

FACT SHEET FOR HEALTHCARE PROVIDERS

TaqPath™ COVID-19 Combo Kit

June 11, 2020

Coronavirus
Disease 2019
(COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the TaqPath™ COVID-19 Combo Kit.

The TaqPath™ COVID-19 Combo Kit is for use on respiratory specimens from people who meet clinical and/or epidemiological criteria for Coronavirus Disease 2019 (COVID-19) testing.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: TaqPath™ COVID-19 Combo Kit.

What are the symptoms of COVID-19?

Most 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 4 days.

Public health officials have identified cases of COVID-19 infection across the globe which may pose risks for public health. Cases of COVID-19 have now been identified in over 60 international locations. There also are reports of human to human transmission through close contact with an individual confirmed to be ill with COVID-19.

What do I need to know about COVID-19 testing?

- The TaqPath™ COVID-19 Combo Kit can be used to test nasopharyngeal/oropharyngeal swabs, bronchoalveolar lavage, nasal swab and mid-turbinate swab.
- The TaqPath™ COVID-19 Combo Kit should be ordered for the presumptive detection of COVID-19 in individuals who meet the clinical and/or epidemiological criteria for COVID-19 testing. Specimens should be collected with appropriate infection control precautions.

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

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having COVID-19.

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 presumptively infected with the virus 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.

The TaqPath™ COVID-19 Combo Kit 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 COVID-19 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 the virus that causes COVID-19?

A 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.

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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 indicate 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 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.

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