

FACT SHEET FOR PATIENTS		CORONA VIRUS
Wren Laboratories LLC	Wren Laboratories COVID-19 Test	COVID-19 qPCR Test

UPDATED: June 23, 2020

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using Wren Laboratories COVID-19 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 speak to your healthcare provider.

What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. The virus, can cause mild to severe respiratory illness, and is likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc).

What is the Wren Laboratories COVID-19 Test?

This is a PCR test designed to detect the virus that causes COVID-19 in nasopharyngeal, oropharyngeal (throat) swab, anterior nasal swab, and mid-turbinate nasal swab samples.

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:

- 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,
- you have been in close contact with an individual suspected of or confirmed to have COVID-19.
- You work in an environment where it is important to know if you have COVID-19 or have been exposed to the SARS-CoV-2 virus.

Testing of your 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 additional information).

Potential benefits include:

- The test results (along with other medical information), may help your healthcare provider make informed recommendations about your care.
- The test results may help limit the spread of COVID-19 to your family and others in your community.

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
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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.

There is a very small chance that this test can give a positive result that is incorrect (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 negative test result?

A negative test result means that the virus that causes COVID-19 was not found in your sample. For COVID-19, a negative test result for a sample collected while a person has symptoms usually means that COVID-19 did not cause your recent illness. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. If this is the case, 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.

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

Is the Wren Laboratories COVID-19 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 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).

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