

FACT SHEET FOR HEALTHCARE PROVIDERS

Laboratory Corporation of America (Labcorp)
Clear Dx SARS-CoV-2 WGS v3.0 Test

August 01, 2023

Coronavirus
Disease 2019
(COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Clear Dx SARS-CoV-2 WGS v3.0 Test.

The Clear Dx SARS-CoV-2 WGS v3.0 Test is authorized for the identification and differentiation of SARS-CoV-2 Phylogenetic Assignment of Named Global Outbreak (PANGO) lineages, when clinically indicated, from individuals with a positive SARS-CoV-2-diagnostic test result.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Laboratory Corporation of America (Labcorp) - Clear Dx SARS-CoV-2 WGS v3.0 Test.

What are the symptoms of COVID-19?

Many patients with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, new loss of taste or smell, nausea or vomiting or diarrhea. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in “*Where can I go for updates and more information?*” section.

Public health officials have identified cases of COVID-19 throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in “*Where can I go for updates and more information?*” section at the end of this document) or your local jurisdiction’s website for the most up to date information.

What do I need to know about COVID-19 testing?

Current information on COVID-19 for healthcare providers is available at CDC’s webpage, *Information for*

This test is to be performed only using SARS-CoV-2-positive samples.

Healthcare Professionals (see links provided in “*Where can I go for updates and more information?*” section).

- The Clear Dx SARS-CoV-2 WGS v3.0 Test is a next generation sequencing (NGS) test on the MinION sequencer from Oxford Nanopore Technologies (ONT) intended for the identification and differentiation of SARS-CoV-2 Phylogenetic Assignment of Named Global Outbreak (PANGO) lineages, when clinically indicated, from individuals with a positive SARS-CoV-2-diagnostic test result.
- The Clear Dx SARS-CoV-2 WGS v3.0 Test is intended to be used in conjunction with patient history and other diagnostic information, when clinically indicated, i.e., in situations where results may aid in determining appropriate clinical management.
- The Clear Dx SARS-CoV-2 WGS v3.0 Test is not intended for use as an aid in the primary diagnosis of infection with SARS-CoV-2 or to confirm the presence of SARS-CoV-2 infection, and it is not intended for identification of specific SARS-CoV-2 genomic mutations.
- The Clear Dx SARS-CoV-2 WGS v3.0 Test is authorized for use in laboratories designated by Labcorp that are certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests

Specimens should be collected with appropriate infection control precautions. Current guidance is available at the CDC’s website (see links provided in “*Where can I go for updates and more information?*” section).

When collecting and handling specimens from individuals suspected of being infected with the virus that causes COVID-19, appropriate personal protective equipment should be used as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)*. For additional information,

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling **1-800-FDA-1088**

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refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)* (see links provided in “Where can I go for updates and more information?” section).

What does it mean if the test result is a SARS-CoV-2 lineage call?

The clinical applicability of a SARS-CoV-2 lineage identification is under investigation as the virus continues to evolve. Viral lineage represents a group of closely related viruses with a common ancestor, while individual mutations may occur within that definition. Healthcare providers may use the SARS-CoV-2 lineage identified by the Clear Dx SARS-CoV-2 WGS v3.0 Test together with other laboratory and clinical findings as well as evolving scientific information in determining appropriate clinical management for their patient. For further information on SARS-CoV-2 viral lineage refer to the CDC *SARS-CoV-2 Variant Classifications and Definitions*, and for guidance on clinical management of COVID-19 please refer to the NIH *Coronavirus Disease 2019 (COVID-19) Treatment Guidelines* (see links provided in “Where can I go for updates and more information?” section).

Laboratory test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making final patient management decisions. Patient management should be made by a healthcare provider and follow current CDC and/or NIH guidelines.

The Clear Dx SARS-CoV-2 WGS v3.0 Test has been designed to minimize the likelihood of incorrectly identifying a SARS-CoV-2 lineage. In the event of an incorrect SARS-CoV-2 lineage identification, risks to patients could potentially include the following: unnecessary or otherwise inappropriate treatment, including any associated adverse effects, or conversely, missed opportunity to initiate time-sensitive treatment. Specific risks may be identified with future evolution of the virus and available therapies.

All laboratories using this test must follow the standard testing and reporting guidelines, as appropriate, according to their appropriate public health authorities.

What does it mean if the test result is “no lineage was able to be determined”?

When the report states that “no lineage was able to be determined” it means that the genomic sequencing of the SARS-CoV-2 positive specimen was unsuccessful and therefore no SARS-CoV-2 information could be reported for that patient. There can be a number of reasons why genomic sequencing was unsuccessful from a SARS-CoV-2 positive specimen, including if the concentration of the virus was too low or the quality of the specimen was degraded. If clinically indicated, the healthcare provider may want to consider collecting additional specimens from the patient.

Risks to a patient of no result from the Clear Dx SARS-CoV-2 WGS v3.0 Test include: delayed treatment, resulting in missed opportunity to initiate time-sensitive treatment, or other unintended adverse events. ***The clinical management of COVID-19 should be initiated once a diagnosis has been made based on available information, established guidance, and the clinician’s judgment; initiation of treatment should not be delayed solely to obtain results of a lineage-calling test.***

The performance of this test was established based on the evaluation of a limited number of clinical specimens. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

What is an EUA?

The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA 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 (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

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An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless the declaration is terminated or the EUA is revoked (after which the test may no longer be used).

What are the approved available 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>.

Where can I go for updates and more information?

CDC webpages:

General: <https://www.cdc.gov/coronavirus/2019-ncov/index.html>

Symptoms:

<https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>

Healthcare Professionals:

<https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html>

Information for Laboratories:

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html>

Laboratory Biosafety: <https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html>

Isolation Precautions in Healthcare Settings:

<https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html>

Specimen Collection: <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

Infection Control: <https://www.cdc.gov/coronavirus/2019-ncov/php/infection-control.html>

SARS-CoV-2 Variant Classifications and Definitions:

<https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-classifications.html>

FDA webpages:

General: www.fda.gov/novelcoronavirus

EUAs: (includes links to fact sheet for individuals and manufacturer's instructions) <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>

NIH webpages:

General: <https://www.covid19treatmentguidelines.nih.gov/>

Therapies: (includes information on antivirals and monoclonal antibody products)

<https://www.covid19treatmentguidelines.nih.gov/therapies/>

Laboratory Corporation of America:

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531 S Spring St
Burlington, NC 27215

Website: <http://www.labcorp.com>

Email: covid19requests@labcorp.com

Customer Service: 1 (800) 222-7566

COVID-19 Main Page: <https://www.labcorp.com/coronavirus-disease-covid-19/covid-19-news-education>

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