This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Simplexa™ COVID-19 Direct assay.

The Simplexa COVID-19 Direct assay is authorized for use with respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: DiaSorin Molecular LLC - Simplexa™ COVID-19 Direct.

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 infection 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 respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider.

- The Simplexa COVID-19 Direct assay can be used to test nasopharyngeal swabs (NPS), anterior nasal swabs (NS), nasal washes/aspirates (NW) or bronchoalveolar lavage (BAL) specimens.
- The Simplexa COVID-19 Direct assay should be ordered for the detection of COVID-19 in individuals suspected of COVID-19 by their healthcare provider.
- The Simplexa COVID-19 Direct assay 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 or moderate 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 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 decision about patient management.

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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FACT SHEET FOR HEALTHCARE PROVIDERS
DiaSorin Molecular LLC
Simplexa™ COVID-19 Direct

Updated: July 22, 2021
Coronavirus Disease 2019 (COVID-19)

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

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Website: www.DiaSorin.com

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