This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the SARS-CoV-2 IgG assay.

SARS-CoV-2 IgG assay is authorized for the detection of IgG antibodies to SARS-CoV-2 in human serum (including collected using a serum separator tube), and plasma (ACD, CPD, CPDA-1, dipotassium EDTA, tripotassium EDTA, lithium heparin, lithium heparin in a separator tube, sodium citrate, sodium heparin).

> **All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Novel Coronavirus (COVID-19) Antibody - Patient FAQs.**

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, 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 throughout the world, including the United States, which poses risks to public health. Please check the CDC webpage for the most up to date information.

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

> **This test measures human SARS-CoV-2 IgG antibodies that are generated as part of the adaptive immune response to the virus and is to be performed only using human serum (including collected in a serum separator tube), and plasma (ACD, CPD, CPDA-1, dipotassium EDTA, tripotassium EDTA, lithium heparin, lithium heparin in a separator tube, sodium citrate, sodium heparin).**

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).

- SARS-CoV-2 IgG assay can 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.

- SARS-CoV-2 IgG 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 moderate or high complexity tests.

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 with the SARS-CoV-2 IgG assay indicates that antibodies to SARS-CoV-2 were detected, and the individual has potentially been exposed to COVID-19.

IgG antibodies are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

When IgG antibodies are present it often indicates a past infection but does not exclude recently infected individuals who are still contagious. It is unknown how long IgG antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection.

A positive result for IgG may not mean that an individual's current or past symptoms were due to COVID-19 infection. 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.

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 SARS-CoV-2 IgG assay 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: 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 individual, monitoring of household or other close contacts for symptoms, isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19-infected individuals, limits in the ability to work, or other unintended adverse effects.

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 the 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, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment, patient management decisions, or to rule out active infection.

Individuals tested early after infection may not have detectable IgG antibody despite active infection; in addition, not all individuals will develop a detectable IgG response to SARS-CoV-2 infection. The absolute sensitivity of the SARS-CoV-2 IgG assay 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. The possibility of a false negative result should especially be considered if the individual's recent exposure or clinical presentation indicate that COVID- 19 is likely 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 individual suspected of COVID-19, regardless of the SARS-CoV-2 IgG assay result.

Risks to an individual of a false negative result include: restriction of activities deemed acceptable for individuals with evidence of an IgG response to SARS-CoV-2, 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 IgG antibodies 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).

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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