



FACT SHEET FOR HEALTH CARE PROVIDERS

COVID-19 ELISA IgG Antibody

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 COVID-19 ELISA IgG Antibody Test.

The COVID-19 ELISA IgG Antibody Test is authorized for use on serum or plasma specimens from people suspected of previous coronavirus disease 2019 (COVID-19) by their health care provider.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Mount Sinai COVID-19 ELISA Antibody Test

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, 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 from 2-14 days.

Public health officials have identified cases of COVID-19 throughout the world, including in the United States. Please check the CDC webpage for the most up-to-date information.

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

Current information on COVID-19 for health care 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 COVID-19 ELISA IgG Antibody Test can be used to test serum or plasma specimens.
- The COVID-19 ELISA IgG Antibody Test can be ordered by a health care provider to detect if there has been an immune response to COVID-19 in the diagnosis of individuals suspected of previous SARS-CoV-2 infection.

This test measures human SARS-CoV-2 IgG antibodies that are generated as part of the human immune response to the virus, and is to be performed using only serum or plasma specimens collected from individuals suspected of COVID-19 by a health care provider. The test may also be used for identifying patients with higher titers of SARS-CoV-2 IgG antibodies, or for documenting IgG seroconversion during acute SARS-CoV-2 infection when necessary.

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**



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- The COVID-19 IgG ELISA 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 high-complexity tests.

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

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of being infected with 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 IgG antibodies against the virus that causes COVID-19?

A positive test result with the COVID-19 ELISA IgG Antibody Test indicates that antibodies to SARS-CoV-2 were detected, and the patient has potentially been exposed to COVID-19.

IgG antibodies develop later than IgM antibodies following infection, and generally do not begin to appear until 7 to 10 days after infection. When 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 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 a patient's current or past symptoms are 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.

The COVID-19 ELISA IgG Antibody Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: risk of infection by exposure to persons with active COVID-19.

All laboratories using this test must follow standard confirmatory testing and reporting guidelines according to their appropriate public health authorities.

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

A negative test result with this test means that SARS-CoV-2 specific antibodies were not detected in the specimen above the limit of detection. However, a negative result does not rule out previous COVID-19 and should not be used as the sole basis for treatment, patient management decisions, or to rule out possible active infection.

Patients tested early after infection may not have detectable IgG antibody despite active infection; in addition, not all patients will develop a detectable IgG response to SARS-CoV-2 infection. The absolute sensitivity of the COVID-19 ELISA IgG Antibody Test is unknown.

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.

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 virus (e.g., PCR testing) should always be performed in any patient suspected of acute COVID-19, regardless of the COVID-19 ELISA IgG Antibody Test result.

Risks to a patient of a false negative result include the restriction of activities deemed acceptable for patients with evidence of an IgG response to SARS-CoV-2

What is an EUA?

The United States Food and Drug Administration (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 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.

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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/lab/index.html>

Laboratory Biosafety:

<https://www.cdc.gov/coronavirus/2019nCoV/lab-biosafety-guidelines.html>

Specimen Collection:

<https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

Infection Control:

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/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/emergencysituations-medical-devices/emergency-use-authorizations>

Laboratory:

Mount Sinai Laboratory (MSL)
Center for Clinical Laboratories (CLIA# 33D1051889)
New York, NY -10029
Phone: (212) 659-8181

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