FACT SHEET FOR PATIENTS

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

Updated: June 14, 2022

Coronavirus Disease 2019 (COVID-19)

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 Duo 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 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 cobas® SARS-CoV-2 Duo test?
The test is designed to detect the virus that causes COVID-19 in the following respiratory specimens: nasopharyngeal or nasal swabs (anterior nares and mid-turbinate).

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; or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19; or.
- You and your healthcare provider believe there is another reason to investigate your COVID-19 status.

Testing of your nasopharyngeal or nasal sample 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 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. In addition, the assay will also provide information about the amount of viral nucleic acid level in your specimen that can further aid the diagnosis and care of 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

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possibility that this test can give a positive result that is wrong (a false positive or over-quantified result) particularly when used in a population without many cases of COVID-19. 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. If your sample is positive, your Healthcare provider may give you the positive result of your sample accompanied by a numerical value that indicates the concentration of SARS-CoV-2 RNA in your sample. You should not interpret the number to mean that having a low measurement of the virus will indicate that you are not infectious to people around you. You should also not interpret the number to mean that the measurement indicates the severity or duration of your SARS-CoV-2 infection. These topics are being studied, but the information is still unknown. Regardless of your test result, you should continue to follow CDC guidelines to reduce the risk of infection, including social distancing and wearing masks.

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 or under-quantified) in some people with COVID-19. You might test negative or under-quantified if the sample was collected early or in the late phase 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 or under-quantified, 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.

Is this test FDA-approved or cleared?
No. This test is not yet approved or cleared by the United States FDA,but it has been issued an Emergency Use Authorization (EUA). FDA may issue an 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) 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 the emergency use of in vitro diagnostics, unless it is terminated or revoked by FDA (after which the test may no longer be used).

If you develop symptoms or your symptoms get worse you should seek medical care. If you have the following symptoms you should seek immediate medical care at the closest emergency room:

- Trouble breathing
- Persistent pain or pressure in the chest
- New confusion
- Inability to wake up or stay awake
- Bluish lips or face

What are the approved alternatives?
Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. 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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