This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Diversified Medical Healthcare SARS-CoV-2 Assay.

The Diversified Medical Healthcare SARS-CoV-2 Assay is authorized for use with anterior nasal swab 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: Premier Medical Laboratory Services - Diversified Medical Healthcare SARS-CoV-2 Assay.

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 anterior nasal swab specimens collected from individuals consistent with the Emergency Use Authorization (EUA).

- The Diversified Medical Healthcare SARS-CoV-2 Assay can be used to test anterior nasal swab specimens.
- The Diversified Medical Healthcare SARS-CoV-2 Assay can be used to test individual anterior nasal swab specimens that are collected at home using the DoINeedaCOVID19Test.com Self-Collection Kit by any individual, 18 years or older (self-collected), 14 years and older (self-collected under adult supervision) or 2 years and older (collected with adult assistance), including individuals without symptoms or other reasons to suspect COVID-19, when determined to be appropriate by a healthcare provider.
- The Diversified Medical Healthcare SARS-CoV-2 Assay is also for use with anterior nasal swab specimens that are collected using the RapidRona Self-Collection Kit when used consistent with its authorization.
- The Diversified Medical Healthcare SARS-CoV-2 Assay is only authorized for use at laboratories designated by Premier Medical Laboratory Services which are certified under the 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

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
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 Diversified Medical Healthcare SARS-CoV-2 Assay has been 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 prescription of a treatment or therapy, 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 test result for this test means that SARS-CoV 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 Diversified Medical Healthcare SARS-CoV-2 Assay.

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 never infected.

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 with an alternative method 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 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
SARSCoV-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-
advise-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:
Symptoms: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-
testing/symptoms.html
Information for Laboratories: https://www.cdc.gov/coronavirus/2019-
CoV/lab/index.html
Laboratory Biosafety: https://www.cdc.gov/coronavirus/2019-
CoV/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-
CoV/lab/guidelines-clinical-specimens.html
Infection Control: https://www.cdc.gov/coronavirus/2019-
ncov/php/infection-control.html

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

Premier Medical Laboratory Services:
6000A Pelham Road
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Customer Support:
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