TRIDENT LABORATORIES

Fact Sheet for Patients

Interpreting SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR Test Results

You are being given this Fact Sheet because your sample(s) were tested for the Coronavirus Disease 2019 (COVID-19) using qualitative real-time RT-PCR test available through Trident Laboratories.

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/nCoV

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus. COVID-19 can cause mild to severe respiratory illness in humans and was first identified in Wuhan, China. Limited information is available to characterize the spectrum of clinical illness associated with COVID-19 but it likely spreads to others when a person shows signs or symptoms of being sick (eg, fever, coughing, sneezing, difficulty breathing, etc).

What is the Trident test?
The test is designed to detect the virus that causes COVID-19 in respiratory specimens, for example, nasopharyngeal or oral swabs.

Why were my sample(s) tested?
Your sample(s) 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 (eg, 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
- Because you have been in close contact with an individual suspected of or confirmed to have COVID- 19.

The sample(s) collected from you were tested to help find out whether 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.
- Risk that the test result is incorrect (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.

What does it mean if I have a detected test result?
If you have a detected test result, it is interpreted as a presumptive positive test result, and 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 wrong (a false positive result).

However, your healthcare provider will work with you to determine how best to care for you based on the test results along with other factors of your medical history, such as symptoms, possible exposures, and geographic location of places you have recently traveled.

What does it mean if I have a not detected (negative) test result?

A not detected (negative) test result means that the virus that causes COVID-19 was not found in your sample. For COVID19, a negative test result for a sample collected while a person has symptoms usually means that COVID-19 did not cause your recent illness.

It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19, meaning you could possibly still have COVID-19 even though the test is negative. Therefore, while a negative test most likely means you do not have COVID-19, 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.

What does it mean if I have an inconclusive test result?

An inconclusive test result means that the test results were unable to determine if the sample was positive or negative. In this case an additional test should be performed with your health care provider as soon as possible.

Is this test FDA-approved or cleared?

No. This test is not yet approved or cleared or authorized by the United States Food and Drug Administration (FDA). This is laboratory developed test that has been submitted to the FDA for review. 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.

1. FDA's independent review of this test is pending.
2. **Report Adverse events**, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling 1800-FDA-1088