 at 10 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	Test Performance	page 17
9	Safely dispose of your test	page 17

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

This instruction booklet only refers to SureScreen SARS-CoV-2 Antigen Rapid Test Cassette (Nasal Swab) (Gold)

Advice about taking the test

Storage and Handling Guidance

- Store as packaged at room temperature (2-30°C). Do not freeze.
- The kit should be used at room temperature (15°C to 30°C). If the kit has been stored in a cool area (less than 15°C), leave it at normal room temperature for 20 minutes before using.
- Use a separate test kit for each person. You can only use each item in the test kit once. Do not re-use the items. You'll need to report each person's result.
- If you have problems with your hands or vision, you may need someone to assist you with the swabbing and testing process.
- If you have a nose piercing, remove the piercing before conducting the test.
- Avoid using bloody samples. If you've had a nose bleed within the last 24 hours you should wait 24 hours before doing a test.
- Do not touch the swab head when handling the swab.
- Avoid touching the test kit and results window area where the sample is added.

Warnings

- Do not use after the expiration date. Please follow the expiration date on the box.
- The cassette should remain in the sealed pouch until ready to use.
- These test kits are only designed for human use.
- Do not use any nasal sprays 15 minutes prior to testing.
- 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.

Follow these instructions carefully, this test may be different from those you have used before.

Product Code: COVID19AGVCGS7

About this test

Why you should self-test

This COVID-19 self-test kit is a swab test for the nose. It can be used for people who have 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: <u>nhs.uk/conditions/coronavirus-covid-19/</u> <u>self-isolation-and-treatment/</u>
- 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

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 **<u>111.nhs.uk</u>**

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: <u>nhs.uk/conditions/</u> <u>coronavirus-COVID-19/symptoms/coronavirus-in-children/</u>

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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 as necessary.



Children under 12

An adult should test children under 12 years of age. Do not conduct this test if you feel uncomfortable testing a child. Do not continue the test if the child feels any significant discomfort or pain.

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

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Product Code: COVID19AGVCGS7

1. Prepare your test area

IMPORTANT

The kit should be used at room temperature (15°C to 30°C). If the kit has been stored in a cool area (less than 15°C), leave it at normal room temperature for 20 minutes before using.





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Check your kit contents



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, report to:

coronavirus-yellowcard.mhra.gov.uk

Product Code: COVID19AGVCGS7

2. Set up your test





6

Take the test cassette out of the sealed pouch and place it onto a clean flat surface.

WARNING

Once opened, use within 1 hour, or the test will be void. Discard the cassette and contents of the pouch that have been outside the sealed pouch for more than 1 hour.



Place the extraction tube in the extraction tube holder (perforated circular area on lid of the box) to avoid spilling the liquid.



Carefully twist to snap open the liquid sachet. Open it away from your face and be careful not to spill any of the liquid.

WARNING

The extraction buffer contains materials which may create irritation if it comes into contact with the face or skin. If the solution makes contact with the skin or eye, wash with lots of water. If skin irritation occurs please seek medical attention.

Take care

Open the extraction tube and gently squeeze all of the liquid from the sachet into the tube.

Take care and place the empty liquid sachet in the plastic waste bag provided.

This instruction booklet only refers to SureScreen SARS-CoV-2 Antigen Rapid Test Cassette (Nasal Swab) (Gold)

8



Gently blow your nose into a tissue and throw the tissue away in a closed bin.

If you are helping someone else or testing a child, help them to blow their nose and throw the tissue away in a closed bin.



9

Product Code: COVID19AGVCGS7

3. Take your swab sample

If you are testing someone else, please refer to the instructions on page 11.

IMPORTANT

The test should be performed using a nose sample only.



Insert the fabric tip of the swab just inside one nostril (about 1.5cm up your nose).



Gently wipe the swab around the inside of your nostril in a circular motion **5 times** for at least **5 seconds**.

Slowly remove it. No force is needed and you do not have to push far into your nostril. Do not return the swab to the original paper packaging.

Using the same swab, place the fabric tip of the swab just inside the other nostril (which is about 1.5cm up your nose.)

Gently wipe the swab around the inside of your nostril in a circular motion **5 times** for at least **5 seconds.**

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15

5

seconds

Doing a test on someone else

ADVICE

Children under 12 should be tested by an adult. Follow the guidelines below on how to prepare and test a child. You can watch a demonstration video at **gov.uk/covid19-self-test-help**



If you're testing a child, show them the test kit and talk about what you are going to do. If possible, sit them on someone's lap or have someone hold their hand.



V VV 5 seconds 15 v x5 Insert the fabric tip of the swab just inside their nostril (up to 1.5cm), or until you feel resistance. Gently wipe the swab around the inside of their nostril in a circular motion **5 times** for at least **5 seconds.** Slowly remove it. No force is needed and you do not have to push far into their nostril. Do not return the swab to the original paper packaging.

Using the same swab, place the fabric tip of the swab just inside their other nostril (up to 1.5cm) or until you feel resistance.

Gently wipe the swab around the inside of their nostril in a circular motion **5 times** for at least **5 seconds**.

Product Code: COVID19AGVCGS7

4. Process the swab sample

TIP

For best performance, test the swab as soon as possible after collecting your sample.



Breakpoint

Pick up the extraction tube and place the swab's fabric tip in the extraction tube, so it is in the liquid

Press the swab head firmly against the inside of the tube body by pinching the bottom of the tube with your thumb and fingers.

Whilst pinching, rotate the swab for at least 10 seconds.



Place the swab handle in the plastic waste bag provided.

Fit the dropper cap tightly onto the top of the extraction tube.



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Ensure the test cassette is on a clean and flat surface.

Do not move the cassette during the test.

Gently squeeze the extraction tube to place 3 drops of the liquid into the sample well (S) on the test strip.

Make sure that you are dropping liquid and not an air bubble.

Put the extraction tube in the plastic waste bag.

Start a timer and wait 10 minutes before reading the result.

Do not move the test once it is running. Interpret the result after 10 minutes. Do not read after 20 minutes.

You must wait the full 10 minutes' development time before you read your test result.

Product Code: COVID19AGVCGS7

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10

minutes

5. Read your result

IMPORTANT



Wait for 10 minutes to read the result.



Do not leave the test to develop for longer than **20 minutes**. This will make the test 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, shows the test is positive.

IMPORTANT

If you test positive you should self-isolate, your household should follow government guidelines on self-isolating: <u>nhs.uk/conditions/</u> <u>coronavirus-covid-19/self-isolation-and-</u> <u>treatment/</u>



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6. Report your result

You should report your positive, negative or 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**

If you live in Scotland visit covidtest.scot



Or report by telephone.

If you cannot report your result online, call **119** (free from mobiles and landlines).

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

Product Code: COVID19AGVCGS7

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 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-andtreatment/

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Negative Result

If you get a negative result, you were likely not infectious at the time you took the test. A negative test result, however, **is not a guarantee that you do not have COVID-19.**

If you test negative, you must continue to follow national and local rules and guidelines, including regular hand washing, 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** 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.

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Void result

If you get a void result, this means that the test has not run correctly and it is not possible to say if you had the virus when the test was done. You need to use another test from the pack as soon as possible. Do not reuse anything from the first test, and start the test procedure from step 1.

If the problem persists, discontinue using the test kit immediately. Order a new pack of test kits by visiting: **gov.uk/get-coronavirus-test**, through the NHS COVID-19 App or 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

Once your test is complete, put all of the used contents in the waste bag provided and put this in your general household waste.

Wash your hands thoroughly after disposal.

The information in this booklet is correct as of (29 September 2021). Product code: COVID19AGVCGS7 Product name: SureScreen SARS-CoV-2 Antigen Rapid Test Cassette (Nasal Swab) (Gold)

Product Code: COVID19AGVCGS7

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**

If you live in Scotland visit covidtest.scot

Date	Time	Test result
	Date	Date Time Image: Constraint of the second

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Your kit contains the following materials

Items	7-Pack
Instruction for use (this booklet)	1
Test cassettes in sealed pouches	7
Liquid sachets (Extraction buffer vials)	7
Extraction tubes	7
Swabs	7
Plastic waste bags	7

Product Code: COVID19AGVCGS7

Summary of Further Information

Additional self testing support Alternative language versions and video demonstrations Guidance for preparing and testing a child	gov.uk/covid19-self-test-help
Guidance on Self isolation and treatment information	nhs.uk/conditions/coronavirus-covid-19/ self-isolation-and-treatment/
NHS Guidance on COVID-19 and COVID-19	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:	<u>111.nhs.uk</u> Or call NHS 111 if you do not have internet access
COVID-19 symptoms in children	nhs.uk/conditions/coronavirus- COVID-19/symptoms/coronavirus-in- children
If you are harmed by a device, report to	<u>coronavirus-yellowcard.mhra.gov.uk</u>
Report a result online (England, Wales or Northern Ireland):	gov.uk/report-covid19-result
Report a result online (Scotland):	<u>covidtest.scot</u>
Order a current recommended test	gov.uk/get-coronavirus-test
Something damaged, broken or missing Language support (including British Sign Language) Report your result (if you do not have internet access)	Call 119

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Product Code: COVID19AGVCGS7

Notes:

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

SureScreen Diagnostics



Manufacturer:

SureScreen Diagnostics 1 Prime Parkway, Prime Enterprise Park, Derby, DE1 3QB, United Kingdom.

Swab Information:

Zhejiang Gongdong Medical Technology Co., Ltd. Address: No.10 Beiyuan Ave., Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China or

Jiangsu ChangFeng Medical Industry Co., LTD Address: Tougiao Town, Guangling District, Yangzhou, 225109 Jiangsu P.R. China

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Symbols













STERILE EO

Contains sufficient for 7 tests

Expiry date

Sterilized using

ethylene oxide



In vitro diagnostic medical device

Do not re-use

product when the package is damaged

Don't use the

Consult 'Advice about taking the test' section for general guidance and warnings

REF

Catalogue number

Version 5 Effective date 29/09/2021

This instructions for use, relates to the SARS-CoV-2 Antigen Rapid Test Cassette (Nasal Swab) (Gold), manufacturer: SureScreen Diagnostics and product code: COVID19AGVCGS7

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