



COVID-19 FACT SHEET FOR HEALTHCARE PROVIDERS

2019 Trident's COVID-19 RT-PCR Test

This Fact Sheet informs you of the significant known and potential risks and benefits of Trident's COVID-19 RT-PCR test.

Trident's COVID-19 RT-PCR Test is designed for use on respiratory specimens from individuals suspected of Coronavirus Disease 2019 (COVID-19) by their healthcare provider.

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).

- This COVID-19 RT-PCR Test can be used to test upper and lower respiratory specimens (such as nasal, nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates,

bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate).

- This COVID-19 RT-PCR test should be ordered for the detection of COVID-19 in individuals suspected of COVID-19 by their healthcare provider.
- This COVID-19 RT-PCR test is only authorized for use at Trident Labs, Michigan, or other laboratories designated by Trident 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).

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.

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**

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.

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 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.

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 by healthcare providers 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 does it mean if the specimen tests inconclusive for the virus that causes COVID-19?

Some samples, after repeated testing, do not give a positive or a negative result. In this case another sample should be submitted for testing.

Is this test FDA approved?

This test is not FDA approved. This test was submitted to the FDA for review.

Where can I go for updates and more information?

CDC webpages:

General: <https://www.cdc.gov/COVID19>

Healthcare Professionals:

<https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html>

Information for Laboratories:

<https://www.cdc.gov/coronavirus/2019nCoV/guidance-laboratories.html>

Laboratory Biosafety:

<https://www.cdc.gov/coronavirus/2019nCoV/lab-biosafety-guidelines.html> **Isolation Precautions in Healthcare**

Settings:

<https://www.cdc.gov/coronavirus/2019-ncov/infection-control/controlrecommendations.html>

Specimen Collection:

<https://www.cdc.gov/coronavirus/2019nCoV/guidelines-clinical-specimens.html>

Infection Control: <https://www.cdc.gov/coronavirus/2019ncov/infection-control/index.html>

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FDA webpages:

General: www.fda.gov/novelcoronavirus

EUAs:(includes links to patient fact sheet and manufacturer's instructions)

<https://www.fda.gov/medical-devices/emergencysituations-medical-devices/emergency-use-authorizations>

Trident Laboratories:

Trident Laboratories

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Holland, MI 49423

Website: <http://www.tridentbiometrics.com>

Email: info@tridentbiometrics.com

Customer Service: 1-(855)-875-2532

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