FACT SHEET FOR HEALTHCARE PROVIDERS

Bio-Rad Laboratories **July 1, 2021**

BioPlex 2200 SARS-CoV-2 IgG

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 BioPlex 2200 SARS-CoV-2 IgG.

You should not interpret the results of this test as an indication or degree of immunity or protection from infection.

The BioPlex 2200 SARS-CoV-2 IgG is authorized for the detection of antibodies to SARS-CoV-2 in human serum and plasma (dipotassium EDTA, tripotassium EDTA, lithium heparin, sodium heparin, and sodium citrate).

All individuals whose specimens are tested with this test will receive the Fact Sheet for Recipients – Bio-Rad Laboratories – BioPlex 2200 SARS-CoV-2 IgG.

This test detects human SARS-CoV-2 antibodies that are generated as part of the human adaptive immune response to the COVID-19 virus and is to be performed on only human serum and plasma (dipotassium EDTA, tripotassium EDTA, lithium heparin, sodium heparin, and sodium citrate) specimens.

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 jurisdiction's 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).

- The BioPlex 2200 SARS-CoV-2 IgG can be ordered by healthcare providers to test human serum and plasma (dipotassium-EDTA, tripotassium-EDTA, lithium heparin, sodium heparin, and sodium citrate) to detect if there has been an adaptive immune response to COVID-19, indicating recent or prior infection.
  The BioPlex 2200 SARS-CoV-2 IgG 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.
- The performance of the BioPlex 2200 SARS-CoV-2 IgG has not been established in individuals that have received a COVID-19 vaccine.
- The BioPlex 2200 SARS-CoV-2 IgG provides a semiquantitative result. The clinical applicability of a semiquantitative result is currently unknown and cannot be interpreted as an indication or degree of immunity or protection from infection. Because semiquantitative SARS-CoV-2 antibody assays are not standardized, and the performance characteristics of each semiquantitative SARS-CoV-2 antibody test is uniquely established, results from different semiquantitative SARS-COV-2 antibody assays are not comparable.
- The BioPlex 2200 SARS-CoV-2 IgG is authorized for use in laboratories certified under the Clinical

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 Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high or moderate complexity tests.
- Please refer to the BioPlex 2200 SARS-CoV-2 IgG instructions for use for additional information.

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

Antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection. Individuals may have detectable virus present for several weeks following seroconversion. If antibodies are present, it often indicates a past infection but does not exclude recently infected patients who are still contagious.

The clinical significance of a positive antibody result for individuals that have received a COVID-19 vaccine is unknown.

This test may give a numerical result, but you should not interpret the number to mean that having any measurement of antibodies to SARS-CoV-2 will protect the individual tested from getting infected again or help reduce the severity or duration of a future COVID-19 infection. This topic is being studied, but the information is unknown. It is also not known how long antibodies to SARS-CoV-2 will remain present in the body after infection.

Incorrect assumptions of immunity may lead to premature discontinuation of physical distancing requirements and increase the risk of infection for individuals, their households and the public.

Regardless of the test result, individuals should continue to follow CDC guidelines to reduce the risk of infection, including social distancing and wearing masks.

False positive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

The BioPlex 2200 SARS-CoV-2 IgG has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to the patient include the following: risk of infection by exposure to persons with active COVID-19. If a recent infection is suspected a false positive result may lead to a recommendation for isolation of the patient, monitoring household or other close contacts for symptoms, patient isolation that might limit contact with family or friends, increase contact with other potentially COVID-19-infected patients, limits in the ability to work, or other unintended adverse effects.

Due to the risk of false positive results, confirmation of positive results should be considered – using a second, different antibody assay that detects the same type of antibodies.

Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making patient management decisions.

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 antibodies against virus that causes COVID-19?
A negative test result with this test means that

SARS-CoV-2 specific antibodies were not present in the specimen above the limit of detection. ***However, patients tested early after infection may not have detectable antibodies despite active infection; in addition, it is not certain that all infected patients will develop a detectable antibody response to SARS-CoV-2 infection. A negative result should not be used to rule out infection. Direct testing of SARS-CoV-2 should be performed if acute infection is suspected.***

The absolute sensitivity of the BioPlex 2200 SARS-CoV-2 IgG is unknown.

The clinical significance of a negative antibody result for individuals that have received a COVID-19 vaccine is unknown.

Risks to a patient of a false negative result include: restriction of activities potentially deemed acceptable for patients with evidence of an antibody response to SARS-CoV-2, 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 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 at diagnosing recent or prior infection with SARSCoV-2 by identifying individuals with an adaptive immune response to 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).

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/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/index.html
Information for Laboratories: https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html
Laboratory Biosafety: https://www.cdc.gov/coronavirus/2019-nCoV/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/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 fact sheet for individuals and manufacturer's instructions) https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/invitro-diagnostics-euas

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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.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**