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

The LumiraDx SARS-CoV-2 RNA STAR Complete is authorized for use with upper respiratory specimens collected from individuals consistent with the Emergency Use Authorization (EUA).

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: LumiraDx UK Ltd. - LumiraDx SARS-CoV-2 RNA STAR Complete.

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

This test is to be performed only using upper respiratory specimens collected from individuals consistent with the Emergency Use Authorization (EUA).

- The LumiraDx SARS-CoV-2 RNA STAR Complete can be used to test anterior nasal, mid-turbinate nasal, nasopharyngeal and oropharyngeal swab specimens, collected dry or in transport media from individuals suspected of COVID-19 by their healthcare provider (HCP).
- The LumiraDx SARS-CoV-2 RNA STAR Complete can be used to test anterior nasal swab specimens collected dry or in transport media from any individual, including individuals without symptoms or other reasons to suspect COVID-19 when collected by a HCP or self-collected under the supervision of a HCP.
- The LumiraDx SARS-CoV-2 RNA STAR Complete can be used to test anterior nasal swab specimens that are collected using a collection kit that conforms to HealthPulse@homewhen used consistent with its authorization.
- The LumiraDx SARS-CoV-2 RNA STAR Complete can be used to test pooled samples containing up to five individual anterior nasal swab specimens, using specified workflows, collected in individual vials either dry or containing transport medium from any individual, including individuals without symptoms or other reasons to suspect COVID-19.
- The LumiraDx SARS-CoV-2 RNA STAR Complete 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 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, 
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 specimen tests positive for 
The virus that causes COVID-19?
A positive test result for COVID-19 indicates that RNA 
from SARS-CoV-2 was detected, and therefore the 
patient 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 making a final 
diagnosis and patient management decisions. Patient 
management should be made by a healthcare provider 
and follow current CDC guidelines.

The LumiraDx SARS-CoV-2 RNA STAR Complete has 
designed to minimize the likelihood of false positive 
test results. However, it is still possible that this test can 
give a false positive result, even when used in locations 
where the prevalence is below 5%. In the event of a 
false positive result, risks to patients could include the 
following: a recommendation for isolation of the patient, 
monitoring of household or other close contacts for 
symptoms, patient isolation that might limit contact with 
family or friends and may increase contact with other 
potentially COVID-19 patients, limits in the ability to 
work, delayed diagnosis and treatment for the true 
infection causing the symptoms, unnecessary 
prevention of a treatment or therapy, or other 
unintended adverse effects.

What does it mean if the specimen tests negative for 
the virus that causes COVID-19?
A negative test result for this test means that SARS-
CoV-2 RNA was not present in the specimen above the 
limit of detection. 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. It 
is possible to test a person too early or too late during 
SARS-CoV-2 infection to make an accurate diagnosis 
via LumiraDx SARS-CoV-2 RNA STAR Complete.

In addition, asymptomatic people infected with the virus 
that causes COVID-19 may not shed enough virus to 
reach the limit of detection of the test, giving a false 
negative result. In the absence of symptoms, it is difficult 
to determine if asymptomatic people have been tested 
too late or too early. Therefore, negative results in 
asymptomatic individuals may include individuals who 
were tested too early and may become positive later, 
individuals who were tested too late and may have 
serological evidence of infection, or individuals who were 
ever infected.

Specimens with low viral loads may not be detected in 
sample pools due to the decreased sensitivity of pooled 
testing. Your interpretation of negative results should 
take into account clinical and epidemiological risk factors.

When diagnostic testing is negative, the possibility of a 
false negative result should be considered in the context 
of a patient’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 patient’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 using a 
new sample with a sensitive method or without pooling 
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.

---

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
FACT SHEET FOR HEALTHCARE PROVIDERS

LumiraDx UK Ltd.
LumiraDx SARS-CoV-2 RNA STAR Complete

Updated: November 30, 2021

Coronavirus Disease 2019 (COVID-19)

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 spread of COVID-19 within the community, or other unintended adverse events.

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. 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 terminated or 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:
Isolation Precautions in Healthcare Settings: https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html

FDA webpages:
General: www.fda.gov/novelcoronavirus

LumiraDx UK Ltd.:
LumiraDx Ltd.
G Park Doncaster, West Moor Park – Unit 1
Doncaster, N3 3FT, United Kingdom

LumiraDx U.S. Office
221 Crescent Street Suite 502
Waltham, MA 02453

Email (US): customerservices.US@lumiradx.com
Phone: 1-888-586-4721.

For technical support, contact LumiraDx at:
Email: technicalservices@lumiradx.com

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