FACT SHEET FOR PATIENTS

Cepheid
Xpert Xpress SARS-CoV-2/Flu/RSV

Updated: October 1, 2020

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 Xpert Xpress SARS-CoV-2/Flu/RSV 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 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 Xpert Xpress SARS-CoV-2/Flu/RSV test?
The test is designed to detect the virus that causes COVID-19 in respiratory specimens, for example nasopharyngeal swabs, nasal swabs, or nasal wash/aspirate specimens.

Why was my sample tested?
You were tested because 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, and/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:

- 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.

- **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.

- 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 for SARS-CoV-2?
If you have a positive test result, it is very likely that you have COVID-19. Therefore, it is also likely that specific isolation or social distancing action will be recommended so that you can avoid spreading the virus to others. You should follow CDC guidance to reduce the potential transmission of disease. 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 along with medical history, and your symptoms.

What does it mean if I have a positive test result for influenza A, influenza B, and/or RSV?
If you have a positive test result for the presence of influenza A, influenza B, and/or RSV viruses, it is very likely that you are infected with a virus. If you have a positive result for an influenza A, influenza B, and/or RSV, 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 and influenza A, influenza B, and/or RSV viruses?
It is possible for an individual to be infected with one or more viruses 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 a negative test result for SARS-CoV-2, influenza A, influenza B, and/or RSV viruses?
A negative test result for any of the viruses detected by this test means that these viruses were not found in your sample. For COVID-19, influenza A, influenza B, or RSV, a negative test result for a sample collected while a person has symptoms usually means that SARS-CoV-2, influenza A, influenza B, or RSV viruses are unlikely to be the cause of your current illness.

However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19, influenza or RSV. This means that you could possibly still have COVID-19, influenza or RSV even though the test is negative. Your healthcare provider will consider the test result together with your symptoms, possible exposures and other health information in deciding how to care for you. It is possible that your healthcare provider may collect another sample in order to repeat the test or conduct other tests.

It is important that you talk with your healthcare provider to help you understand what your results mean and 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 Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection

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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 tests. 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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