

FACT SHEET FOR PARTICIPANTS

George Mason University Laboratory Developed Test
Saliva SARS-CoV-2 Real-Time RT-PCR

Updated: February 23, 2021

Coronavirus
Disease 2019
(COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for Coronavirus Disease 2019 (COVID-19) using the George Mason University Laboratory Developed 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 George Mason University Laboratory Developed Test for SARS-CoV-2?

The test is designed to detect the virus that causes COVID-19 in saliva samples .

Why was my sample tested?

You were tested as part of the university COVID surveillance program, and/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),
- 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 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.

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- **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.
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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.

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 infection. 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. This means that you could possibly still have COVID-19 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.

Laboratories may use pooling when testing your specimen, which means they combine your sample with other individuals samples prior to testing. If your test result indicates your specimen was pooled and you have a negative test result there a small chance that your result is incorrect. 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.

Is this test FDA-approved or cleared?

No. This test is not yet approved or cleared by the United States FDA. This Laboratory Developed Test detects the N1 gene of SARS-CoV-2 in saliva specimens by extraction-free nucleic acid amplification probe detection, performed on a ThermoFisher QuantStudio 7 Pro RT-PCR instrument. The control gene in this assay is the human RNase P gene

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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