# FACT SHEET FOR HEALTHCARE PROVIDERS

**Vela Operations Singapore Pte Ltd.** **August 5, 2020**

**ViroKey™ SARS-CoV-2 RT-PCR Test** **Distributed by: Vela Diagnostics USA, Inc.**

**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 ViroKey™ SARS-CoV-2 RT-PCR Test.

The ViroKey SARS-CoV-2 RT-PCR Test is authorized for use with certain respiratory specimens collected 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: Vela Operations Singapore Pte Ltd. - ViroKey™ SARS-CoV-2 RT-PCR Test.**

**What are the symptoms of COVID-19?**
Many patients with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, new loss of taste or smell, nausea or vomiting or diarrhea. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in "*Where can I go for updates and more information?*" section.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdictions website 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 test is to be performed only using certain respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider.**

- The ViroKey SARS-CoV-2 RT-PCR Test can be used to test upper respiratory specimens (such as nasal, mid-turbinate, nasopharyngeal, oropharyngeal swab specimens and nasopharyngeal wash/aspirate or nasal aspirate specimens).
- The ViroKey SARS-CoV-2 RT-PCR Test should be ordered for the detection of COVID-19 in individuals suspected of COVID-19 by their healthcare provider.
- The ViroKey SARS-CoV-2 RT-PCR Test is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Specimens should be collected with appropriate infection control precautions. Current guidance is available at the CDC's website (see links provided in "*Where can I go for updates and more information?*" section).

When collecting and handling specimens from individuals suspected of being infected with COVID-19, appropriate personal protective equipment should be used 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 therefore 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 (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management should be made by a healthcare provider and follow current CDC guidelines.

The ViroKey SARS-CoV-2 RT-PCR Test has been designed to minimize the likelihood of false positive test results. However, it is still possible that this test can give a false positive result, even when used in locations where the prevalence is below 5%. 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, 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. It is possible to test a person too early or too late during COVID-19 infection to make an accurate diagnosis via ViroKey SARS-CoV-2 RT-PCR Test.

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 with an alternative method should be considered by healthcare providers in consultation with public health authorities. Additional testing may be helpful to ensure testing was not conducted too early.

Risks to a patient of a false negative test result 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 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 diagnosing 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).

**What are the approved available alternatives?**
There are no approved available alternative tests. FDA has issued EUAs for other tests that can be found at:

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

## Where can I go for updates and more information?

### CDC webpages:

**General:** https://www.cdc.gov/COVID19
**Symptoms:**
https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
**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/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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# FACT SHEET FOR HEALTHCARE PROVIDERS

**TaqPath™ COVID-19 Combo Kit** **Updated: April 20, 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 TaqPath™ COVID-19 Combo Kit.

The TaqPath™ COVID-19 Combo Kit 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: 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 in the United States, which may pose risks for public health. 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-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 TaqPath™ COVID-19 Combo Kit can be used to test upper respiratory specimens (such as nasopharyngeal, oropharyngeal, nasal, and mid-turbinate swabs, and nasopharyngeal aspirate) and bronchoalveolar lavage (BAL) specimens.
- The TaqPath™ COVID-19 Combo Kit should be ordered for the detection of COVID-19 in individuals suspected of COVID-19 by their healthcare provider.
- The TaqPath™ COVID-19 Combo Kit 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 high complexity tests.

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

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

**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**

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.

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).

## 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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# FACT SHEET FOR HEALTHCARE PROVIDERS

**Becton, Dickinson & Company (BD)**

**BD SARS-CoV-2/Flu for BD MAX™ System** **Updated: April 9, 2021**

**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 BD SARS-CoV-2/Flu for BD MAX™ System test.

The BD SARS-CoV-2/Flu for BD MAX™ System is authorized for use with nasopharyngeal and anterior nasal swab specimens collected from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

**All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Becton, Dickinson & Company (BD) - BD SARS-CoV-2/Flu for BD MAX™ System.**

**What are the symptoms of COVID-19?**
Many patients with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, new loss of taste or smell, nausea or vomiting or diarrhea. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in "*Where can I go for updates and more information?*" section.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdictions website for the most up to date information.

**What are the signs and symptoms of influenza?**
The signs and symptoms of influenza usually develop suddenly and are similar to those of COVID-19.

**This test is to be performed using nasopharyngeal and anterior nasal swab specimens collected from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider.**

Common signs and symptoms of influenza are fever, cough, sore throat, runny/stuffy nose, body aches, headaches, and fatigue.

**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 BD SARS-CoV-2/Flu for BD MAX™ System can be used to test nasopharyngeal and anterior nasal swab specimens.
- The BD SARS-CoV-2/Flu for BD MAX™ System test can be ordered for the simultaneous detection and differentiation of nucleic acids from SARS-CoV-2, influenza A and influenza B in in individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider.
- The BD SARS-CoV-2/Flu for BD MAX™ System is only authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate or high complexity tests.

Specimens should be collected with appropriate infection control precautions. Current guidance is available at the CDC's website (see links provided in "Where can I go for updates and more information" section).

When collecting and handling specimens from individuals suspected of being infected with COVID-19, appropriate personal protective equipment should be used 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 SARS-CoV-2, the virus that causes COVID-19?**
A positive test result for COVID-19 indicates that RNA from SARS-CoV-2 was detected, and therefore 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 (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management should be made by a healthcare provider and follow current CDC guidelines.

The BD SARS-CoV-2/Flu for BD MAX™ System test has been designed to minimize the likelihood of false positive test results. However, it is still possible that this test can give a false positive result, even when used in locations where the prevalence is below 5%. 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, 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 SARS-CoV-2, 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. It is possible to test a person too early or too late during COVID-19 infection to make an accurate diagnosis via the BD SARS-CoV-2/Flu for BD MAX™ System test.

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 with an alternative method should be considered by healthcare providers in consultation with public health authorities.

Risks to a patient of a false negative test result 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.

The performance of this test was established based on the evaluation of a limited number of clinical specimens. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

**What does it mean if the specimen tests positive for influenza A and/or influenza B viruses?**
A positive test result for influenza A and/or influenza B virus indicates that RNA from one or more of these viruses was detected, the patient is infected with the virus(es) and is presumed to be contagious. Laboratory test results should always be considered in the context of clinical findings and observations and epidemiological data in making a final diagnosis. Patient management decisions should be made by a healthcare provider and follow current CDC guidelines. Results (positive and negative) for influenza should be interpreted with

caution. If an influenza result is inconsistent with clinical presentation and/or other clinical and epidemiological information, FDA-cleared Influenza NAATs are available for confirmation if clinically indicated.

The BD SARS-CoV-2/Flu for BD MAX™ System test has been designed to minimize the likelihood of false-positive test results. However, in the event of a false-positive result, risks to individuals 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 of friends, limits in the ability to work, delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of an antiviral medication or other therapy, or other unintended adverse effects.

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

When diagnostic testing results are 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 influenza. The possibility of a false-negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that influenza A and/or influenza B is likely, and diagnostic test results for other causes of illness (e.g., other respiratory illness) are negative. If influenza A, and/or influenza B is still suspected based on exposure history and clinical findings, re-testing should be considered by healthcare providers in consultation with public health authorities.

Laboratory test results should always be considered in the context of clinical findings and observations and/or epidemiological data in making a final diagnosis. Patient management decisions should be made by a healthcare provider and follow current CDC guidelines. Results (positive and negative) for influenza should be interpreted with caution. If an influenza result is inconsistent with clinical presentation and/or other clinical and epidemiological information, FDA-cleared Influenza NAATs are available for confirmation if clinically indicated.

Risks to a individuals from a false-negative BD SARS-CoV-2 for BD MAX™ System test result for influenza A and/or influenza B include: delayed or lack of supportive treatment; lack of monitoring of infected patients and their household or other close contacts for symptoms, resulting in increased risk of spread of influenza A and/or influenza B within the community; or other unintended adverse events.

**What does it mean if the specimen tests positive for SARS-CoV-2, influenza A and/or influenza B viruses? Is co-infection possible?**
Yes, it is possible for an individual to be infected with more than one virus simultaneously. A positive test result for the viruses that cause COVID-19, influenza A and/or influenza B indicates that RNA from these viruses was detected, the patient may be co-infected, and is presumed to be contagious. Laboratory test results should always be considered in the context of clinical findings and observations and epidemiological data in making a final diagnosis. Patient management decisions should be made with a healthcare provider and follow current CDC guidelines.

**What is an EUA?**
The United States 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 diagnosing 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).

**What are the approved available alternatives?**
Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medical-devices/deviceadvice-comprehensive-regulatory-assistance/medicaldevice-databases. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-andresponse/mcm-legal-regulatory-and-policyframework/emergency-use-authorization.

## Where can I go for updates and more information?

**CDC webpages:**
**General:** https://www.cdc.gov/COVID19
**Symptoms:**
https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
**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/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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# 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

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).

## 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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# FACT SHEET FOR HEALTHCARE PROVIDERS

**Elecsys Anti-SARS-CoV-2** **May 2, 2020**

Roche Diagnostics

**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 Elecsys Anti-SARS-CoV-2 immunoassay.

The Elecsys Anti-SARS-CoV-2 immunoassay is authorized for on the detection of antibodies to SARS-CoV-2 in human serum or plasma.

**All individuals whose specimens are tested with this assay will receive the Fact Sheet for Patients: Elecsys Anti-SARS-CoV-2.**

**What are the symptoms of COVID-19?**
Most individuals 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 4-5 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 poses 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 Elecsys Anti-SARS-CoV-2 immunoassay can be used to test human serum or plasma (Heparin, EDTA).
- The Elecsys Anti-SARS-CoV-2 immunoassay should be ordered by a healthcare provider to detect if there has been an adaptive immune response to COVID-19, indicating a recent or prior infection.

**This test measures human SARS-CoV-2 antibodies that are generated as part of the adaptive human immune response to the virus and is to be performed only using serum or plasma specimens.**

- The Elecsys Anti-SARS-CoV-2 immunoassay is only authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) 42 U.S.C. §263a, to perform moderate or high complexity tests.
- The Elecsys Anti-SARS-CoV-2 immunoassay should not be used to diagnose or exclude acute infection and should not be used as the sole basis for treatment or patient management decisions. Direct testing for SARS-CoV-2 should be performed if acute infection is suspected.

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)*. 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 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 antibodies against the virus that causes COVID-19?**
A positive test result for this test indicates that antibodies against SARS-CoV-2 were detected, and the individual has potentially been exposed to SARS-CoV-2.

**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**

Antibodies are generally detectable several days following infection. A positive result can indicate recent or past infection but does not exclude recently infected individuals who are still contagious. It is unknown how long antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection.

A positive antibody result may not mean that an individual's current symptoms are due to COVID-19 infection. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making patient management decisions.

The Elecsys Anti-SARS-CoV-2 immunoassay 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 antibodies against the virus that causes COVID-19?**
A negative test result for this test means that anti-SARS-CoV-2 specific antibodies were not present in the specimen above the limit of detection of the assay. 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 .

Individuals tested early after infection may not have detectable antibody response despite active infection; in addition, not all patients will develop a detectable antibody response to SARS-CoV-2 infection. The absolute sensitivity of the Elecsys Anti-SARS-CoV-2 immunoassay is unknown.

When testing is negative, the possibility of a false negative result should be considered in the context of an individual's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. This is especially important if the individual has had recent exposure to COVID-19, or clinical presentation suggestive of COVID-19, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. Direct testing for virus (e.g., PCR testing) should always be performed in any patient suspected of COVID-19 regardless of Elecsys Anti-SARS-CoV-2 Immunoassay results.

Risks to a patient resulting from a false negative result 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 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).

## 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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# FACT SHEET FOR HEALTHCARE PROVIDERS

**Lyra® Direct SARS-CoV-2 Assay - Quidel Corporation** **May 18, 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 Lyra Direct SARS-CoV-2 Assay.

The Lyra Direct 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: Lyra Direct 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). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell. 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 Lyra Direct SARS-CoV-2 Assay can be used to test nasal, nasopharyngeal and oropharyngeal swab specimens.

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

- The Lyra Direct SARS-CoV-2 Assay should be ordered for the detection of COVID-19 in individuals suspected of COVID-19 by their healthcare provider.
- The Lyra Direct SARS-CoV-2 Assay is only authorized for use in laboratories 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. 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 Lyra Direct SARS-CoV-2 Assay has been designed to minimize the likelihood of false positive test results.

**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**

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 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. Molecular tests that use heat extraction may be less sensitive than molecular tests that include a chemical lysis step and solid phase extraction of nucleic acid for the detection of viral nucleic acids. Therefore, negative results should be treated as presumptive and confirmed with an alternative molecular assay, if necessary for patient management. 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 with an alternative method 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 is an EUA?**
The United States 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).

## 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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