FACT SHEET FOR HEALTHCARE PROVIDERS

CDC - 2019-nCoV Real-Time RT-PCR Diagnostic Panel **February 4, 2020**

2019 Novel Coronavirus (2019-nCoV)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Centers for Disease Control and Prevention (CDC) 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

Testing is to be conducted on specimens from people who meet CDC criteria for 2019-nCoV testing, available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section). The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel should be ordered only to presumptively detect 2019-nCoV infection. If outside the U.S., testing should follow appropriate public health authority consultation and/or guidance for the diagnosis and reporting of 2019-nCoV infection. All information and guidance, including for 2019-nCoV laboratory testing, may change as more data is gathered on this virus. Please check the CDC's 2019 Novel Coronavirus, webpage (see links provided in "Where can I go for updates and more information" section) regularly for the most current information.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

What are the symptoms of 2019-nCoV?
Most patients with confirmed 2019-nCoV infection 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 2019-nCoV infection. Based on what is known about MERS-CoV and SARS-CoV, signs and symptoms may appear any time from 2 to 14 days after exposure to 2019-nCoV virus. The median incubation period is unknown at this time.

Public health officials have identified cases of 2019-nCoV infection in the United States, which may pose risks for public health. To date most reported cases of 2019-nCoV infection outside of China have been directly or indirectly linked through residence in or travel to Wuhan City, China. There also are reports of human to human transmission through close contact with an individual confirmed to be ill with 2019-nCoV in countries outside China. 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 criteria for 2019-nCoV testing.

What do I need to know about 2019-nCoV testing?
Current information on 2019-nCoV infection 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 CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel can be used to test upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, bronchoalveolar lavage, sputum, lower respiratory tract aspirate, nasopharyngeal wash/aspirate or nasal aspirate).
- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel should be ordered for the presumptive detection of 2019-nCoV in individuals who meet CDC criteria for 2019-nCoV testing.
- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is authorized for use in qualified laboratories designated by CDC and in the U.S., certified under CLIA to perform high complexity tests.

Specimens should be collected with appropriate infection control precautions following CDC *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007).*

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of being infected with 2019-nCoV as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with*

2019 Novel Coronavirus (2019-nCoV). 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 Patients Under Investigation (PUIs) for 2019 Novel Coronavirus (2019-nCoV)* (see links provided in "Where can I go for updates and more information" section).

What does it mean if the specimen tests positive for 2019-nCoV?
A positive test result for 2019-nCoV indicates that RNA from 2019-nCoV was detected, and the patient is presumptively infected with 2019-nCoV and presumed to be contagious. 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. Patient management should follow current CDC guidelines.

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel 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 potentially 2019-nCoV infected patients, 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.

All laboratories using this test must follow the standard confirmatory testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for 2019-nCoV?
A negative test result for this test means that 2019-nCoV RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out 2019-nCoV infection and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of 2019-nCoV infection.

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 2019-nCoV infection. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that 2019-nCoV infection is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If 2019-nCoV infection 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 2019-nCoV within the community, or other unintended adverse events.

What is an EUA?
The United States (U.S.) 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 use of in vitro diagnostics (IVDs) under EUA for the detection and/or diagnosis of 2019-nCoV.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. However, based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in the detection of 2019-nCoV.

The EUA for this test is in effect for the duration of the 2019-nCoV emergency, unless terminated or revoked (after which the test may no longer be used). An FDA approved or cleared IVD should be used instead of an IVD under EUA, when applicable and available.

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**

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:(includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Manufacturer: CDC
CDC Emergency Operations Center (EOC)
1600 Clifton Road
Atlanta, Georgia, USA, 30329
Phone: **CDC EOC (770-488-7100)**

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**