REF RCOM-00273

QRI-RCOM-E / Rev. C / January 2022 **ENGLISH**

CareStart™ COVID-19 Antigen Home Test

USER INSTRUCTIONS

AccessBio

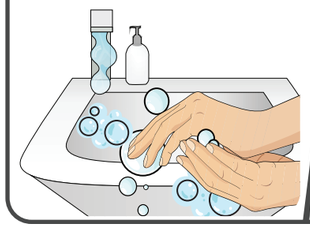
You must follow the test directions carefully to get an accurate result. Each test can only be used once.
This test must be used within 5 days of when you first experienced symptoms.

IMPORTANT: Swabbing the nostrils is critical for obtaining an accurate result.
If you do not swab your nose, the device will produce a false negative result.

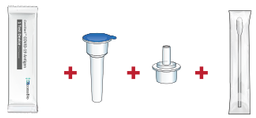
IVD

1 °C 34 °F — 30 °C 86 °F

1 Wash your hands thoroughly for at least 20 seconds before the test.



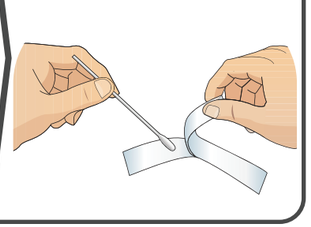
2 Unpack the test components.



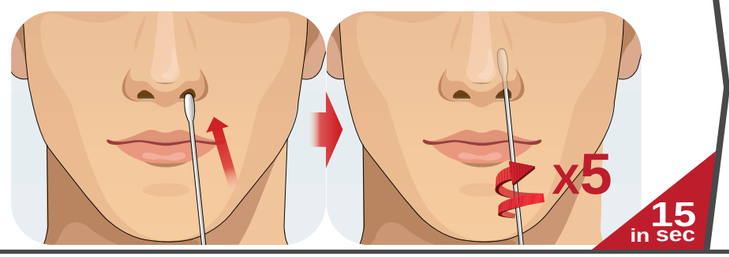
3 Remove the test cassette and place it on a flat, clean surface.

4 Locate the extraction vial and gently peel off the aluminium foil seal, being sure to keep the vial upright. The tray (available for pack sizes of 1 and 2 tests only) can assist with keeping the vial upright.

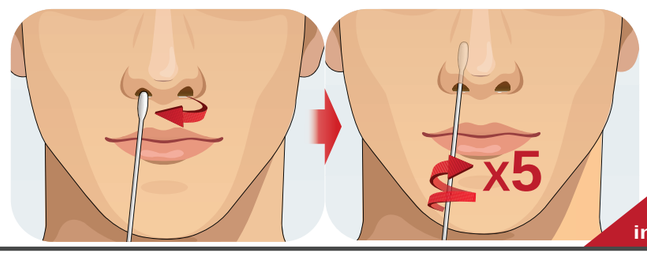
5 Locate a nasal swab and remove from the pouch. Be careful not to touch the swab tip.



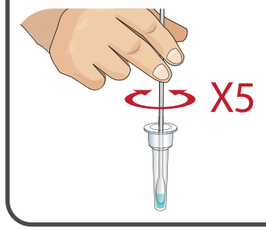
6 Gently insert the swab no more than 2 centimeters (3/4 inch) into the **LEFT** nostril. Then, slowly rotate the swab at least **5 times** in a circular path for a total of **15 seconds**.



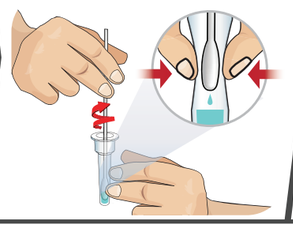
7 Gently remove the swab from the LEFT nostril and place directly into the **RIGHT** nostril, repeating the process of rotating at least **5 times** in a circular path for a total of **15 seconds**. Remove the swab from the RIGHT nostril.



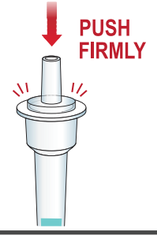
8 Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.



9 Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab.

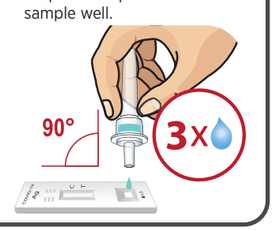


10 Close the vial by pushing the cap firmly onto the vial.



11 With your finger, mix thoroughly by flicking the bottom of the vial.

12 Invert the extraction vial and hold the sample vertically above the sample well. Squeeze the vial gently. Allow **THREE (3)** drops of sample to fall into the sample well.

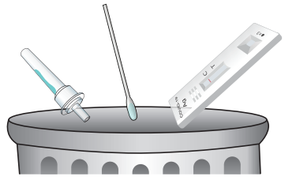


13 **Start a timer.**
Read the result at **10 minutes**.
The test result should not be read after 15 minutes.

IMPORTANT
Do not move or lift the test cassette during this time.

Disposal

Carefully wrap the used test kit components and swab samples and dispose in normal household waste.



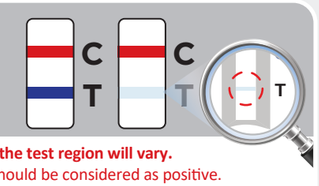
Results Interpretation

Make sure you wait the full 10 minutes.

NOTE: The test results should be read at 10 minutes after the sample application. The test result must be read before 15 minutes as test results after 15 minutes may not be accurate.

COVID-19 Detected (Positive)

One red-colored line next to "C" and one blue-colored line next to "T" indicates COVID-19 positive result.



IMPORTANT **Look very closely! The color intensity in the test region will vary.**
Any faint colored line in the test region should be considered as positive.

A positive test result indicates that antigens from SARS-CoV-2 were detected, and you are likely to be infected and presumed to be contagious. Refer to your local state and territory COVID support services for guidance on confirmation testing where necessary.

COVID-19 Not Detected (Negative)

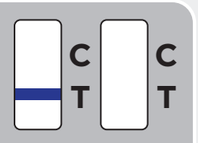
One red-colored line only next to "C" indicates a negative result.

Re-test in 24-48 hours if your first test result is negative.

A negative test result indicates that antigens from SARS-CoV-2 were not detected from the specimen. However, a negative result does not rule out COVID-19. You should continue to monitor for COVID symptoms and get tested at the first sign of any symptoms.

Invalid

If a red-colored line in the control "C" is not visible, the result is invalid.



Re-test with a COVID-19 test may be needed.
An invalid test result indicates that your test has experienced an error and is unable to interpret the result of the test. You will need to re-test with a new test or consult a healthcare professional. If you still have symptoms, you should self-isolate at home and avoid contact with others prior to the retest.

Customer Support

For assistance regarding the use of the product and interpretation of test results call 1800 195 055. This service is available between 9 am and 7 pm (AEST), or 9 am and 8 pm (AEDT), 7 days per week.

SCAN ME

CareStart™ Mobile Application

Scan the QR code for further information on how to complete the CareStart™ COVID-19 Antigen Home test.

Intended Use

CareStart™ COVID-19 Antigen Home Test is intended to aid the diagnosis of COVID-19 in symptomatic patients and for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens.

This test is authorised for home use in individuals:

- aged 12 years or older
- aged 2 – 11 who will have their test supervised by a parent or legal guardian
- who have experienced covid like symptoms within the last 5 days

The test must be used with the nasal swab provided in the kit.

Warnings and Limitations:

- Each test can only be used once
- Test results must be read at 10 minutes and no later than 15 minutes
- Interpretation of any result after 15 minutes may yield inaccurate test results
- If you receive a positive result, **refer to your state or territory health department information for guidance on confirmation testing**, where necessary.
- A positive result cannot determine whether you are infectious
- False negative results are more likely to occur if the test is performed after 5 days of symptom onset
- False negatives are more likely to occur in the later phase of infection and in asymptomatic individuals
- A negative result does not rule out infection with another type of respiratory virus
- Negative results should be treated as presumptive only and may not mean you are not infectious. If you are experiencing any COVID symptoms you must seek immediate further laboratory PCR testing and follow up clinical care.
- Repeat testing is recommended (between 24-48 hours after your first test) if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or other requirement

DO's

- Children between 2 – 11 years of age must be tested by a parent or legal guardian
- Wear a safety mask or other face-covering when collecting the sample from another individual
- Wash hands thoroughly for at least 20 seconds before and after handling the sample
- In order to obtain accurate results, you must follow the instructions for use
- Only open the kit when you are ready to complete the test
- Complete the test immediately after opening the test device in the pouch
- Keep the test device on a flat surface during the testing
- Keep testing kit and kit components away from children and pets before and after use
- Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false-positive result. Avoid touching any bleeding areas of the nasal cavity when collecting specimens.
- When collecting a sample, use only the nasal swab provided in the kit
- Keep foreign substances and household cleaning products away from the test during the testing process as contact with foreign substances and household cleaning products may result in an incorrect test result
- Handle all specimens as though they contain infectious agents

DON'Ts

- Do not re-use any contents in the kit as they are single-use only.
- Do not interpret the test result before 10 minutes or after 15 minutes of starting the test
- Do not use on anyone under 2 years of age
- Do not operate your test outside of the storage conditions
- Do not touch the tip (specimen collection area) of the swab
- Do not use on anyone who is prone to nosebleeds or has had facial or head injury/surgery in the last 6 months.
- Do not use if the test device packaging is damaged or shows signs of being tampered with
- Do not interchange kit contents from different packs
- Do not use the kit contents beyond the expiration date
- Do not eat or drink in the area where the specimens and kit contents are being handled
- Avoid eye and skin contact with the extraction solution
- Do not ingest the extraction solution

Safety Information:

Carefully wrap the used test kit components and swab samples and dispose in normal household waste.

To help slow the spread of Covid and protect yourself and others:

- practice good hygiene (eg washing your hands, covering your coughs)
- practice physical distancing
- wearing a mask can help protect you and those around you if you are in an area with community transmission and physical distancing is not possible.
- follow the directions of your local state or territory government health department
- speak to your healthcare professional regarding other measures

Explanation of Symbols

- IVD — ***In vitro* diagnostic medical device** — Indicates a medical device that is intended to be used as an *in vitro* diagnostic medical device.
- **Consult instructions for use** — Indicates the need for the user to consult the instructions for use.
- **Manufacturer** — Indicates the medical device manufacturer.
- LOT — **Batch code** — Indicates the manufacturer's batch code so that the batch or lot can be identified.
- **Do not re-use** — Indicates a medical device that is intended for one use.
- **Use by date** — Indicates the date after which the medical device is not to be used.
- REF — **Catalog number** — Indicates the manufacturer's catalog number so that the medical device can be identified.
- **Caution** — Indicates the need for the user to consult accompanying documents.
- **Date of manufacture** — Indicates the date when the medical device was manufactured.
- **Temperature limit** — Indicates the temperature limits to which the medical device can be safely exposed.
- **Do not use if the package is damaged** — Indicates a medical device that should not be used if the package has been damaged or opened.
- **Contains sufficient for <n> tests** — Indicates the total number of IVD tests that can be performed with the IVD.

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Victoria 3931 Australia

Performance Characteristics:

Variants:

In-house performance evaluation using the recombinant nucleocapsid proteins demonstrated the Alpha, Beta, Gamma, Kappa, Lamda and Delta variants were detectable with the CareStartTM COVID-19 Antigen Home Test.

Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

Clinical performance:

The CareStart™ COVID-19 Antigen Home Test was compared to the US FDA Emergency Use Authorized RT-PCR molecular assay. Subjects self-sampled and self-tested using the CareStart™ COVID-19 Antigen Home Test.

CareStart™ COVID-19 Antigen Home Test correctly identified 87.18% (34 out of 39 people) of positive samples and 100% (53 out of 53 people) of negative samples.

Analytical specificity:

The potential cross-reactivity of common organisms (refer to table below) was evaluated with SARS-CoV-2 negative and positive samples using the CareStart™ COVID-19 Antigen Home Test, with no interference detected.

Virus tested		**Bacteria tested**
Adenovirus 1	MERS-Coronavirus, Irradiated Lysate	*Bodetella pertussis*
Adenovirus 7	Parainfluenza virus type 1	*Candida albicans*
Enterovirus 71, Tainan/4643/1998	Parainfluenza virus type 2	*Chlamydophila pneumoniae*
Human coronavirus (OC43)	Parainfluenza virus type 3	*Haemophilus influenzae*
Human coronavirus (229E)	Parainfluenza virus type 4	*Legionella pneumophila*
Human coronavirus (NL63)	Respiratory syncytial virus Type B	*Mycoplasma pneumoniae*
Human metapneumovirus(hMPV)	Rhinovirus	*Staphylococcus aureus*
Influenza A/Michigan/45/2015	SARS-Coronavirus	*Staphylococcus epidermidis*
Influenza B/Wisconsin/01/2010	Pooled human nasal wash	*Streptococcus pneumoniae*
		Streptococcus pyogenes, Group A

To estimate the likelihood of cross-reactivity with SARS-CoV-2 of organisms that were not available for 'wet' testing, in *silico* analysis was used to assess the degree of protein sequence homology.

The homology between SARS-CoV-2 nucleocapsid protein and

- **human coronavirus HKU1 nucleocapsid protein** is relatively low (36.7% across 86.4% of sequences)
- **human coronavirus 229E nucleocapsid protein** is relatively low (28.8% across 72.1% of sequences)

Although the cross reactivity determined in these studies was relatively low, homology-based cross-reactivity cannot be ruled out.

Analytical Sensitivity: Limit of Detection (LoD):

The LoD for direct swab was established using heat-inactivated SARS-CoV-2 isolate USA-WA1/2020 (NR-52286). The strain was spiked into the pooled human nasal swab matrix obtained from multiple healthy volunteers eluted in VTM and confirmed as SARS-CoV-2 negative by RT-PCR to prepare positive samples. The estimated LoD found from the initial two-fold serial dilution test was confirmed by testing 20 replicates. The confirmed LoD for direct swab was 8 x 10^2 $TCID_{50}$/mL.

Endogenous Interfering Substances Effect:

The following substances were tested with CareStart™ COVID-19 Antigen Home Test and no interference was observed:

Substance (Concentration), Acetyl salicylic acid (15mg/mL), Beclomethasone (0.5mg/mL), Benzocaine (5mg/mL), Budesonide (2mg/mL), Chlorpheniramine maleate (5mg/mL), Dexamethasone (1mg/mL), Dextromethorphan hydrobromide (2mg/mL), Diphenhydramine hydrochloride (5mg/mL), Ephedrine hydrochloride (10mg/mL), Flunisolide (5mg/mL), Fluticasone (1mg/mL), Guaiacol glyceryl ether (20mg/mL), Histamine dihydrochloride (10mg/mL), Menthol (10mg/mL), Mometasone (1mg/mL), Mucin (2%), Mupirocin (1mg/mL), OTC Throat drops – Halls and Ricola (15%), OTC Nasal spray – Afrin, Vicks Sinex and Zicam (15%), Oxymetazoline hydrochloride (10mg/mL), Paracetamol (10mg/mL), Phenylephrine hydrochloride (5mg/mL), Phenylpropanolamine (5mg/mL), Tobramycin (1mg/mL), Triamcinolone (1mg/mL), Whole blood (4%), Zanamivir (1mg/mL)

In a separate study, biotin concentrations up to 1.25 µg/ml did not lead to false results, whereas, biotin concentrations ≥2.5 µg/ml can cause false-negative COVID-19 results.

Pack Sizes:

CareStart™ COVID-19 Antigen Home Test is available in pack sizes of 1, 2, 5, 7 and 20 tests. Each pack size includes a test cassette, extraction vial tube, extraction vial cap, nasal swab and user instructions. The 1 and 2 test pack size also include a tray.

Contact Information:

For assistance regarding the use of the product or for reporting any issues associated with the performance of the test call 1800 195 055. This service is available between 9 am and 7 pm (AEST), or 9 am and 8 pm (AEDT), 7 days per week.

You can also contact the Therapeutic Goods Administration (TGA) to report performance or usability issues via the online Users Medical Device Incident Report, emailing iris@tga.gov.au or calling 1800 809 361.

Support Services:

Information regarding available support services can also be obtained by contacting your local state and territory health department at:

ACT: 02 5124 9213
www.health.act.gov.au

NSW: 1300 066 055
www.health.nsw.gov.au

NT: 08 8922 8044
www.health.nt.gov.au

QLD: 13 432 584
www.health.qld.gov.au

SA: 1300 232 272
www.sahealth.sa.gov.au

TAS: 1300 135 513
www.health.tas.gov.au

VIC: 1300 650 172
www.dhhs.vic.gov.au

WA: 08 9222 4222
www.healthywa.wa.gov.au