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Fact Sheet for Healthcare Providers:

SARS-CoV-2 by PCR Laboratory-Developed Test (LDT)

Physicians Laboratory Services

The **SARS-CoV-2 by PCR** LDT is authorized for emergency use (EUA) on nasopharyngeal specimens from individuals suspected of having Coronavirus Disease 2019 (COVID-19) by their healthcare provider. This *Fact Sheet* is to inform you of the potential risks and benefits of the emergency use of this test.

Patients who are tested for COVID-19 with this test should be provided the *Fact Sheet for Patients: SARS-CoV-2 by PCR Laboratory-Developed Test (LDT)* which can be found at http://www.physlab.com.

What are the symptoms of COVID-19?
Fever and symptoms of acute respiratory illness (e.g. cough, difficulty breathing) are most commonly reported, however, limited information is currently available to fully characterize the illness. Based on preliminary data, the median incubation period is approximately 5 days, but may range from 2 to 14 days.

What do I need to know about COVID-19 testing?
The most up to date infection control and case definition information is available on the CDC's website (see pg. 2 of this document).

- This test is for the detection of SARS-CoV-2 in individuals suspected of having COVID-19 by their healthcare providers.
- This test can only be performed on nasopharyngeal swabs.
- Appropriate personal protective equipment when collecting and handling specimens from patients suspected of having COVID-19 is outlined on the CDC website.
- This test is a laboratory-developed test utilizing primer and probe sequences published by the CDC on the Luminex®ARIES® System.
- Preliminary verification studies on the SARS-CoV-2 by PCR performed by Physicians Laboratory Services showed 100% sensitivity and 95.5% specificity for SARS-CoV-2.

Risk to the patient of a false negative includes: delayed or lack of supportive treatment, lack of monitoring of infected individuals in the same household or other close contacts for symptoms resulting in increased community risk, or other unintended adverse events.

What does it mean if the specimen result is "Detected"?
A result of "Detected" on the SARS-CoV-2 by PCR test indicates that RNA from SARS-CoV-2 was detected, and the patient is presumptively infected with the virus and presumed to be contagious. This result should be correlated with clinical observations and epidemiological data.

In the event of a false positive, risks to patients could include the following: isolation of the patient, monitoring of household or close contacts for symptoms, isolation which may increase contact with other potential COVID-19 patients, limits in ability to work, delayed diagnosis and treatment for the true infection causing symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

What does it mean if the specimen result is "Not Detected"?
A result of "Not Detected" on the SARS-CoV-2 by PCR test indicates that RNA from SARS-CoV-2 was not detected in the specimen above the limit of detection. However, this result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions.

When the test result is "Not Detected," 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. Re-testing should be considered in consultation with public health authorities if false negative results are suspected.

What is an EUA?
The United States FDA has authorized this test for use under an emergency access mechanism called Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist that justify the emergency use of *in vitro* diagnostic (IVD) test for the detection of the virus SARS-CoV-2.

An IVD test made available under an EUA has not undergone the same type of review as an FDA-approved or -cleared IVD. FDA may issue EUA when certain criteria are met for the verification of the test and there are no approved and available alternatives. The EUA for this test is in effect for the duration of the COVID-19 declaration justifying it, unless terminated or revoked, after which the test may no longer be used.

Where can I go for updates or more information on COVID-19?

CDC General
https://www.cdc.gov/coronavirus/2019-nCoV/

Information for Healthcare Professionals:
https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html

Information for Laboratories:
https://www.cdc.gov/coronavirus/2019-nCoV/guidance-laboratories.html

Isolation Precautions in Healthcare Settings
https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html

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

Infection control
https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html

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

EUAs:
https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

References:
Luminex Corporation ARIES SARS-CoV-2 Assay Fact Sheet for Healthcare Providers. April 3, 2020.

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