FACT SHEET FOR PATIENTS

Laboratory Corporation of America (Labcorp)
Labcorp VirSeq SARS-CoV-2 NGS Test

June 10, 2022

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) was tested using the Labcorp VirSeq SARS-CoV-2 NGS Test.

This Fact Sheet contains information to help you understand the risks and benefits of using this next generation sequencing (NGS) test for identifying which lineage of SARS-CoV-2 is present in your SARS-CoV-2 positive specimen. 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 Labcorp VirSeq SARS-CoV-2 NGS Test?
The test is designed to identify the SARS-CoV-2 lineage in your SARS-CoV-2 positive specimen. NGS tests "read" the entire sequence of the viral genome and match it to a global database to identify which lineage is present. For more information on SARS-CoV-2 lineages, go to https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-classifications.html.

Why was my sample tested?
Healthcare providers may use the SARS-CoV-2 lineage identified by the Labcorp VirSeq SARS-CoV-2 NGS Test together with other laboratory and clinical findings in determining appropriate clinical management for you. ***Treatment for COVID-19 is time-sensitive and should not be delayed while waiting for results of a lineage-calling test.***

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

- 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.

What does it mean if I have a SARS-CoV-2 lineage call?
The clinical applicability of SARS-CoV-2 lineage identification is under investigation as the virus continues to evolve. Your healthcare providers may use the SARS-CoV-2 lineage identified together with other laboratory and clinical findings to determine how best to care for you based on the test results along with medical history, your symptoms, current epidemiologic information, and other up-to-date scientific information.

What does it mean if I do not receive a SARS-CoV-2 lineage call?
If you do not receive a SARS-CoV-2 lineage call, it means that the genomic sequencing of your SARS-CoV-2 positive specimen was unsuccessful and therefore no SARS-CoV-2 information could be reported. This may happen if the concentration of virus in the sample was

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.

too low or for other reasons. Your healthcare provider may want to collect an additional sample from 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, 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 the declaration is terminated or the EUA is 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 (i.e., 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.

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.