MEDICAL PROFESSIONALS INFORMATION GUIDE
COVID-19 (SARS-CoV-2) IgG/IgM Antibody Test

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Dear Medical Professional

This Information Guide provides you with a background on available Coronavirus (COVID-19) testing and the significant known and potential risks and benefits of the emergency use of the BIOTRINETIX COVID-19 IgG/IgM Antibody Test. The BIOTRINETIX COVID-19 IgG/IgM Antibody Test is authorized for use on whole blood, serum, or plasma specimens from individuals suspected of contracting the Coronavirus Disease 2019 (COVID-19) by their healthcare provider.

Background on COVID-19 Testing:

For the Coronavirus (also referred to as COVID-19 or SARS-CoV-2), there are currently three types of available testing formats either available or in development. Each of these testing methods identify/detect the virus differently:

• Host Antibody Tests (Serology) - These tests (such as the BIOTRINETIX COVID-19 IgG/IgM Antibody Test) identify the IgG and IgM antibodies present in patients' blood specimen (serum samples). These antibodies indicate that your patient has developed an immune response to the virus however, this does not provide definitive evidence of an active infection. The FDA has indicated these tests should not be used as the sole basis for diagnosis of COVID-19.

• Viral Antigen Tests—Currently several manufacturers are working to develop these tests. Expected availability is unknown at present however it is anticipated these will be a visual read or reader type device similar to commonly used influenza tests.

• Molecular— This test format requires an instrument. While there are a few manufacturers of this test format, due to demand, the initial distribution has been targeted in regions with highest infection levels. These tests works by detecting the presence of a virus by identifying a small section of the virus' genome collected from a patient's nasal swab, then amplifying that portion until there's enough for it to be detected.

The 'Need-to-Know' on COVID-19 Testing:

Healthcare providers can obtain current information on COVID-19 on the CDC's webpage, Information for Healthcare Professionals (see links provided in our "Resources for Updates and Information" section).

• The BIOTRINETIX COVID-19 IgG/IgM Antibody Test can be used to test samples of whole blood, serum or plasma.

• The BIOTRINETIX COVID-19 IgG/IgM Antibody Test can be ordered by a doctor or healthcare provider to determine if there has been an immune response to COVID-19 in the diagnosis of individuals suspected of a Coronavirus 2019 infection.

• The BIOTRINETIX COVID-19 IgG/IgM Antibody Test 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 and high complexity tests.

Specimens should be collected using appropriate infection control precautions as detailed by the CDC. Refer to the CDC's website (see links provided in the "Resources for Updates and Information" section) for current guidance for COVID-19 infection control precautions.

Use appropriate PPE (Personal Protective Equipment), as outlined in the CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19), when collecting and handling specimens from individuals suspected of having 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 the "Resources for Updates and Information" section).

Symptoms of COVID-19:

According to the CDC symptoms exhibited by many patients with a confirmed COVID-19 diagnosis include:

• Fever and/or

• Cough and/or

• Symptoms of acute respiratory illness (e.g., shortness of breath, difficulty breathing).

Currently limited information is available to detail the full spectrum of clinical illness associated with COVID-19. Based on what is presently known about the Coronavirus, signs and symptoms may appear anywhere 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 from 2-14 days.

In addition to the United States, public health officials have identified cases of COVID-19 infection worldwide. This realization poses risks to public health. Please check the CDC's COVID webpage for the most up to date information: **https://www.cdc.gov/coronavirus/2019-ncov/**

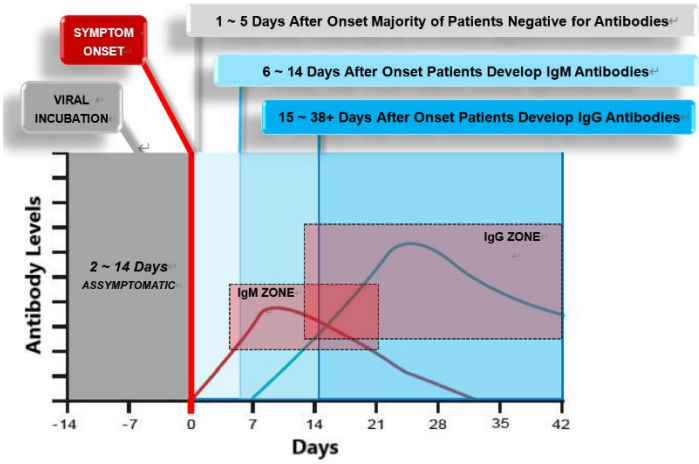
The BIOTRINETIX COVID-19 IgG/IgM Antibody Test measures human SARS-Co-V-2 antibodies (IgG and IgM) that are generated as part of the immune response to the Coronavirus SARS-CoV-2 and is to be conducted using only whole blood, serum or plasma specimens collected from individuals suspected of having a COVID infection.

What does a positive COVID-19 IgG and/or IgM antibodies test result mean?

When the BIOTRINETIX COVID-19 IgG/IgM Antibody Test provides a positive test result, it indicates that antibodies to SARS-CoV-2 were present, and that the patient has potentially been exposed to the COVID-19 virus. When IgM antibodies are detected, they can indicate that a patient has an active or recent infection with SARS-CoV-2. IgG antibodies develop later following infection, and generally do not begin to appear until 7 – 10 days after infection. Present IgG antibodies often reflect a past infection but do not exclude recently infected patients who are still contagious, especially if detected with IgM antibodies. Currently it is unknown how long IgM or IgG antibodies to the Coronavirus 2019 will remain present in the body after infection and if they confer immunity to infection.

Please note that a preliminary positive result for IgM or IgG does not conclusively mean that a patient's current symptoms are due to a COVID-19 infection. In addition to this test, laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and a patient's treatment decisions.

While it is unlikely that the BIOTRINETIX COVID-19 IgG/IgM Antibody Test will yield false positive test results, in the event of a false positive result, risks to patients could include the following:



• A recommendation for isolation/quarantine of patient
• Monitoring of household members or other close contacts for symptoms
• Patient isolation that may limit contact with family or friends and may increase contact with other potentially COVID-19-infected patients,
• Limits in the ability to work,
• A delayed diagnosis and treatment for the true infection causing the symptoms,
• The unnecessary prescription of a medicine, treatment or therapy or other unintended adverse effects.

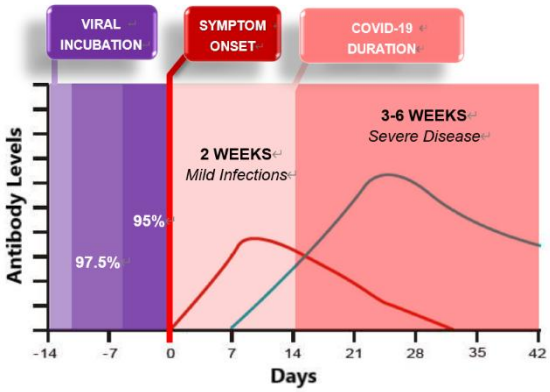
Standard confirmatory testing and reporting guidelines, according to their appropriate public health authorities, must be used by all laboratories using this test device.

A "Patient Information Guide: BIOTRINETIX COVID-19 IgG/IgM Antibody Test" should be provided to all patients whose specimens are tested with this in vitro diagnostic test device.

What does it mean if the specimen tests negative for IgG and/or IgM antibodies against virus that causes COVID-19?

When the BIOTRINETIX COVID-19 IgG/IgM Antibody Test displays a negative test result this indicates that the COVID-19 specific antibodies were not present in the specimen above the limit of detection. However, a negative result does not rule out possible infection with COVID-19 and should not be used as the sole basis for treatment, patient management decisions, or to rule out active infection.
False negative results may occur if:
• Patients tested too soon after infection may not have a detectable IgM antibody despite having an active infection.

• Not all patients will develop a detectable IgM and/or IgG response to SARS-CoV-2 infection. The absolute sensitivity of the BIOTRINETIX COVID-19 IgG/IgM Antibody Test is unknown.



In the event a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19 prompted screening but testing is negative, the possibility of a false negative result should be considered. This is especially important if the patient has had recent exposure to COVID-19, or clinical presentation indicates that COVID-19 is likely and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative.

Direct testing for the virus (e.g., PCR testing) should always be performed in any patient suspected of a COVID-19 infection, regardless of the BIOTRINETIX COVID-19 IgG/IgM Antibody Test. Risks to a patient of a false negative result include:

• Delayed or lack of treatment
• Lack of monitoring of infected individuals and their family/close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

Resources for Updates and Information:

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

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/lab/
• Laboratory Biosafety: https://www.cdc.gov/coronavirus/2019-nCoV/lab/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/lab/guidelines-clinical-specimens.html
• Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/

Emergency Use Authorization (EUA):

The FDA has made this test available for use under an emergency access mechanism referred to as the 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 COVID-19.
Please note however that an in vitro diagnostic made available under an EUA has not undergone the same type of review as an FDA-cleared or approved IVD. The FDA may issue an EUA when certain criteria are met:

• There currently are no adequate, approved, and/or available alternatives.

• Based on the totality of scientific evidence available, it is reasonable to believe that this in vitro diagnostic test may be effective in the detection of IgG/IgM antibodies to the SARS-CoV-2 virus.

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 under an EUA).

COVID-19 CPT Codes

On April 10, 2020, the American Medical Association (AMA) announced two new CPT Codes for accurate reporting and tracking of blood tests performed to specifically detect antibodies associated with the SARS-CoV-2 virus

• **86318**—Parent code
• **86328**—Child Code to parent code 86318 is to report a qualitative or semi-quantitative single-step method immunoassay for COVID-19 antibodies.

Other types of COVID-19 testing methods have their own CPT codes. Code 86769 falls under parent code 86710 and is specific to antibody tests using a multi-step method using a microtiter plate, while code 87635 is for detection using nucleic acid methods.

For questions about CPT Codes refer to the American Medical Association's Website at https://www.ama-assn.org/practice-management/cpt/covid-19-coding-and-guidance or check out their Assistant Guide at https://www.ama-assn.org/system/files/2020-04/cpt-assistant-guide-coronavirus-april-2020.pdf

IMPORTANT NOTE:
Report Adverse events, including problems with test performance or results, to MedWatch by calling **1-800-FDA-1088** or submitting the online FDA Form 3500

(https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)

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