

TECHNICAL BULLETIN: RAPID COVID-19 ANTIGEN SELF-TEST

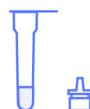
This kit contains:



Technical Bulletin
(this leaflet, a quick guide to
the Instructions for Use)



Disposable swab



Extraction tube with buffer (sealed
with lid, the liquid inside is the buffer)
and tip (tube cap)



Lateral flow
cassette
(test device)



Instructions
for Use



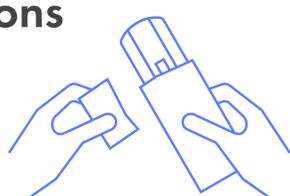
Procedure
card

Please make sure that you have a timer or stopwatch and a plastic bag for waste (not provided).

Before you get started

- Please read the instructions carefully prior to use and follow them strictly. Specimens must be processed as indicated in the Instructions for Use. Failure to follow these instructions can result in inaccurate results.
- The cassette should remain in the sealed pouch until use. Cassettes that have been outside of the sealed pouch for more than 1 hour should be discarded.
- Do not use the test kit past its expiration date or if the cassette pouch is damaged.
- Do not interchange or mix components from other kits. Testing should only be performed using the swabs provided with the kit.
- To obtain accurate results, do not use visually bloody or overly viscous (thick, sticky) samples. Inadequate or inappropriate specimen collection can affect results.
- Use of the test in very humid areas or when the temperature is below 15°C or above 30°C can adversely affect the results. The test should be performed at room temperature (15-30 °C).
- You will need internet access to **register the QR code** on your cassette.
- If you do not register your QR code, we will be **unable** to process your results.
- Nasal swab samples from individuals aged below 12 years should be collected by or under the supervision of adults.
- Swabs, tubes and cassettes are for single use only.

Instructions



Step 1

Wash and sanitise your hands. Make sure they are dry before starting the test. Unseal the foil pouch and put the cassette on a clean, dry and level surface.

[chronomics.com/
register](https://www.chronomics.com/register)

Step 2

If you haven't done it yet, register your kit online at www.chronomics.com/register and enter the QR code found on your cassette. Please note this is different to the QR code that you may have used to register your kit ID.



Step 3

Insert the tube into the workstation found in the packaging. Remove the lid from the top of the extraction tube.



Step 4

Open the swab package where indicated. Pull the swab out by grasping the plastic end. Do not touch the absorbent swab tip.



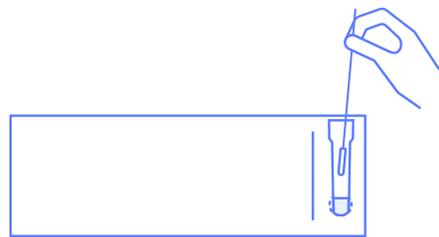
Step 5

Carefully insert the absorbent tip of the swab into your left nostril. Ensure that the entire swab tip is inside your nostril (~ 2-3 cm deep). Do not insert the swab further after you feel resistance. Roll the swab at least 5 times against the insides of your nostril. Ensure good contact between the swab and the insides of your nostril.



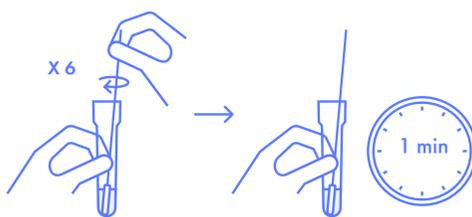
Step 6

Remove the swab and insert it into the right nostril. Repeat step 5.



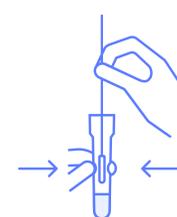
Step 7

Remove the swab from your nostril and insert the absorbent tip of the swab into the extraction tube in the workstation.



Step 8

Mix well by rolling the swab at least 6 times while pressing the head of the swab against the bottom and sides of the tube. Start the timer or stopwatch. Leave the swab in the tube for 1 minute.



Step 9

Squeeze the tube several times from the outside to try to release as much solution from the swab as possible. Remove the swab and discard in a plastic bag.



Step 10

Push the tip provided in the kit into the tube and ensure it fits tightly. Add 4 drops of the solution into the sample well (S) of the cassette by gently squeezing the tube.



Step 11

Start the timer or stopwatch and wait 15 minutes. It is important to read the result (and upload a picture if necessary) at 15 minutes.



Step 12

Finalise the registration of your result following the instructions found at www.chronomics.com/register. Once your test is complete, collect all the kit components and swab sample in a plastic bag and discard it as general household waste.

chronomics.com/register

Warnings and limitations

For a complete list of warnings and limitations please refer to the Instructions for Use.

- Clinical diagnosis of SARS-CoV-2 infection should not be made only based on the results of this product. As with all *in vitro* diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
- Respiratory infection caused by microorganisms other than SARS-CoV-2 will not be established with this test.
- Positive results do not differentiate between SARS-CoV and SARS-CoV-2. Positive results do not rule out co-infections with other pathogens. All specimens with positive results must be confirmed using an appropriate test such as RT-PCR or equivalent.
- A false-negative test may occur if the level of antigen in a sample is below the limit of detection of the test or if the sample was collected incorrectly (e.g. if the swab is not mixed well in the tube). A negative result does not rule out at any time the presence of SARS-CoV-2 in the sample, as it may be present below the minimum detection level of the test.
- The amount of antigen in a specimen may decrease as the disease progresses. Therefore, specimens collected more than ten days after COVID-19 infection may have low antigen levels that are below the minimum detection level of the test. Testing such a specimen is more likely to result in a false negative rapid test result than testing based on a PCR assay (the evaluation which is performed in a laboratory).
- Negative results do not rule out SARS-CoV-2 infection and do not liberate you from applicable rules for spread control (such as avoiding contact with others and protective measures).
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended.
- Do not use the kit if any of the components are damaged or missing. If you have any concerns please contact us at: support@chronomics.com or 0208 146 0960.
- Keep away from children to reduce the risk of accidental drinking of buffer liquid or swallowing of small parts.
- Do not touch or drink the liquid inside the buffer bottle. Do not allow it to come into contact with your skin, your eyes or any external surface.
- If the solution makes contact with your skin, immediately wash your skin with water for at least 15 minutes.
- If the solution gets into your eyes, immediately wash them with water for at least 15 minutes.
- If you experience any symptoms after contact with the liquid, seek medical help immediately.
- If the liquid inside the buffer bottle is spilled, clean it using gloves and absorbent tissue.

Label legend



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GCCOV-502a



Store at 2-30°C and keep away from direct sunlight.



For in Vitro Diagnostic Use.



Single use only.



Contents sufficient for <1> test



Always consult package instructions.



LOT number



Expiration date