This General Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of certain SARS-CoV-2 Antibody Tests. For a list of the tests being referenced in this Fact Sheet, see https://www.fda.gov/media/137471/download

A number of SARS-CoV-2 Antibody Tests are authorized for the detection of antibodies to SARS-CoV-2 in human serum and/or plasma.

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

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). 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 antibody 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).

SARS-CoV-2 Antibody Tests can be ordered by healthcare providers to test human plasma or serum to detect antibodies that are generated as part of the human adaptive immune response to the SARS-CoV-2 virus and is to be performed on only plasma or serum specimens.

This test detects human SARS-CoV-2 antibodies that are generated as part of the human adaptive immune response to the SARS-CoV-2 virus and is to be performed on only plasma or serum specimens.

Be used as the 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 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 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).

There are no approved alternative tests. 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#2019-ncov.

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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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 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 antibodies to SARS-CoV-2 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 antibody test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, it may lead to the patient include the following: risk of infection 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’s household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may impact the patient’s ability to work, or other unintended adverse events. 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.

Laboratories using this test must follow standard confirmatory testing and reporting guidelines according to the appropriate public health authorities.

What does it mean if the specimen tests negative for antibodies against 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, patients tested early after infection may not have detectable antibodies despite active infection. In addition, not all patients will develop a detectable antibody response to SARS-CoV-2 infection. A negative result should not be used to rule out infection.

The absolute sensitivity of the SARS-CoV-2 antibody test is unknown.

False negative results may occur due to failure to capture disease related antibodies or other possible causes.

Laboratories using this test must follow standard confirmatory testing and reporting guidelines according to the appropriate public health authorities.

Due to the risk of false negative results, confirmation of negative 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.

Laboratories using this test must follow standard confirmatory testing and reporting guidelines according to the appropriate public health authorities.

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Where can I go for updates and more information?

**CDC webpages:**
- **General:** [https://www.cdc.gov/COVID19](https://www.cdc.gov/COVID19)

**FDA webpages:**
- **General:** [www.fda.gov/novelcoronavirus](http://www.fda.gov/novelcoronavirus)
- **EUAs:** (includes links to recipient fact sheet and manufacturer’s instructions) [https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations](https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations)

**Manufacturer Contact Information:**
Contact information for the manufacturer that developed the SARS-CoV-2 antibody test must be provided to the Authorized Laboratories performing the test and to healthcare providers receiving this fact sheet.

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