

COVID-19 Fact Sheet

You are being given this Fact Sheet because you provided a sample(s) that was tested for Coronavirus Disease 2019 (COVID-19) using the Kailos Assure™ 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.

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>

What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. This virus, initially identified in Wuhan, China (which has now spread globally, including the United States), can cause mild to severe illness. Symptoms may include, but are not limited to, fever, coughing, shortness of breath, fatigue, body aches, headache, loss of taste or smell, sore throat, congestion, nausea or vomiting, and/or diarrhea.

What is the Kailos Assure Test?

The Kailos Assure test is designed to detect SARS-CoV-2 in respiratory specimens, for example mouthwash or nasal swabs.

Why is my sample being tested?

Your sample is being tested as part of a screening program to reduce workplace exposure to SARS-CoV-2. Participating in the program will help

determine if you have been infected by the CoV-2 virus.

What are the known and potential risks of the test?

Potential risks include a 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 the 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 have to 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 the test results, medical history, and your symptoms

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 means that you could possibly still have COVID-19 even though the test result is negative. Your healthcare provider will consider the results of your test in combination

Where can I go for updates and more information? The most up-to-date information on 2019-nCoV 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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with other aspects of your medical history, including your symptoms, possible exposure, and geographical location of recent travel in deciding how to care for you.

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

Is this test FDA-approved or cleared?

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



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