

# FACT SHEET FOR INDIVIDUALS

Cue Health Inc.

Cue COVID-19 Test for Home and Over The Counter (OTC) Use

March 5, 2021

Coronavirus  
Disease 2019  
(COVID-19)

You are being given this Fact Sheet because you are self-collecting and testing an individual anterior nasal swab specimen at home using the Cue COVID-19 Test for Home and Over The Counter (OTC) Use.

This Fact Sheet contains information to help you understand the risks and benefits of using this over the counter (OTC)/non-prescription use product 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 Cue COVID-19 Test for Home and Over The Counter (OTC) Use?

The product is a molecular nucleic acid amplification test (NAAT) that detects the genetic material of the SARS-

CoV-2 virus using a molecular amplification reaction that is a similar, alternative amplification method to polymerase chain reaction (PCR). When you have COVID-19 the SARS-CoV-2 virus can be present in your nostrils. This test can detect genetic material from the SARS-CoV-2 virus in your nostrils.

There are different kinds of tests for diagnosing COVID-19. This test is a molecular tests (for example PCR tests) which detects genetic material from the virus. Antigen tests detect proteins, small parts of the virus. Another type of test is the antibody test. A COVID-19 antibody test detects antibodies that have been made by your immune system in response to a previous COVID-19 infection. This molecular test and antigen tests cannot detect a previous COVID-19 infection. Antibody tests are not suitable to diagnose an active COVID-19 infection.

## Clinical Performance

In a clinical study conducted in the USA from December 2020 to February 2021, individuals self-tested or tested their children using the Cue COVID-19 Test for Home and Over The Counter (OTC) Use. The Cue COVID-19 Test for Home and Over The Counter (OTC) Use was compared to a FDA authorized molecular laboratory PCR test for COVID-19. In comparison to the laboratory test, Cue correctly identified 97% (37/38) of positive samples and 99% (231/233) of negative samples. The Cue test correctly identified 96% (27/28) of positive samples from individuals known to have symptoms and correctly identified 100% of 10 positive samples from individuals known to be without symptoms.

## Why should my sample be tested?

You may want to have your sample tested because you or 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 because you:

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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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- live in or have recently traveled to a place where transmission of COVID-19 is known to occur, and/or
- have been in close contact with an individual suspected of or confirmed to have COVID-19.
- believe there is another reason to investigate your COVID-19 infection status

Testing of your sample will help find out if you may have COVID-19.

## 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 spread of COVID-19 to your family and those you come in contact with.

## 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. If you have a positive result you should follow up with your healthcare provider who will work with you to determine how best to care for you based on the test results along with medical history, and your symptoms. You should follow the latest CDC guidance to avoid spreading the virus to others, such as self-isolation for a minimum of 10 days, to reduce the potential transmission of disease. There is a small possibility that this test can give a positive result that is wrong (a false positive result) particularly when used in a population without many cases of COVID-19 infection.

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

A negative test result means that the virus that causes COVID-19 was not found in your sample. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19, this may be more common in individuals with no symptoms. You might test negative if the sample was collected early during your infection. You could also be exposed to COVID-19 after your sample was collected and then have become infected. In particular, people infected with COVID-19 but who have no symptoms may not shed enough virus to trigger a positive test. This means that you could possibly still have COVID-19 even though the test result is negative. 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.

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**If you develop symptoms or your symptoms get worse you should seek medical care. If you have the following symptoms you should seek immediate medical care at the closest emergency room:**

- Trouble breathing
- Persistent pain or pressure in the chest
- New confusion
- Inability to wake up or stay awake
- Bluish lips or face

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If your test is negative, but you either develop symptoms or continue to have symptoms and/or they get worse, you should reach out to your healthcare provider who will work with you to determine the next steps you should take. For example, your healthcare provider may suggest you need another molecular test performed in a

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laboratory to determine if you have contracted the virus causing COVID-19. If you have no symptoms but have been tested because you thought you may have been exposed to COVID-19, you should continue to monitor your health and let your healthcare provider know if you develop any symptoms of COVID-19. You should talk with your healthcare provider if you are concerned. It is important that you work with your healthcare provider to help you understand the next steps you should take.

A negative test result should not be the sole basis used to determine if an individual can end isolation precautions.

## Is this product FDA-approved or cleared?

No. This product is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared products available, and other criteria are met, FDA can make products available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this product is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of medical devices, unless the declaration is terminated or authorization is revoked by FDA (after which the test may no longer be used).

## What are the approved alternatives?

There are no approved available alternative products. FDA has issued EUAs for other products 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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