FACT SHEET FOR PATIENTS

Twist Bioscience Corporation
SARS-CoV-2 NGS Assay

Updated: July 28, 2022

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) was tested using the Twist Bioscience SARS-CoV-2 NGS Assay.

This Fact Sheet contains information to help you understand the risks and benefits of using this next generation sequencing (NGS) test for detecting SARS-CoV-2 viral genetic material and identifying which mutations and lineage of SARS-CoV-2 are present in your sample. 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 SARS-CoV-2 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. SARS-CoV-2 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 SARS-CoV-2 NGS Assay?
The test is designed to detect SARS-CoV-2 genetic material and identify the mutations and lineage of the virus in your sample (nasopharyngeal, oropharyngeal, nasal, and bronchoalveolar specimens).

NGS tests "read" the entire sequence of the viral genome, identify mutations that differ from the original virus that was sequenced in early 2020, and match them to a global database to identify which lineage is present. For more information on SARS-CoV-2 lineages and mutations, go to https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-classifications.html.

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 the samples will help find out if you may have COVID-19.

Healthcare providers may use the information provided by the SARS-CoV-2 NGS Assay 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 mutation- or lineage-calling test.

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.

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.

- Possible incorrect or invalid 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 for SARS-CoV-2?
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. 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 you are at high risk for severe disease based on your age or medical conditions, treatment may be recommended.

What does it mean if I have a SARS-CoV-2 lineage call and mutations reported?
This test reports the viral mutations detected most reliably, and the lineage which is the best match for the virus in your sample. It is possible for a sample to contain additional mutations that are not reported if they are present only rarely, or if the sequencing quality is poor for that particular spot. It is possible for a lineage to be identified even if some of its characteristic mutations are not detected. Very occasionally new lineages of SARS-CoV-2 will arise which will be added to the reference database, which is updated regularly; however if the lineage is very rare or new it may not be in the database yet.

The clinical applicability of SARS-CoV-2 mutation and lineage identification is under investigation as the virus continues to evolve. The presence of individual mutations does not always directly predict how a virus will "behave" in practice. Your healthcare providers may use this information 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, treatment options, and other up-to-date scientific information.

What does it mean if I have an invalid test result, or if SARS-CoV-2 is detected but I do not receive a lineage call or mutations report?
If your test result is "invalid," it means the test could not return a reliable result due to a problem with the sample or the performance of the test. If you do not receive a SARS-CoV-2 lineage call or mutations report, it means that the genomic sequencing and/or matching of your sample was unsuccessful and therefore this detailed information could not be reported. This may happen if the concentration of virus in the sample was 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.

What does it mean if I have a negative test result for SARS-CoV-2?
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

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provider will consider the test result together with all other aspects of your medical history 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, 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.

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