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HEALTHCARE PROVIDER FACT SHEET FOR COVID-19

QuantiVirus™ SARS-CoV-2 Test

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of DiaCarta's QuantiVirus™ SARS-CoV-2 Test.

The QuantiVirus™ SARS-CoV-2 Test is authorized for use on respiratory specimens from individuáis suspected of Coronavirus Disease 2019 (COVID-19) by their healthcare provider.

All patients whose specimens are tested with this assay will receive the Patient Fact Sheet for the QuantiVirus™ SARS-CoV-2 Test.

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID -19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage 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 web page, Information for Healthcare Professionals (see links provided in "Where can I go for updates and more information" section).

- The QuantiVirus™ SARS-CoV-2 Test can be used to test upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspírate).
- The QuantiVirus™ SARS-CoV-2 Test should be ordered for the detection of COVID-19 in individuáis suspected of COVID-19 by their healthcare provider.
- The QuantiVirus™ SARS-CoV-2 Test is only authorized for use at laboratories that are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions are available at the CDC's website (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 individuáis suspected of COVID-19 by their healthcare provider.

Use appropriate personal protective equipment when collecting and handling specimens from individuáis suspected of having COVID-19 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 "detected" (positive) for the virus that causes COVID-19?

If you have a "detected" test result, it is very likely that you have COVID-19. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give a "detected" result that is wrong (a false positive result). Your healthcare provider will work with you to determine how best to care for you based on the test results along with other factors of your medical history, and your symptoms, possible exposures, and geographic location of places you have recently traveled.

What does it mean if the specimen tests "not detected" for the virus that causes COVID-19?

A "not-detected" test result for this test means that SARS-CoV-2 RNA was not present in the specimen above the limit of detection. However, a "not-detected" result does not rule out COVID-19 and should not be used as the solé basis for treatment or patient management decisions. A negative result does not exelude the possibility of COVID-19.

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 indícate 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 should be considered by healthcare providers in consultation with public health authorities.

Risks to a patient of a false negative inelude: delayed or lack of supportive treatment, lack of monitoring of infected individuáis and their household or other cióse contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended 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-I088

What does it mean if the specimen tests "Inconclusive" for the virus that causes COVID-19?

An "Inconclusive" test result means that on initial and repeat testing the presence or absence of COVID-19 targets could not be satisfactorily determined. It may also mean that the initial test was inconclusive and there was not enough sample for repeat testing. Further testing is recommended. Please contact DiaCarta with any questions.

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 ineludes 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 the detection of the virus that causes 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).

Where can I go for updates and more information?

CDC webpages:

- **General:** https://www.cdc.gov/C0VID19
- **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
- **Laboratory Biosafety:** https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.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 webpages:

- **General:** www.fda.gov/novelcoronavirus
- **EUAs:(includes links to patient fact sheet and manufacturéis instructions)** https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

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