

FACT SHEET FOR HEALTHCARE PROVIDERS

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the BD SARS-CoV-2 Reagents for BD MAX™ System.

The BD SARS-CoV-2 Reagents for BD MAX™ System is authorized 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: BD SARS-CoV-2 Reagents for BD MAX™ System

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 in the United States which may pose risk for public health. Cases of COVID-19 have now been identified in 46 US States, the District of Columbia and over 115 international locations. There also are reports of human to human transmission through close contact with an individual confirmed to be ill with COVID-19, in the United States and globally. Please check the CDC webpage for the most up to date information.

What do I need to know about COVID Testing?

Current information on COVID-19 for healthcare providers, including case definitions and infection control, is available at CDC's website, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information").

- The BD SARS-CoV-2 Reagents for BD MAX™ System can be used to test nasal, nasopharyngeal, and oropharyngeal swab samples.
- The BD SARS-CoV-2 Reagents for BD MAX™ System should be ordered for the detection of COVID-19 in individuals who meet the COVID-19 clinical and/or epidemiological criteria for testing.

The BD SARS-CoV-2 Reagents for BD MAX™ System is only authorized for use in laboratories in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate and high complexity tests.

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

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)*. 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 tests 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 data in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines.

The BD SARS-CoV-2 Reagents for BD MAX™ System has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risk 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.

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 presentations indicate that COVID-19 is likely, and diagnostic tests for other cases 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 with 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 Services' (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in the detection of the virus that causes COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

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/2019-nCoV/guidancelaboratories.html> **Laboratory Biosafety:**

<https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafetyguidelines.html>

Isolation Precautions in Healthcare Settings:

<https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html> **Specimen Collection:**

<https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinicalspecimens.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/emergencysituations/medical-devices/emergency-use-authorizations>

BD Integrated Diagnostic Solutions

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Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdate.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling **1-800-FDA-1088**

FACT SHEET FOR HEALTHCARE PROVIDERS

ARIES® SARS-CoV-2 Assay – Luminex Corporation

April 3, 2020

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 ARIES® SARS-CoV-2 Assay.

The ARIES® SARS-CoV-2 Assay is authorized for use on respiratory specimens from individuals suspected of COVID-19 by their healthcare provider.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: ARIES® 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 in 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, 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 ARIES® SARS-CoV-2 Assay can be used to test nasopharyngeal swab specimens.
- The ARIES® SARS-CoV-2 Assay should be ordered for the detection of COVID-19 in individuals who are suspected of COVID-19 by their healthcare provider.

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

- The ARIES® SARS-CoV-2 Assay is only authorized for use in laboratories in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate and high complexity tests.

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions are available at 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 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. Patient management should follow current CDC guidelines.

The ARIES® SARS-CoV-2 Assay 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

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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.

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.

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 emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in the detection of the virus that causes COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

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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/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/coronavirus/2019-ncov/infection-control/control-recommendations.html>

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

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

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