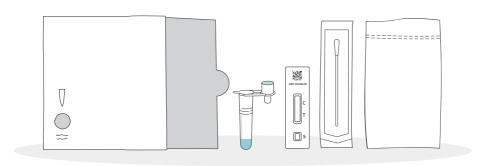


Read this whole guide carefully before you start the test. This test may be different from those you have used before.

Your step-by-step guide for ACON Flow flex™ SARS-CoV-2 Antigen Rapid Test (Self-Testing)



These instructions for use relate to ACON Flow*flex*™ SARS-CoV-2 Antigen Rapid Test (Self-Testing), product code: L031-118Y5 only.

The guide explains how to test yourself or another person for 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

ACON Flow*flex*[™] SARS-CoV-2 Antigen Rapid Test (Self-Testing) is a rapid test for the detection of COVID-19 where the users take their swab sample from their nose.

It is for self-testing and in vitro diagnostic use only.

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.

Please carefully read the instructions before performing the test.

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2	Set up your test	page	9
3	Take your swab sample	page	11
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Around 1 in 3 people with COVID-19 do not know they have it.

Advice about taking the test

Precautions

- Do not eat, drink, smoke or vape 30 minutes prior to or during the test.
- Do not use the test if any part is damaged.
- All used test materials should be safely disposed of in the household waste.
- Wash hands thoroughly before and after use.
- Avoid using samples that contain blood.
- Assistance with the swabbing and testing process may be required by those with hand and vision issues.
- Keep the test kit away from children and animals.

Storage and handling

- The test kit should be stored at temperatures between 2 30 °C. DO NOT FREEZE.
- Do not use the test after the expiration date printed on the sealed pouch.
- Test should be performed at temperature range 15 30 °C.

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 self-isolate following 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.

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/**

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

Should be tested by an adult. Do not conduct this test if you do not feel confident testing a child.

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: ${\bf gov.uk/covid19\text{-}self\text{-}test\text{-}help}$

This instructions booklet only refers to ACON Flow*flex*[™] SARS-CoV-2 Antigen Rapid Test (Self-Testing), Product code: L031-118Y5.

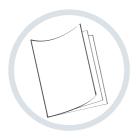
1. Prepare your test area

TIP

Do not eat, drink, smoke or vape 30 minutes prior to or during the test.

ADVICE

You'll need a timer (a watch or clock) during your test.



Read this instruction guide carefully.
You can also watch the swab test video online if you need more help:
gov.uk/covid19-self-test-help



2 Clear, clean and dry a flat surface immediately before starting the test.

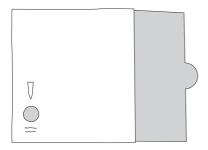


Wash or sanitise your hands. Make sure they are dry before starting the test.

If you are testing more than one person or repeating a void test, rewash your hands between each test.

Check your kit contents

In your test box you should have:



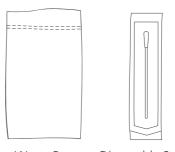
Extraction Buffer Tube Holder



Test Cassette in sealed pack



Extraction Buffer Tube in sealed pack



Waste Bag Disposable Swab

ADVICE

What to do if something is damaged, broken or missing

If you notice anything damaged, broken, missing or difficult to use in the kit, do not use it. 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 reporting it could help others, please go to: coronavirus-yellowcard.mhra.gov.uk

2. Set up your test

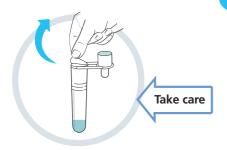




5 Take the test cassette out of the sealed bag and place it onto a clean flat surface.

WARNING

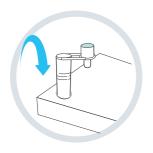
Once opened, start the test within 30 minutes.



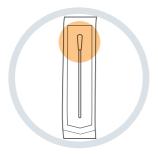
Keeping the extraction buffer tube away from your face, carefully peel off the sealing film on the tube to avoid spilling any fluid.

WARNING

If the liquid in the extraction buffer tube gets onto the skin or into eyes, wash immediately and seek medical help if necessary.



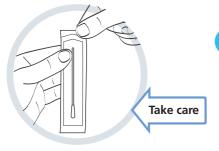
7 Insert the extraction buffer tube into the tube holder to avoid spilling the buffer.



8 Find the swab in the sealed wrapper and identify the soft, fabric tip.

WARNING

Do not touch the soft, fabric tip of the swab.



Peel open the swab packaging only when you are ready to use. Gently take out the swab and avoid touching the fabric tip.

3. Take your swab sample

WARNING

ACON Flow*flex*™ SARS-CoV-2 Antigen Rapid Test (Self-Testing) should be performed using a nose sample only. Do not swab your nostril if you have a nosebleed.

Adolescents aged 12-17 can self-test with adult supervision. The adult may conduct the test, as necessary.

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



Insert the entire fabric tip of the swab into one nostril. Using gentle rotation, push the swab less than 2.5 cm from the edge of the nostril.

This may feel uncomfortable. Do not insert the swab any deeper if you feel





Rotate the swab 5 times brushing against the inside of the nostril.

strong resistance or pain.





Remove the swab and insert the same swab into the other nostril. Repeat step 10 and step 11.

Doing a test on someone else

ADVICE

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



Put the fabric tip of the swab gently into one of their nostrils until you feel some resistance.



Rotate the swab 5 times brushing against the inside of the nostril.



Remove the swab and insert the same swab into the other nostril. Repeat step 13 and step 14.

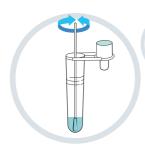
4. Process the swab sample

TIP

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

WARNING

If the liquid in the extraction buffer tube gets onto the skin or into eyes, wash immediately and seek medical help if necessary.



30 seconds

Pick up the extraction buffer tube and place the fabric tip of the swab into the tube so it is in the liquid.

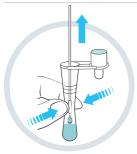
Press the tip against the edge of the extraction buffer tube with force, while rotating it around the tube for 30 seconds.



x5

17 Rotate the swab 5 times while squeezing the side of the tube.

This is to transfer your sample into the liquid.



Pinch the extraction buffer tube against the swab as you remove it. Make sure you remove all liquid from the soft tip of the swab.

Place the swab in the waste bag provided.



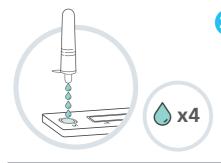
19 Attach the dropper tip firmly onto the extraction buffer tube. Mix thoroughly by swirling or flicking the bottom of the tube.



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

Do not move the cassette during the

test.



Gently squeeze the extraction buffer tube to place 4 drops of the liquid into the specimen well (S) on the test cassette. Make sure that you are dropping liquid and not an air bubble.

Put the extraction buffer tube in the waste bag.





Check the time and set a timer. Wait 15 minutes before you read your result. Read the result when the timer reaches 15-30 minutes. Do not read after 30 minutes.

5. Read your result

IMPORTANT

Wait for **15 minutes** to read the result. Do not read the result **after 30 minutes**







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

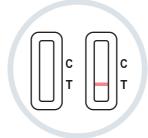
nhs.uk/conditions/coronavirus-covid-19/self-isolation-and-treatment/





Negative result

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



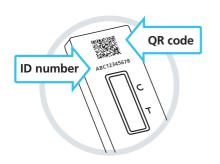


Void result

Control line (C) fails to appear.

6. Report your result

You should report your positive, negative 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:

www.gov.uk/report-covid19-result

If you live in Scotland visit:

www.covidtest.scot



Or report by telephone

Call **119**

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

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. 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, should 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 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 of COVID-19, you and your household should self-isolate and the guidelines are to get another test at:

gov.uk/get-coronavirus-test or by calling the customer contact centre on **119**. Lines open every day, 7am to 11 pm.



If you get a void result, this means that the test has not run correctly. There may have not been enough specimen volume or you may not have completed the test correctly.

You need to use another lateral flow test from the pack. Do not reuse anything from the first kit 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. Safely dispose of your test kit



Once your test is complete, put all of the used test kit contents in the waste bag provided and put this 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 16 for information).

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

www.gov.uk/report-covid19-result

If you live in Scotland visit: www.covidtest.scot

Who took the test	Date	Time	Test result

Your kit contains the following materials

Items	7-Pack
Test Cassettes	7
Extraction Buffer Tubes	7
Disposable Swabs	7
Waste Bags	7
Extraction Buffer Tube Holder	1
Instructions for Use (this document)	1



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



Flow*flex*™ SARS-CoV-2 Antigen Rapid Test (Self-Testing)

ACON Biotech (Hangzhou) Co., Ltd. No.210 Zhenzhong Road, West Lake District, Hangzhou, P.R. China, 310030

Website: www.aconbio.com

Email: COVID19selftest@aconlab.com.cn

Disposable Swabs

444

Jiangsu Changfeng Medical Industry Co., Ltd. Touqiao Town, Guangling District, Yangzhou 225109, Jiangsu, P.R. China

OR



Jiangsu HanHeng Medical Technology Co., Ltd. 16-B4, #1 North Qingyang Road, Tianning District, Changzhou, 213017 Jiangsu P.R. China **(** € 0123

EC REP

MedNet GmbH Borkstrasse 10 48163 Muenster, Germany

(€ 0197

EC REP

Llins Service & Consulting GmbH Obere Seegasse 34/2, 69124 Heidelberg, Germany

(6 0197

EC REP

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

Manufacturer



Contains sufficient for <n> tests



Temperature limit

IVD

In vitro diagnostic medical device



Use-by date



Do not reuse

i

Consult instructions for use

LOT

Batch code

REF

Catalogue number

EC REP

Authorized representative in the European Community



Date of manufacture



Keep dry



Don't use the product when the package is damaged



Do not resterilize



Keep away from sunlight



Sterilized using ethylene oxide



Recyclable

 \triangle

Warning, please refer to the instruction

Version 1151355103 Effective date 2021-09-07

This instructions for use, relates to ACON Biotech (Hangzhou) Co., Ltd.

Flowflex™ SARS-CoV-2 Antigen Rapid Test (Self-Testing), Product Code: L031-118Y5