FACT SHEET FOR INDIVIDUALS

3EO Health™ Inc.
3EO Health COVID-19 Test™

September 19, 2023

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 3EO Health COVID-19 Test.

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.

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 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 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 3EO Health COVID-19 Test?
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 test 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 in April 2023, individuals > 14 years of age self-tested and parents/guardians tested their children using the 3EO Health COVID-19 Test. The 3EO Health COVID-19 Test was compared to a FDA authorized molecular laboratory PCR test for SARS-CoV-2. In comparison to the laboratory test, the 3EO Health COVID-19 Test correctly identified 95% (38/40) of positive samples and 100% (155/155) of negative samples from symptomatic individuals.

Why was my sample 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 live in or have recently traveled to a place where transmission of COVID-19 is known to occur; or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

Testing of the samples 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:

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.

- 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 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. 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. 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.
If your test is negative, but you 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 laboratory to determine if you have contracted the virus causing 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 test FDA-approved or cleared?
No. This test is not yet approved or cleared by the United States FDA, but it has been issued an Emergency Use Authorization (EUA). FDA may issue an 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 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 the emergency use of in vitro diagnostics, unless it is terminated or revoked by FDA (after which the test may no longer be used).

What are the approved alternatives?
Any tests that have received full marketing status (i.e., 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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