FACT SHEET FOR HEALTHCARE PROVIDERS
Emergency Use of SARS-CoV-2 IgM/IgG Antibody Assay Kit
During the COVID-19 Pandemic

May 7, 2020

Coronavirus Disease 2019 (COVID-19)

This General Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of SARS-CoV-2 IgM/IgG Antibody Assay Kit.

A number of SARS-CoV-2 Antibody Tests are authorized for the detection of SARS-CoV-2 antibodies in human serum, heparin- and sodium citrate-anticoagulated plasma, or EDTA-anticoagulated whole blood.

All individuals whose specimens are tested with one of these tests will receive the Fact Sheet for Recipients: Emergency Use of SARS-CoV-2 IgM/IgG Antibody Assay Kit.

What are the symptoms of COVID-19?

Many individuals with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, fever, difficulty breathing, etc.). However, only 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 at 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 from 2 to 14 days.

Public-health officials have identified cases of COVID-19 infection throughout the world, including the United States, which poses risks to public health. Please check the CDC website for the most up-to-date information.

What do I need to know about COVID-19 antibody testing?

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

This test detects human SARS-CoV-2 IgM and IgG antibodies that are generated as part of the human adaptive immune response to the COVID-19 virus and is to be performed only on serum, heparin- and sodium citrate-anticoagulated plasma, or EDTA-anticoagulated whole-blood specimens.

- SARS-CoV-2 Antibody Tests can be ordered by healthcare providers to test human plasma or serum to detect if there has been an adaptive immune response to COVID-19, indicating recent or prior infection.
- SARS-CoV-2 Antibody Tests 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.
- SARS-CoV-2 Antibody Tests are 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.
- Please refer to the test-specific instructions for use for additional information.

Specimens should be collected with appropriate infection-control precautions. Current guidance for COVID-19 infection-control precautions is available at the CDC's website (see links provided in the "Where can I go for updates and more information?" section).

Use appropriate personal protective equipment (PPE) 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 the 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 "Where can I go for updates and more information?" section).

There are no approved alternative tests available. The FDA has issued EUAs for other antibody tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

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 SARS-CoV-2 antibodies were detected, and the individual has potentially been exposed to COVID-19. SARS-CoV-2 antibodies are generally detectable in blood several days after initial infection. Individuals may have detectable virus present for several weeks following seroconversion. If IgG antibodies are present, it often indicates a past infection but does not exclude recently-infected patients who are still contagious. ***It is unknown how long SARS-CoV-2 antibodies will remain present in the body after infection, and it is not known if they confer immunity to infection.***

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

The SARS-CoV-2 IgM/IgG Antibody Assay Kit 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 risk of infection by exposure to individuals 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 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-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 a final diagnosis and patient-management decisions.

All laboratories using this test must follow 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 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, not all patients will develop a detectable antibody in 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 SARS-CoV-2 IgM/IgG Antibody Assay Kit is unknown.

Risks to a patient of a false-negative result include: restriction of activities 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, and other unintended adverse events.

What is an EUA?
The United States (U.S.) FDA has made these tests available under an emergency access mechanism called an emergency use authorization (EUA). The EUA is supported by the secretary of the U.S. Department of Health and Human Services (HHS), declaring 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. The FDA may issue an EUA when certain criteria are met, which include 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. The EUA for the test you received is in effect for the duration of the COVID-19 declaration, justifying emergency use of IVDs, unless terminated or revoked by the FDA (after which the test may no longer be used).

Where can I go for updates and more information?

Centers for Disease Control and Prevention (CDC) website:
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/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/coronavirus/2019-ncov/hcp/infection-control-recommendations.html
Specimen Collection: https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html
https://www.cdc.gov/csels/dls/locs/2020/updated_interim_pui_guidelines_for_covid-19.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control.html

U.S. Food and Drug Administration (FDA) website:
General: www.fda.gov/novelcoronavirus
EUAs (including links to recipient fact sheet and manufacturer's instructions):
https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

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