FACT SHEET FOR PATIENTS
Roche Molecular Systems, Inc.
cobas SARS-CoV-2 & Influenza A/B

September 3, 2020

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

For the most up to date information on Influenza, please visit the CDC Influenza webpage: https://www.cdc.gov/flu

Why was my sample tested?
Your sample was tested because your healthcare provider believes you might have been exposed to the virus that causes COVID-19 based on your signs and symptoms and/or because:

- You have been in close contact with a person who might have, or who is known to have, COVID-19, and/or
- You live in or have recently traveled to a place where transmission of the virus that cause COVID-19 is known to occur.

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 are the known and potential risks and benefits of the test?
Potential risks include:

- Possible discomfort or other complications 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 decisions about your care.
- The results of this test may help limit the spread of the viruses that cause COVID-19, influenza A, and/or influenza B to your family and others in your community.

What does it mean if I have a positive test result for SARS-CoV-2?
If you have a positive test result for the presence of SARS-CoV-2, it is very likely that you have COVID-19. Therefore, it is also likely that specific isolation or social distancing actions will be recommended so that you can 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). Your healthcare provider will work with you to determine how best to care for you based on the test results, medical history, and your symptoms.

What does it mean if I have a positive test result for influenza A and/or B viruses?
If you have a positive test result for the presence of influenza A and/or influenza B viruses, it is very likely that you have the flu. If you have a positive result for an influenza virus, your healthcare provider will determine the best way to care for you based on the test results along with other factors in your medical history. There is a very small chance that this test can give a positive result that is wrong (a false positive result). Your healthcare provider will work with you to determine how best to care for you based on the test results, medical history, and your symptoms.

What does it mean if I have a positive test result for SARS-CoV and influenza (A and/or B) viruses?
It is possible for an individual to be infected with influenza A virus, influenza B virus, and/or SARS-CoV-2 virus at the same time. Your healthcare provider will work with you to determine how best to care for you based on these test results, your medical history, and your symptoms.

What does it mean if I have a negative test result for SARS-CoV-2, influenza A, or influenza B viruses?
A negative test result for any of the viruses detected by this test means that these viruses were not found in your sample. For COVID-19 and influenza, a negative test result for a sample collected while a person has symptoms usually means that SARS-CoV-2, influenza A or influenza B viruses are unlikely to be the cause your current illness.

However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19 or influenza. This means that you could possibly still have COVID-19 or influenza even though the test is negative. Your healthcare provider will consider the test result together with your symptoms, possible exposures and other health information in deciding how to care for you. It is possible that your healthcare provider may collect another sample in order to repeat the test or conduct other tests.

It is important that you talk with your healthcare provider to help you understand what your results mean and the next steps you should take.

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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 Service’s (HHS’s) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

What are the approved alternatives?
There are approved/cleared influenza tests, but there is not yet an approved available alternative test for influenza combined with COVID-19 in one test. 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#2019-ncov.

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