REF RCPM - 00271, RCPM-00471, RCPM-02071

ENGLISH

CareStart™ COVID-19 Antigen Home Test

USER INSTRUCTIONS

AccessBio

You must follow the test directions carefully to get an accurate result. Call Technical Support at 1-888-898-1270 or visit accessbio.net to obtain the complete instructions for use. **FOR USE UNDER EMERGENCY USE AUTHORIZATION (EUA) ONLY.**

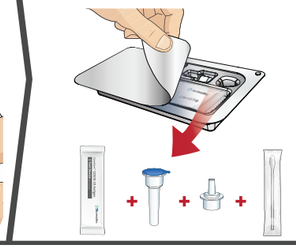
IMPORTANT: Swabbing the nostrils is critical for obtaining an accurate result.
If you do not swab your nose, the device will produce a false negative result.

IVD

1 ℃ 34 ℉ – 30 ℃ 86 ℉

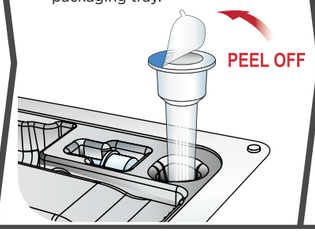
1 Wash your hands thoroughly for at least 20 seconds before the test.

2 Unpack the test components from the tray.

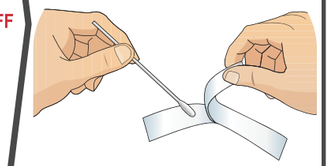


3 Remove the test cassette and place it on a flat, clean surface.

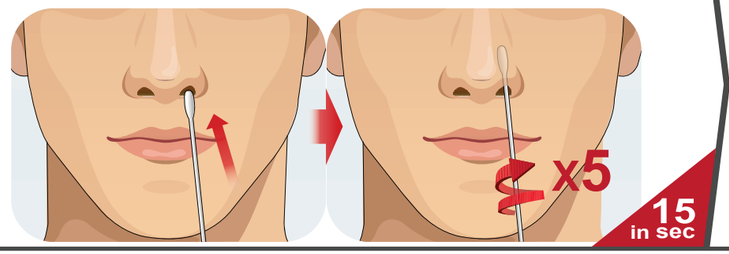
4 Locate the extraction vial and gently peel off the aluminum foil seal, being sure to keep the vial upright and place it in the packaging tray.



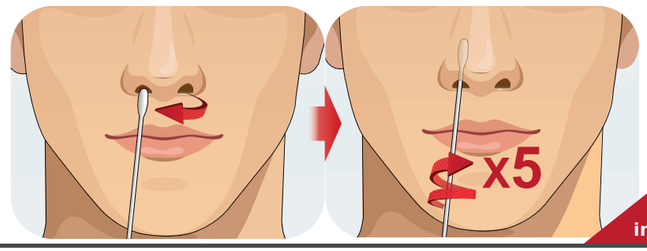
5 Locate a nasal swab and remove from the pouch. Be careful not to touch the swab tip.



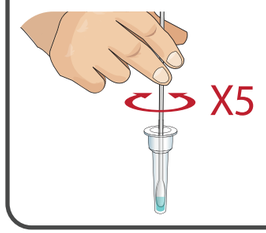
6 Gently insert the swab no more than 3/4 inch into the **LEFT** nostril. Then, slowly rotate the swab at least **5 times** in a circular path for a total of **15 seconds**.
If you have questions, see the CDC Guidelines.



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.

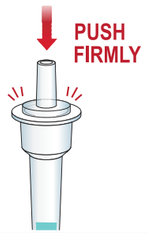


8 Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.



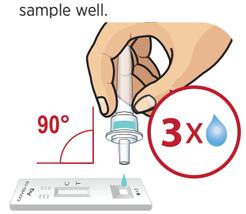
9 Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Discard the swab in trash.

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.

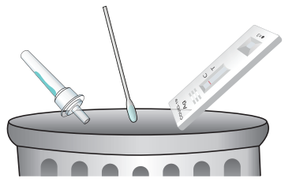
12 Invert the extraction vial and hold the sample vertically above the sample well. Squeeze the vial gently. Allow **THREE (3)** drops of sample to fall into the sample well.



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. Do not exit the mobile app during this process.

Disposal
Dispose of all used test kit components and swab samples in household trash.



Using Mobile Application

Scan the QR code to download

- Ensure you have an internet connection and download the App prior to start the test.
- Ensure you are using a compatible smartphone.
  (iOS13 or newer for Apple iPhone and Android10 or newer for Android Phone)
- Only open the foil pouch packaging when the App instructed to do so.

Please start the test follows the in-app self-paced, step-by-step test instructions.

1. Download and open App, on/go™ Mobile Application
Download the App on the App Store or Google Play Store. Ensure you are connected to the internet during your test.

2. Answer a few questions in the App

3. Watch the instruction video.

4. Follow step-by-step instructions for your test.

5. Test result
The App will assist in the visual result interpretation. Please follow the instructions provided in the App. You will be required to take a picture of the test device and then look at the device and answer some questions to the result interpretation.

Results Interpretation

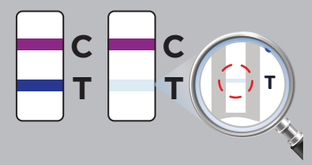
Make sure you wait the full 10 minutes.

The test results will be interpreted by visual reading following the in-app interpretation instructions or provided Quick Reference Instructions.

NOTE: The test results should be read by visual and interpreted at 10 minutes after the sample application and the reading and interpretation of the results should not exceed 15 minutes as it may yield inaccurate results.

COVID-19 Detected (Positive)

One purple-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 the patient is very likely to be infected with the virus and presumed to be contagious. Test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. You should self-isolate at home and avoid contact with others as per CDC recommendations to stop spreading the virus to others.

COVID-19 Not Detected (Negative)

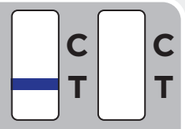
One purple-colored line only next to "C" indicates a negative result.

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 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID19 and confirmed with a molecular assay, if necessary, for patient management.

Invalid

Invalid barcode or absence of a purple-colored line next to "C".



Re-test with a COVID-19 test may be needed. An invalid test result indicates that your test has experienced an error and unable to interpret the result of the test. You will need to retest 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.

Intended Use

The *CareStart*™ COVID-19 Antigen Home Test is a rapid, lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens from individuals with or without symptoms or other epidemiological reasons to suspect a COVID-19 infection when tested twice over two or three days with at least 24 hours and not more than 48 hours between tests. This test is authorized for non-prescription home use with self-collected direct anterior nasal (nares) swab samples from individuals aged 14 years or older or adult collected anterior nasal swab samples from individuals aged 2 years or older.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. The antigen is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definite cause of disease. Individuals who test positive with the *CareStart*™ COVID-19 Antigen Home Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as presumptive and confirmation with a molecular assay for patient management, may be performed if necessary. Negative results do not rule out SARS-CoV-2 infection, and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LVID) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The *CareStart*™ COVID-19 Antigen Home Test is authorized for non-prescription self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older in a non-laboratory setting. The *CareStart*™ COVID-19 Antigen Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Important Note

- For *in vitro* diagnostic use only.
- This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA).
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for the detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.

DO's

- Children aged 13 years old and younger should be tested by a parent or legal guardian.
- Wear a safety mask or other face-covering when collecting anterior nares swab specimen from a child or another individual.
- Wash hands thoroughly for at least 20 seconds before and after handling nasal swab samples.
- In order to obtain accurate results, the user must follow the instructions for use.
- Immediately use 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.
- Inadequate or inappropriate sample collection, storage, and transport can result in incorrect results. If specimen storage is necessary, swabs can be placed into the extraction vial for up to four hours. Specimens should not be stored dry.
- When collecting a nasal swab 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. Contact with foreign substances and household cleaning products may result in an incorrect test result.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
- Handle all specimens as though they contain infectious agents.

DON'Ts

- Do not operate your test outside of storage conditions.
- Do not use on anyone under 2 years of age.
- Do not close the App during processing as it may cause an error and you will need a new test kit.
- Do not interpret the test result before 10 minutes and after 15 minutes starting the test.
- 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 package is damaged.
- Do not touch the tip (specimen collection area) of the swab.
- Do not use the kit contents beyond the expiration date.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- Do not interchange kit contents from different lots.
- Do not re-use any contents in the kit as they are single-use only.
- Eye and skin contact with the extraction solution should be avoided.
- Extraction solution should not be ingested.

Hazardous Ingredients for Liquid Reagent

The extraction solution in the vial contains potentially harmful chemicals (see table below). If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: https://www.poison.org/contact-us or 1-800-222-1222.

Chemical Name	GHS Code for each Ingredient	Concentration
Triton X-100	H315, skin irritation	1.5%
N-Lauroylsarcosine sodium salt	H315, skin irritation	0.15%

Frequently Asked Questions

What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

What are the symptoms of COVID-19?

Many individuals with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell, nausea or vomiting or diarrhea. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days.

What is serial testing?

Serial testing is when a single person is tested for COVID-19 more than once. Because antigen tests are less sensitive than other COVID-19 tests and false results may occur, repeated testing may identify more individuals with COVID-19 infection than a single test. By repeating testing, it may be possible to more quickly identify cases of COVID-19 infection and reduce spread of infection. Additional testing with molecular COVID-19 test may be necessary, depending on your individual risk factors and test results.
It is important that you work with your healthcare provider to help you understand the next steps you should take.

What are the known and potential risks and benefits of the test?

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the potential spread of COVID-19 to your family and others in your community.

What if I have a positive test result?

If you have a positive test result, it is very likely that you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive result). If you test positive with the *CareStart*™ COVID-19 Antigen Home Test you should self-isolate and seek follow-up care with your healthcare provider as additional testing may be necessary. Your healthcare provider as additional testing may be necessary. Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical history, and your symptoms.

What if I have a negative test result?

A negative test result means that proteins from the virus that causes COVID-19 was not found in your sample. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means you could possibly still have COVID-19 even though the test is negative. The amount of antigen in a sample may decrease the longer you have symptoms of infection. In symptomatic people, specimens collected after you have had symptoms for more than five days may be more likely to be negative compared to a molecular assay.
If you test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider. For example, your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. If you are concerned about your COVID-19 infection status after testing or think you may need follow up testing, please contact your healthcare provider.

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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Website: www.accessbio.net

Technical Support
Tel: 888-898-1270 (Toll Free)
Email: TShelp@accessbio.net

QRI-RCPM-E / 2021-06-14

For use with or without symptoms

AccessBio

CareStart™ COVID-19 ANTIGEN HOME TEST

CareStart™ COVID-19 AN I HOME TEST

Kit Components

1 *CareStart*™ COVID-19 Ag Home Test - 2ea

3 Extraction Vial Tube - 2ea

2 Nasal Swab - 2ea

4 Extraction Vial Cap - 2ea

5 Quick Reference Instructions & Fact Sheet for Individuals Included

UDI Print Here

Store between 34-86° F (1-30° C) until use

Made in the USA www.accessbio.net

CareStart™ COVID-19 AN I HOME TEST

Using Mobile Application

You will need to download the mobile App and follow the test instructions for testing.

1 **Download and open App, on/go™**

Download the App on the App Store or Google Play Store or scan the QR code, Ensure you are connected to the internet during your test.

2 **Answer a few questions in the App**

3 **Watch the instruction video**

4 **Follow step-by-step instructions for your test**

5 **Test result**

The App will assist in the visual result interpretation. Please follow the instructions provided in the App. You will be required to take a picture of the test device and then look at the device and answer some questions to the result interpretation.

REF RCPM-00271

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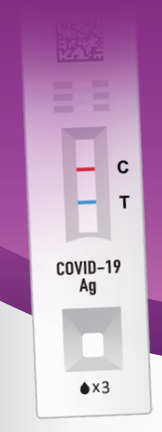
CareStart™ COVID-19 ANTIGEN HOME TEST



FAST RESULT
Results in 10 minutes

10min

EASY TESTING
A Simple Nasal Swab

For use with or without symptoms

2 Tests

CareStart™ COVID-19 AN HOME TEST

Rapid Diagnostic Test for the Detection of SARS-CoV-2 Antigen

- For use under an Emergency Use Authorization (EUA) only
- For *in vitro* diagnostic use only
- The intended use for test twice over two or three days with at least 24 hours and no more than 48 hours between tests.

Do Not Use

- On anyone under 2 years of age
- If you are prone to nosebleeds
- If you have had a facial or head injury/surgery in the last 6 months

Limit of performance

This test does not determine if you had COVID-19 in the past or if you have immunity. It detects proteins from the SARS-Cov-2 virus.

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IVD OTC

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www.accessbio.net

For use with or without symptoms

AccessBio

CareStart™ COVID-19 ANTIGEN HOME TEST

AccessBio

CareStart™ COVID-19 ANTIGEN HOME TEST

CareStart™ COVID-19 AN I HOME TEST

Kit Components

1 *CareStart*™ COVID-19 Ag Home Test - 4ea

3 Extraction Vial Tube - 4ea

2 Nasal Swab - 4ea

4 Extraction Vial Cap - 4ea

5 Quick Reference Instructions & Fact Sheet for Individuals Included

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Made in the USA www.accessbio.net

CareStart™ COVID-19 ANTIGEN HOME TEST

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3 **Watch the instruction video**

4 **Follow step-by-step instructions for your test**

5 **Test result**

The App will assist in the visual result interpretation. Please follow the instructions provided in the App. You will be required to take a picture of the test device and then look at the device and answer some questions to the result interpretation.

REF RCPM-00471

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AccessBio

CareStart™ COVID-19 ANTIGEN HOME TEST

FAST RESULT
Results in 10 minutes
10min

EASY TESTING
A Simple Nasal Swab

For use with or without symptoms

4 Tests

CareStart™ COVID-19 ANTIGEN HOME TEST

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1 °C 34 °F — 30 °C 86 °F IVD Σ 4 OTC

Made in the USA

For Use with or without symptoms

www.accessbio.net

FAST RESULT
Results in 10 minutes
10min

EASY TESTING
A Simple Nasal Swab

CareStart™
COVID-19
ANTIGEN
HOME TEST

C
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COVID-19
Ag
x3

20 Tests

AccessBio

Rapid Diagnostic Test for the Detection of SARS-CoV-2 Antigen

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- For *in vitro* diagnostic use only
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CareStart™
COVID-19
ANTIGEN
HOME TEST

UDI Print Here

REF RCPM-02071

0 850010 224337 6

www.accessbio.net

Individual tests are not to be sold separately.

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Kit Components

1 *CareStart*™ COVID-19 Ag Home Test - 20ea

2 Extraction Vial Tube - 20ea

3 Nasal Swab - 20ea

4 Extraction Vial Cap - 20ea

5 Quick Reference Instructions & Fact Sheet for Individuals Included

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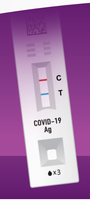
AccessBio

20 Tests



CareStart™
COVID-19
ANTIGEN
HOME TEST

For use with or without symptoms

FAST RESULT
Results in 10 minutes
10min

EASY TESTING
A Simple Nasal Swab

Using Mobile Application

You will need to download the mobile App and follow the test instructions for testing.

1. **Download and open App, on/go™**
   Download the App on the App Store or Google Play Store or scan the QR code. Ensure you are connected to the internet during your test.
2. **Answer a few questions in the App**
3. **Watch the instruction video**
4. **Follow step-by-step instructions for your test**
5. **Test result**
   The App will assist in the visual result interpretation. Please follow the instructions provided in the App. You will be required to take a picture of the test device and then look at the device and answer some questions to the result interpretation.

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