

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the cobas® SARS-CoV-2 test.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. Some risks may happen during sample collection.

- Possible incorrect test result (see below for more information).

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Potential benefits include:

**For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:**

- The results of this test may help limit the spread of COVID-19 to your family and those you come in contact with.

#### **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

# FACT SHEET FOR PATIENTS

Roche Molecular Systems, Inc.  
cobas® SARS-CoV-2

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Coronavirus  
Disease 2019  
(COVID-19)

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. 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.

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) (g)6.1 (en6

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. FDA may issue an Emergency Use

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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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