Test and Trace

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 the MP Biomedicals Rapid SARS-CoV-2 Antigen Test Card

These instructions for use relate to the MP Biomedicals Rapid SARS-CoV-2 Antigen Test Card, 07AG6007BS 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**

Report all your test results to the NHS

What you need to do

Your step-by-step guide

Please follow the instructions for use carefully 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.

[Please note that in the standard print document there are images throughout. The text accompanying the images is self-explanatory and only the text has been transcribed into large print.]

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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.

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 have a nose piercing, remove the piercing before swabbing.
- If you experience a nosebleed 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 young children.
- Follow the swab sampling steps very carefully and always use the swabs provided with this kit. Failure to collect the sample correctly may lead to inaccurate test results.
- Persons requiring additional assistance, including those visually impaired, may be assisted by another adult. Pay particular attention to the additional information on Page 11 when conducting the test.

WARNING

Do not use the product beyond the expiration date.

ADVICE

- Store the test kit in a cool dry place (4°C to 30°C).
- Do not leave in direct sunlight and do not store in a fridge or freezer as this can lead to inaccurate test results.
- Do not use the test card if the sealed wrapper is damaged or the seal is broken.
- 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.

About this test

Why you should self-test

This COVID-19 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/**

- 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**

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

Children under 14

Should be assisted by an adult. Do not conduct this test if you do not feel confident assisting a child. (Please see page 11 for more information on assisting children)

Persons aged 14 and over

Adolescents aged 14-17 can self-test, with adult supervision. All others self-test and report, with assistance if needed.

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**

1. Prepare your test area

You'll need: a timer such as a watch or clock, tissues, surface cleaner, hand sanitiser or soap and access to warm water.

1. Read this Instructions for Use document carefully.

You can also watch the swab test video online if you need more help:
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.

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, rewash your hands between each test.

4. In your test box you should have all the below contents. Make sure that nothing is damaged or broken.

- Tube stand
- Extraction Buffer Bottle
- Sterile Swab in Sealed Wrapper
- Test Card in Sealed Wrapper
- Extraction Tube

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**

2. Set up your test

5. Place the extraction tube in the tube stand to avoid spilling the liquid.

6. Rotate the lid of the extraction buffer bottle.

CAUTION: Open the extraction buffer bottle away from your face and be careful not to spill any of the liquid.

7. Squeeze all buffer solution out of the extraction buffer bottle into the extraction tube.

CAUTION: Avoid touching the bottle against the tube.

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

If you are testing a child, help them to blow their nose. This is so that you get rid of excess mucus.

9. Wash your hands thoroughly again for **20 seconds** using soap and warm water.

10. Find the swab in the sealed wrapper. Identify the soft, fabric tip on the swab

11. Peel open the swab wrapper and carefully pull out the swab.

WARNING

Do not touch the soft, fabric tip of the swab with your hands

3. Take your swab sample

WARNING

The test should be performed using a swab sample from the nose only. If you do not follow the swab instructions carefully, this could lead to inaccurate test results.

If assisting a child under 14, or a person who requires assistance, follow the steps on page 11.

12. Carefully insert the swab into one nostril. The swab tip should be inserted no less than **2.5 cm** from the edge of the nostril.

13. Gently roll the swab around the inside of your nostril in a circular motion **3-4 times**. Slowly remove it. No force is needed and you do not have to push far into your nostril.

CAUTION: This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain.

Using the same swab, repeat steps 12 & 13 for other nostril.

Assisting someone else

Children under 14 should be assisted by an adult. Follow the guidelines below on how to prepare and help a child or a person who requires assistance. You can watch a demonstration video at: **gov.uk/guidance/covid-19-self-test-help**

If you're assisting a child, show them the test kit and talk to them about what you are going to do. Ask the child to blow their nose into a tissue. Place the tissue in a closed bin.

12. Carefully insert the swab into one of their nostrils. The swab tip should be inserted until resistance is felt.

13. Gently roll the swab around the inside of their nostril in a circular motion **3-4 times**. Slowly remove it. No force is needed and you do not have to push far into their nostril.

CAUTION: This may feel uncomfortable. Do not insert the swab any deeper if they feel strong resistance or pain.

Using the same swab, repeat steps 12 & 13 for other nostril.

4. Process the swab sample

TIP

For best performance, test the nasal swab as soon as possible after swabbing your nostrils.

14. Pick up the extraction tube and place the swab with the sample into the extraction tube. Rotate the swab 3-5 times. Leave the swab in the extraction solution for **1 minute**.

15. Pinch the extraction tube together with fingers while removing the swab to leave as much solution in the tube as possible. Place the swab back into the swab wrapper.

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

ADVICE

Wash your hands again after completing this step.

17. Open the foil pouch and remove the test card.

WARNING

Once opened, the test card must be used immediately.

18. Ensure the test card is on a clean, level and flat surface.

Do not move the card during the test.

19. Gently squeeze the extraction tube to place **3 drops** of test specimen into the well (labelled S) on the test card.

CAUTION: Make sure that you are dropping liquid and the well does not contain air bubbles.

20. Set a timer and wait **15 minutes** before you read your result. A positive result can appear at any time, however you should wait for the full 15 minutes to record a negative result as the test line (T) may take this long to appear.

Find out how to read and report your result on the next page. >>

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 and your household should follow government guidelines on self-isolating:
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

If you live in Scotland visit:
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/** or by calling the customer contact centre on **119**. Lines open every day, 7am to 11 pm.

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** 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** 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 your general household waste.

Wash your hands thoroughly after disposal.

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**

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

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Date:
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Test result:

Your kit contains the following materials

Items [in a] 7-Pack

Test Card in Sealed Wrapper - 7

Sterile Swab in Sealed Wrapper - 7

Extraction Tube - 7

Extraction Buffer Bottle - 7

Instructions for Use (this document) - 1

Tube Stand - 1

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

[TM]

Manufacturer:
MP Biomedicals Germany GmbH
Thueringer Str. 15 37269
Eschwege, Germany

CE **0123**

Swab Manufacturer:
Jiangsu Hanheng Medical Technology Co.,Ltd. 16-B4,#1 North Qingyang Road, Tianning District, 213017, Changzhou, Jiangsu, China

CE **0197**

EC REP

Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany

Swab Manufacturer:
Goodwood Medical Care Ltd. 1-2 Floor, 3-919 Yongzheng Street, Jinzhou District, Dalian, 116100 Liaoning, China

CE **0197**

EC REP

CMC Medical Devices & Drugs S.L. C/ Horacio Lengo No18, CP 29006, Màlaga, Spain

Index of symbols


Store within 4 – 30°C

LOT Lot number


Keep away from sunlight


Keep dry

EC REP Authorized Representative

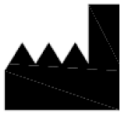


Sterilized using ethylene oxide


Use-by date


Caution


Consult instructions for use


Manufacturer



In vitro diagnostic medical device


Do not re-use


European Conformity


Contains sufficient for 7 tests


Do not use if package is damaged


Recyclable



Catalogue Number

All of the information and images in this document are correct as of 24/09/2021. Version 0002

REF 07AG6007BS

This instructions booklet only refers to the MP Biomedicals Rapid SARS-CoV-2 Antigen Test Card, product code: 07AG6007BS.

Report all your test results to the NHS

Whilst every effort has been taken to ensure the accuracy of this text, the original documentation should be relied upon as the true and accurate version.