

FACT SHEET FOR HEALTHCARE PROVIDERS

New York SARS-CoV Microsphere Immunoassay for Antibody Detection –
Wadsworth Center

April 30, 2020

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 New York SARS-CoV Microsphere Immunoassay for Antibody Detection test.

The New York SARS-CoV Microsphere Immunoassay for Antibody Detection test is authorized for the detection of total antibody (IgG, IgM, and IgA) to SARS-CoV-2 in human serum.

All individuals whose specimens are tested with this assay will receive the Fact Sheet for Recipients: New York SARS-CoV Microsphere Immunoassay for Antibody Detection.

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?

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).

- The New York SARS-CoV Microsphere Immunoassay for Antibody Detection test can be ordered by healthcare providers to test human serum specimens as an aid in identifying individuals who may have high levels of SARS-CoV-2-reactive antibodies that reflect an adaptive immune response indicating recent or prior infection.

This test measures total human SARS-CoV-2 antibodies that are generated as part of the adaptive immune response to the virus and is to be performed only using human serum.

- The New York SARS-CoV Microsphere Immunoassay for Antibody Detection test 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.
- The New York SARS-CoV Microsphere Immunoassay for Antibody Detection test is only authorized for use at the Wadsworth Center, New York State Department of Health, which is 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 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 total human SARS-CoV-2 antibodies?

A positive test result with the New York SARS-CoV Microsphere Immunoassay for Antibody Detection test indicates that antibodies to SARS-CoV-2 were detected,

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and the individual has potentially been exposed to COVID-19.

The New York SARS-CoV Microsphere Immunoassay for Antibody Detection test detects total antibody as indicative of an adaptive immune response to SARS-CoV-2 infection in individuals suspected of SARS-CoV-2 infection. The New York SARS-CoV Microsphere Immunoassay for Antibody Detection test detects the presence of IgM, IgA, and/or IgG antibodies but does not identify each separately. IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although levels over the course of infection are not well characterized. IgG antibodies to SARS-CoV-2 become detectable later following infection, although detection of IgG antibodies does not exclude recently infected patients who are still contagious. Positive results for IgM, IgA, and IgG could occur after infection and can be indicative of acute or recent infection. It is unknown how long IgM, IgA, and/or 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 New York SARS-CoV Microsphere Immunoassay for Antibody Detection test 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.

The New York SARS-CoV Microsphere Immunoassay for Antibody Detection test has been designed to minimize the likelihood of false positive test results. False positive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes. 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 total human SARS-CoV-2 antibodies?

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 IgM and/or IgG response to SARS-CoV-2 infection. The absolute sensitivity of the New York SARS-CoV Microsphere Immunoassay for Antibody Detection test 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 New York SARS-CoV Microsphere Immunoassay for Antibody Detection test result.

Risks to an individual of a false negative result include: delayed or lack of supportive treatment, 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, 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

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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.

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 recipient fact sheet and manufacturer's instructions) <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

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