FACT SHEET FOR PATIENTS

Quest Diagnostics
Quest SARS-CoV-2 rRT-PCR

Updated: March 10, 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 Quest Diagnostics SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR (Quest SARS-CoV-2 rRT-PCR) 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 a contagious respiratory illness caused by the SARS-CoV-2 virus. COVID-19 can cause a mild to severe illness and has now spread worldwide, including in the United States. Older adults and people of any age who have underlying medical conditions might have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 can result in hospitalization or death. The virus that causes COVID-19 can be spread to others before and after 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 Quest SARS-CoV-2 rRT-PCR?
The test is designed to detect the virus that causes COVID-19 in upper and lower respiratory specimens such as nasopharyngeal, oropharyngeal or anterior nasal swabs, sputum, tracheal aspirates, and bronchoalveolar lavage 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; or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19; or
- .You and your healthcare provider believe there is another reason to investigate your COVID-19 status.

Testing of the samples will help find out if you may have COVID-19.

Laboratories may use pooling when testing your specimen, which means they combine your sample with other individuals samples prior to testing and test them as a "pool". The laboratory may return a result for the entire pool together or may return individual results.

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.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

- **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.

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 be placed in isolation to avoid spreading the virus to others. You should follow CDC guidance to reduce the potential transmission of disease.

If you were tested as part of a pool that returned a positive or invalid test result, you may have COVID-19 and should consider yourself to have a positive test result unless or until you receive a negative test result when re-tested individually. However, as most individuals in a positive pool will likely receive a negative result when re-tested individually, you should isolate until receiving a negative result when re-tested individually and should not be grouped with other individuals who have received a positive or presumptive positive result.

There is a smaller 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. 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 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.

In particular, people infected with the virus that causes COVID-19 but who have no symptoms may not shed enough virus to trigger a positive test. Additionally, unobserved specimens collected using a collection kit from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.

This means that you could possibly still have COVID-19 even though the test 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.

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

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

If you have no symptoms but have been tested because your doctor 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. If you develop symptoms you may need another test to determine if you have contracted the virus causing COVID-19.

If your test result indicates your specimen was pooled and you have a negative test result there a small chance

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that your result is incorrect. You should talk with your healthcare provider if you are concerned.

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 Emergency Use Authorization (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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