COVID-19

FACT SHEET FOR HEALTHCARE PROVIDERS

LUMIRADX SARS-COV-2 AG TEST

LumiraDx UK Ltd.

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All individuals whose specimens are tested with this product will receive the Fact Sheet for Patients for the product.

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the LumiraDx SARS-CoV-2 Ag Test.

WHERE CAN I GO FOR GENERAL INFORMATION ON COVID-19?

For general information on COVID-19, including the symptoms of COVID-19, infection control precautions, and other information please check the CDC COVID-19 webpage (see links 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 WITH THIS PRODUCT?

- The LumiraDx SARS-CoV-2 Ag Test can be used to test direct anterior nasal swab and nasopharyngeal swab specimens.
- The LumiraDx SARS-CoV-2 Ag Test should be ordered for the detection of SARS-CoV-2 antigens by a healthcare provider.
- The LumiraDx SARS-CoV-2 Ag Test is authorized for individuals who are suspected of COVID-19 within the first twelve (12) days of symptom onset when tested at least twice over three days with at least 48 hours between tests and from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests.
- The LumiraDx SARS-CoV-2 Ag Test is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests.
- The LumiraDx SARS-CoV-2 Ag Test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- Please refer to the LumiraDx SARS-CoV-2 Ag Test Instructions for Use for additional information.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the lower sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.

Specimens should be collected with appropriate infection control precautions. 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, refer to CDC *Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing.*

WHAT DOES IT MEAN IF THE SPECIMEN TESTS POSITIVE FOR THE VIRUS THAT CAUSES COVID-19?

A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 were detected, and therefore the individual being tested is infected with the virus and presumed to be contagious. 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 determining individual diagnosis and patient management decisions and should follow current CDC guidelines.

The LumiraDx SARS-CoV-2 Ag Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks could include the following: a needless recommendation for the patient to isolate that might limit contact with family or friends and the ability to work, delayed diagnosis and treatment for the true infection causing the patient's symptoms, potentially increased likelihood that the patient could contract COVID-19 from other potentially COVID-19 positive patients isolated in the same areas, unnecessary prescription of a treatment or therapy, needless monitoring of close contacts for symptoms, or other unintended adverse effects.

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

WHAT DOES IT MEAN IF THE SPECIMEN TESTS NEGATIVE FOR THE VIRUS THAT CAUSES COVID-19?

A negative serial test result for this test means that SARS-CoV-2 antigens was not present in the specimen above the limit of detection. All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions (such as discontinuation of isolation precautions). Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids.

The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day twelve (12) of illness may be more likely to be negative compared to a RT-PCR assay. Therefore, negative results from patients with symptom onset beyond twelve (12) days should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.

It is possible to test a person too early or too late during SARS-CoV-2 infection to make an accurate diagnosis via the LumiraDx SARS-CoV-2 Ag Test.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of an individual's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the individual's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are

negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing or testing with molecular methods should be considered by healthcare providers in consultation with public health authorities. Additional testing may be helpful to ensure testing was not conducted too early.

Risks to a patient of a false negative test result include delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of COVID-19 spread within the community, or other unintended adverse events.

For additional recommendations regarding infection control, refer to CDC's *Ending Isolation and Precautions for People with COVID-19: Interim Guidance* (see links provided in "*Where can I go for updates and more information*?" section).

The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between June 2020 and March 2021. 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 DO I NEED TO KNOW ABOUT SERIAL TESTING?

Serial testing of individuals whose initial test result is negative assists in identifying infected individuals earlier and facilitate timely infection control practices. A negative test result does not rule out infection but repeat testing over three days for symptomatic individuals or five days for asymptomatic individuals with at least 48 hours between tests may decrease the risks of false negative results.

An initial negative test result should be the first of a minimum of two tests. An asymptomatic individual undergoing serial testing who obtained two or more negative test results may require ongoing serial testing or confirmatory testing, depending on patient history and potential exposures. An asymptomatic individual undergoing serial testing who obtained one or more positive results indicates that SARS-CoV-2 antigen is present in the patient's sample but does not rule out coinfection with other pathogens.

For additional recommendations regarding confirmation of antigen test results, please refer to the CDC's Interim Guidance for Antigen Testing for SARS-CoV-2 (see links provided in "*Where can I go for updates and more information*" section).

WHAT IS AN EUA?

The U.S. 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.

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 authorization is revoked sooner.

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 DO I REPORT ADVERSE EVENTS?

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**

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/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

Discontinuation of Isolation: https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html

FDA WEBPAGES:

General: www.fda.gov/novelcoronavirus

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

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