

# Consent Form for Rapid COVID-19 Antigen Test

Student Name:
Student Birthdate:
School:
Parent/Guardian Name(s):
Home Address:
Phone Number:

**Please carefully read the following informed consent notice and sign the authorization to test for COVID-19.**

1. I understand that COVID-19 testing of the above-named student will be conducted through an Access Bio Inc. CareStart Covid-19 Antigen test provided by the Washington State Department of Health and acknowledge that the CareStart Fact Sheet for Patients for the test has been made available to me.
2. I understand that the ability of the above-named student to receive testing is limited to the availability of test supplies.
3. I understand the entity performing the test is not acting as the above-named student's medical provider. Testing does not replace treatment by a medical provider. I assume complete and full responsibility to take appropriate action with regards to the test results, including seeking medical advice, care, and treatment from a medical provider or other health care entity if I have questions or concerns, if the above-named student develops symptoms of COVID-19, or if the above-named student's condition worsens.
4. I understand that, as with any medical test, there is the potential for a false positive or false negative COVID-19 test result.
5. I understand it is my responsibility to inform the above-named student's health care provider of a positive test result, and that a copy will not be sent to the above-named student's health care provider for me.
6. I understand that the antigen test result will be available in 10-15 minutes.
7. I understand and acknowledge that a positive antigen test result is an indication that the above-named student needs to self-isolate to avoid infecting others.
8. I have been informed of the test purpose, procedures, and potential risks and benefits. I will have the opportunity to ask questions before proceeding with a COVID-19 test. I understand that if I do not wish for the above-named student to continue with the COVID-19 diagnostic test, I may decline the test.
9. I understand that to ensure public health and safety and to control the spread of COVID-19, the test results may be shared without my individual authorization.
10. I understand that the test results will be disclosed to the appropriate public health authorities, the Office of Superintendent of Public Instruction, and as otherwise permitted or required by law.
11. I understand that I may withdraw my consent to the testing at any time before it is performed.

**AUTHORIZATION/CONSENT TO TEST FOR COVID-19**

- I consent to authorize the above-named student to undergo COVID-19 testing.

\_\_\_\_\_  
Parent/Guardian Signature

\_\_\_\_\_  
Date

- I consent to undergo COVID-19 testing.

\_\_\_\_\_  
Student Signature

\_\_\_\_\_  
Date

# FACT SHEET FOR PATIENTS

Access Bio, Inc.  
**CareStart™ COVID-19 Antigen**

April 12, 2021

Coronavirus  
Disease 2019  
(COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the *CareStart™* COVID-19 Antigen test.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

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**For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:**  
<https://www.cdc.gov/COVID19>

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## 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 is the *CareStart™* COVID-19 Antigen?

The *CareStart™* COVID-19 Antigen is a type of test called an antigen test. Antigen tests are designed to detect proteins from the virus that causes COVID-19 in anterior nasal swabs.

## Why was my sample tested?

Your sample was tested because i) your healthcare

provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or other risk factors and you are within the first five days of the onset of symptoms, or ii) you are undergoing serial testing even though you do not have symptoms or other risk factors for COVID-19 infection,

## 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 your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

## What does it mean if I have a positive test result?

If you have a positive test result, it is very likely that you have COVID-19. 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). 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.

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- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.
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## What does it mean if I have a negative test result?

A negative test result means that proteins from the virus that causes COVID-19 were 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 that you could possibly still have COVID-19 even though the test is negative. If your test result is negative, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. 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 5 days may be more likely to be negative compared to a molecular assay.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

## What is serial testing?

Serial testing is when a single person is tested for COVID-19 more than once using the same test. 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 testing 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 a 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 differences between antigen tests and other COVID-19 tests?

There are different kinds of diagnostic tests for COVID-19. Molecular tests (PCR) are the most common type of molecular test detect genetic material from the virus.

Antigen tests detect proteins from the virus. Antigen tests are very specific for the virus, but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection.

If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test would help with your care, and when you should discontinue home isolation. If you will not have an additional test to determine if you are contagious, the CDC currently recommends that you should stay home until three things have happened:

- You have had no fever for at least 24 hours (that is one full day of no fever without the use of medicine that reduces fevers).
- AND
- Other symptoms of COVID-19 are improving (for example, when your cough or shortness of breath has improved) \*\*Loss of taste and smell may persist for weeks or months after recovery and need not delay the end of isolation
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- AND
- At least 10 days have passed since your symptoms first appeared.

For up to date guidance on home isolation after you had or likely had COVID-19, please consult: <https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/end-home-isolation.html>

For more information, the CDC has provided guidelines on how to prevent the spread of COVID-19 if you are sick: <https://www.cdc.gov/coronavirus/2019-ncov/downloads/sick-with-2019-nCoV-fact-sheet.pdf>.

## Is this test FDA-approved or cleared?

No. This test is not yet approved or cleared by the United States FDA. FDA may issue an Emergency Use Authorization (EUA) when certain criteria are met, which includes that there are no adequate, approved, available alternatives. The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist

- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.

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to justify the emergency use of *in vitro* diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

## What are the approved alternatives?

There are no approved available alternative antigen tests. Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here:

<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at:

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

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