

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using a SummerBio High-Throughput qualitative Triplex SARS-CoV-2 test by RT-PCR method as a Laboratory Developed Test (LDT) performed in a certified high-complexity CLIA laboratory.

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.

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**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 is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and has now spread globally, including the United States. There is limited information 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 (e.g., fever, coughing, difficulty breathing, etc.).

### What is the Laboratory Developed Test?

The SummerBio High-Throughput Triplex SARS-CoV-2

is designed, for use in a single laboratory, to detect the virus that causes COVID-19 in respiratory specimens, for example nasal or oral swabs.

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

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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?

A positive COVID-19 test means that genetic material from the virus was detected and that you currently have, or recently had, the virus. While positive results are indicative of active infection with SARS-CoV-2; your healthcare provider should review other clinical information, your medical history and other diagnostic information to determine your infection status. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. Positive results do not rule out bacterial infection or co-infection with other viruses.

## What does it mean if I have a negative test result?

A negative COVID-19 test means that genetic material from the virus was not detected, or not detected at a high level, and that you currently do not have the virus or detectable amounts of virus. However, negative results should be reviewed by your healthcare provider in combination with other clinical information, your medical history and other epidemiological information.

## What does it mean if I have an invalid test result?

An invalid COVID-19 test means only that there was an issue in either the sample collection or the test processing. It does not indicate whether you may be positive or negative. If your test was invalid, you should get tested again.

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

An inconclusive COVID-19 test means that nothing can be concluded from the test (an inconclusive test occurs most frequently when low amounts of genetic material are gathered in the sample). If your test was inconclusive, you should get tested again.

## 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 Services (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.

Any COVID-19 test without an Emergency Use Authorization (EUA) from the FDA shall be treated as a high complexity test under the CLIA regulatory scheme. In order to use a test for COVID-19 that does not have a FDA EUA, the laboratory must be a CLIA certified laboratory that meets regulatory requirements to perform high complexity testing under §§493.1441 through 493.1495 of the CLIA regulations.

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