FACT SHEET FOR HEALTHCARE PROVIDERS

BioFire Diagnostics, LLC **Updated: June 05, 2023**

BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ)

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 BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ).

The BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) is a multiplexed polymerase chain reaction (PCR) test authorized for use with nasopharyngeal swab specimens obtained from individuals suspected of respiratory infection consistent with COVID-19 by their healthcare provider.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: BioFire Diagnostics, LLC - BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ).

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 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.

This test is to be performed only using nasopharyngeal swab specimens obtained from individuals suspected of respiratory infection consistent with COVID-19 by their healthcare provider.

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 BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) can be used to test nasopharyngeal swabs (NPS).
- The BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) should be ordered for the detection and differentiation of SARS-CoV-2 and the following organism types and subtypes: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A (including subtypes H1, H3 and H1-2009), Influenza B, Parainfluenza Virus, Respiratory Syncytial Virus, *Bordetella parapertussis, Bordetella pertussis, Chlamydia pneumoniae, Mycoplasma pneumoniae*, in individuals suspected of respiratory infection consistent with COVID-19 by their healthcare provider.
- The BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) 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, moderate, or waived complexity tests.
- The BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

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).

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**

When collecting and handling specimens from individuals suspected of being infected with the virus that causes 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 BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) 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 SARS-CoV-2 infection to make an accurate diagnosis via the BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ).

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.

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 negative for SARS-CoV-2, the virus that causes COVID-19, but positive for another targeted respiratory pathogen?
A negative test result for COVID-19 means that SARS-CoV-2 RNA was not present in the specimen above the limit of detection. However, a positive test result for another respiratory pathogen targeted by the BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) (e.g., Influenza A) indicates that nucleic acid (RNA/DNA) of that pathogen was detected, and therefore the patient is infected with the pathogen and 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 and patient management decisions. Patient management decisions should be made by a healthcare provider and follow current CDC guidelines. Results (positive and negative) for the other pathogens targeted by the BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) should be interpreted with caution. If a result is inconsistent with clinical presentation and/or other clinical and epidemiological information, additional testing may be considered

The BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) 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 another targeted respiratory pathogens?
What does it mean if the specimen tests negative for another targeted respiratory pathogens? A negative test result for another respiratory pathogen targeted by the BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) means that pathogen was not present in the specimen above the limit of detection. However, a negative result does not rule out infection with those targeted pathogens 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 the pathogens targeted by the BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ). The possibility of a false-negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that infection with one of the targeted pathogens is possible, and diagnostic test results for other causes of illness (e.g., other respiratory illness) are negative.

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 the other pathogens targeted by the BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) should be interpreted with caution. If a result is inconsistent with clinical presentation and/or other clinical and epidemiological information, additional testing may be considered.

Risks to individuals from a false-negative BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) result for the targeted pathogens 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 the disease within the community; or other unintended adverse events.

What does it mean if the specimen tests positive for SARS-CoV-2, and another target pathogen detected by this test? 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, and another targeted pathogen 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?
FDA has approved/cleared certain tests for some of the targeted pathogens (e.g., influenza and RSV tests). 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/device-advice-comprehensive-regulatory-assistance/medical-device-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-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/coronavirus/2019-ncov/index.html
Symptoms: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-ncov/hcp/
Information for Laboratories: https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html
Laboratory Biosafety: https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html
Isolation Precautions in Healthcare Settings: https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html
Specimen Collection: https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/php/infection-control.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/in-vitro-diagnostics-euas

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