OHC COVID-19/FLU ANTIGEN TEST PRO

OSANG LLC

March 21, 2024

For the most up to date COVID-19 information, including symptoms, please visit Coronavirus Disease 2019 (COVID-19) | CDC

For the most up to date Influenza information, including symptoms, please visit Influenza (Flu) | CDC

Your sample(s) was tested for COVID-19 and influenza using the OHC COVID-19/Flu Antigen Test Pro.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19 and influenza. 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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WHAT IS COVID-19 (CORONAVIRUS DISEASE 2019)?

COVID-19 is a disease caused by the SARS-CoV-2 virus.

WHAT IS INFLUENZA?

Influenza (flu) is a disease caused by influenza viruses. There are two main types of influenza viruses: types A and B. Both type A and B influenza viruses regularly spread in people and are responsible for seasonal flu each year.

WHAT IS THE OHC COVID-19/FLU ANTIGEN TEST PRO?

The OHC COVID-19/Flu Antigen Test Pro is a type of test called an antigen test. This antigen test is designed to detect proteins from three types of viruses: two viruses that cause influenza (type A and type B) and the virus that causes COVID-19 in nasopharyngeal and anterior nasal swab specimens.

WHY WAS MY SPECIMEN TESTED?

Testing of your specimen(s) will help find out if you may have COVID-19 and/or influenza.

WHAT ARE THE KNOWN AND POTENTIAL RISK AND BENEFITS OF THE TEST?

Potential risks include:

- Possible discomfort or other complications that can happen during specimen 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 and/or influenza to your family and those you come in contact with.

WHAT DOES A POSITIVE TEST RESULT FOR THE SARS-COV-2 VIRUS MEAN?

If you have a positive test result for COVID-19 with the OHC COVID-19/Flu Antigen Test Pro, 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. You should follow CDC guidance to reduce the potential transmission of disease.

There is a chance 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. Your healthcare provider will work with you to determine how best to care for you based on the test results along with medical history, and your symptoms. Your healthcare provider may recommend a confirmatory test, depending on your clinical history and risk factors.

WHAT DOES A POSITIVE TEST RESULT FOR INFLUENZA A AND/OR B VIRUSES MEAN?

If you have a positive test result for the presence of influenza A and/or influenza B viruses, it is very likely that you have the flu. If you have a positive result for an influenza virus, your healthcare provider will determine the best way to care for you based on the test results along with other factors in your medical history. 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 POSITIVE TEST RESULT FOR SARS-COV-2 AND INFLUENZA (A AND/OR B) VIRUSES?

It is possible for an individual to be infected with influenza A virus, influenza B virus, and/or SARS-CoV-2 virus at the same time. Your healthcare provider will work with you to determine how best to care for you based on these test results, your medical history, and your symptoms.

WHAT DOES IT MEAN IF I HAVE AN INITIAL NEGATIVE TEST RESULT FOR SARS-COV-2?

If your initial test result was negative for SARS-CoV-2 you should have serial testing performed (see below) and if after serial testing your test result is negative this means that antigens of the virus that causes COVID-19 were not found in your sample.

WHAT DOES IT MEAN IF I HAVE A NEGATIVE SERIAL TEST RESULT FOR SARS-COV-2, INFLUENZA (A AND/OR B) VIRUSES?

If your test result was negative after serial testing (the second test) for SARS-CoV-2, influenza A and influenza B viruses then antigens to those viruses were not found in your sample. Due to the sensitivity of antigen tests compared to molecular COVID-19 or influenza tests, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19 or influenza. For example, if you are tested too early during your infection. This means that you could possibly still have COVID-19 or influenza even though the test result is negative. If your test 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. For COVID-19 testing, specimens collected after you have had symptoms for more than four (4) 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.

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WHAT IS SERIAL TESTING?

Serial testing is when a single person is tested for COVID-19 more than once using the same test. Because the amount of antigen in your sample may change over time and COVID-19 antigen tests have lower sensitivity than COVID-19 molecular tests, false results may occur. Therefore, repeated testing can identify more individuals with COVID-19 than testing a single time. By repeating testing, it may be possible to more quickly identify cases of COVID-19 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. Because it is possible to have infection with the COVID-19 and influenza, individuals who test positive for influenza but negative for COVID-19 on the initial test should still be tested again 48 hours after the first test.

WHAT ARE THE DIFFERENCES BETWEEN ANTIGEN TESTS AND OTHER COVID-19 TESTS?

There are different kinds of tests for diagnosing COVID-19. Molecular tests (also known as PCR tests) 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 do not have an additional test to determine if you are infected and may spread the infection to others, 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 have improved (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; **AND**
- At least 5 days have passed since your symptoms first appeared.

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/if-you-are-sick/index.html

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WHAT IS AN EUA?

This test has been issued an Emergency Use Authorization (EUA) by the U.S. FDA. 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 the declaration is terminated or authorization is revoked sooner.). An EUA is NOT an FDA-approval or clearance.

WHAT ARE THE APPROVED AVAILABLE ALTERNATIVES?

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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