You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the Advanta Dx SARS-CoV-2 RT-PCR Assay.

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

- 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.
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 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.

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 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) 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).

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](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](https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization)

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