Fact Sheet for Healthcare Providers

Interpreting SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR Test Results

Updated: March 9, 2020

This Fact Sheet informs you of the significant known and potential risks and benefits of the use of the Quest Diagnostics' SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR ("Quest RT-PCR").

The Quest RT-PCR is for use on respiratory specimens from individuals who meet the Centers for Disease Control and Prevention (CDC) Coronavirus Disease 2019 (COVID-19) clinical and/or epidemiological criteria. CDC COVID-19 criteria for testing on human specimens are available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information?" section). Testing is currently limited to Quest Diagnostics Infectious Disease laboratory, San Juan Capistrano, CA.

A Fact Sheet for Patients on the interpretation of SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR is located on the Quest Diagnostics website.

What are the symptoms of COVID-19?
Most patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (eg, 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 MERS-CoV and SARS-CoV-2, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus that causes COVID-19. The median incubation period is unknown at this time.

Public health officials have identified cases of COVID-19 infection in the United States, which may pose risks for public health. Most reported cases of SARS-CoV-2 within the United States have been linked to travel to countries with sustained person-to-person spread of the virus. There also are reports of human to human transmission through close contact with an individual confirmed to be ill with COVID-19. Please check the CDC webpage for the most up to date information.

This test is to be performed only using respiratory specimens collected from individuals who meet CDC clinical and/or epidemiological criteria for COVID-19 testing.

What do I need to know about COVID-19 testing? Current information on COVID-19 for healthcare providers, including case definitions and infection control, is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information?" section).

- The Quest RT-PCR has been validated to test nasopharyngeal/oropharyngeal swabs, bronchial lavage/wash, and sputa/tracheal aspirate samples.
- The Quest RT-PCR should be ordered for the presumptive detection of SARS-CoV-2 in individuals who meet CDC criteria for COVID-19 testing.
- The Quest RT-PCR is only for use in qualified Quest Diagnostics laboratories.

Important information:
The test has been validated according to CLIA, but the FDA's independent review of this validation is pending.
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

Specimens should be collected with appropriate infection control precautions following CDC *Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings.*

Use appropriate personal protective equipment when collecting and handling specimens from individuals 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))*. These specimens are only shipped for analysis to laboratories designated by CDC as qualified for analysis. 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 for the virus that causes COVID-19?
A "detected" test result is interpreted as a presumptive positive test result for COVID-19. This indicates that RNA from SARS-CoV-2 (formerly 2019-nCoV) was detected, and the patient is presumptively infected with the virus and presumed to be contagious. All presumptive positive and inconclusive tests will be sent to the appropriate Public Health laboratory for confirmation. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions.

The Quest RT-PCR has been designed to minimize the likelihood of false positive test results. However, 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 patients potentially infected with COVID-19, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

Quest Diagnostics Infectious Disease laboratory must follow the standard confirmatory testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests not detected for the virus that causes COVID-19?
A not detected (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. A negative result does not exclude the possibility of COVID-19.

When 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 tests for other causes of illness (egf, 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 in consultation with public health authorities.

Risks to a patient of a false negative 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.

What is the regulatory status of this assay?
This test has been validated according to high-complexity testing under the Clinical Laboratory Improvement Amendments and is pending the Food and Drug Administration agency's independent review under the Emergency Use Authorization for novel coronavirus (COVID-19).

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Where can I go for updates and more information?

CDC webpages:

General: https://www.cdc.gov/nCoV

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/infectioncontrol/guidelines/isolation/index.html#a4

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

FDA webpages:

General: www.fda.gov/novelcoronavirus

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

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