

FACT SHEET FOR HEALTHCARE PROVIDERS

Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay

Rutgers Clinical Genomics Laboratory

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Coronavirus
Disease 2019
(COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay.

The Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay is authorized for use on using respiratory specimens from individuals suspected of Coronavirus Disease 2019 (COVID-19) by their healthcare provider.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay.

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 webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

- The Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay can be used to test oropharyngeal (throat) swab, nasopharyngeal swab,

This test is to be performed only using respiratory specimens from individuals suspected of COVID-19 by their healthcare provider.

anterior nasal swab, mid-turbinate nasal swab, saliva specimens and bronchoalveolar lavage (BAL) fluid.

- The Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay should be ordered for the detection of COVID-19 in individuals suspected of COVID-19 by their healthcare provider.
- The Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay is only authorized for use at the Rutgers Clinical Genomics Laboratory (RCGL) at RUCDR Infinite Biologics – Rutgers University, Piscataway, NJ, that is a Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a certified high-complexity laboratory.

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).

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)*. 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 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

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**