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ATTENTION

Public Health Alert

DATE: April 30, 2020

SUBJECT: **2019 NOVEL CORONAVIRUS (COVID-19) Antibody/Serology Testing - Updated Guidance**

As antibody testing becomes available in the community, physicians, other healthcare professionals, and the public should be aware of the limitations of such testing:

- COVID-19 antibody or serology testing **SHOULD NOT BE USED** for:
 - Diagnosing an individual with COVID-19
 - Establishing immunity to COVID-19
 - Determining when persons can safely return to work
 - Determining when to discontinue social isolation measures or appropriate precautions, including the use of PPE

- Most of the currently available COVID antibody test kits have not been FDA reviewed or approved.
- Even the few test kits that have been FDA reviewed and approved under an Emergency Use Authorization (EUA) have significant limitations in their sensitivity and specificity, which can yield either false positive or false negative results.

- Coronaviruses which cause the common cold may cross react with COVID-19 antibody tests and result in false positive COVID-19 results.

- COVID-19 antibody or serology testing is useful for:
 - Testing a population or large groups of people to determine the aggregate percent of a population that has been infected
 - Clinical studies
 - Determining if an individual is a candidate for plasma donation



DATE: April 30, 2020
TO: Clinical Laboratories, Limited Service Labs, Healthcare Providers, Healthcare Facilities, and Local Health Departments
FROM: NYS Department of Health (Department) Bureau of Surveillance and Data Systems (BSBS)

Health Advisory: COVID-19 Serology Testing

Background

Serological tests for determining the presence of antibodies against SARS-CoV-2 are now available from commercial manufacturers. Serology tests are used to determine if antibodies against SARS-CoV-2 are present. Certain serology tests can look for the general presence of SARS-CoV-2 antibodies, while others can determine if specific types of SARS-CoV-2 antibodies, such as IgM and/or IgG, are present.

FDA and Serological Testing

The US Food and Drug Administration (FDA) is allowing commercial manufacturers of COVID-19 serology tests to distribute these tests to laboratories once they notify the FDA that they have validated their test. A list of manufacturers that have notified the FDA can be found at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2>.

Although there are manufacturers that have notified the FDA that their tests have been validated, and the FDA has approved the distribution of the tests, the data demonstrating the accuracy and reliability of the tests has not been reviewed by the FDA. In addition, these tests have not necessarily been granted approval under the FDA's Emergency Use Authorization (EUA) process. Tests being distributed prior to the approval under the FDA's EUA process can only be performed by laboratories approved to conduct high complexity testing. **These tests are not considered waived and, therefore, cannot be used at the point of care.**

Laboratories using COVID-19 serological tests from these commercial manufacturers are required to include specific disclaimers when issuing test results, including the following:

- This test has not been reviewed by the FDA.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in recent contact with the virus. Follow-up testing with a molecular diagnostic test should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection, or to inform infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

The FDA is currently working to review validation data for COVID-19 serological tests and has begun the process to grant EUA approvals. COVID-19 serological tests that have been granted EUA approval can be found at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>.

Currently, facilities approved as a limited service laboratory (LSL) are not allowed to perform testing for SARS-CoV-2 antibodies, since there are no approved waived tests at this time. EUA approval does not mean approval for use at the point of care. The manufacturer's instruction/package insert (available at the link above) must be reviewed to determine if the test is intended to be used by a laboratory approved to perform high and/or moderate complexity tests, or if it can be used in patient care settings outside of the clinical laboratory environment (i.e., at the point of care). Laboratories should continue to check the FDA website for the latest testing authorizations.

NYSED Requirements

Licensure through the New York State Education Department (NYSED) is not currently required for technical staff performing testing for SARS-CoV-2 antibodies. [Executive Order 202.16](#) temporarily suspended the requirement for NYSED licensure to permit individuals to perform testing for the detection of SARS-CoV-2 antibodies in specimens collected from individuals suspected of suffering from a COVID-19 infection. However, individuals performing testing must meet the federal requirements for testing personnel appropriate to the assay or device authorized by the FDA or the New York State Department of Health.

New York State Testing Protocol

On April 26, 2020, the Department issued [Updated Interim Guidance: Protocol for COVID-19 Testing Applicable to All Health Care Providers and Local Health Departments](#) which includes guidance about when diagnostic and/or serologic testing for COVID-19 shall be authorized by a health care provider and the prioritization of testing. Specifically, testing shall be authorized by a health care provider when:

- An individual is symptomatic or has a history of symptoms of COVID-19 (e.g. fever, cough, and/or trouble breathing), particularly if the individual is 70 years of age or older, the individual has a compromised immune system, or the individual has an underlying health condition; or
- An individual has had close (i.e. within six feet) or proximate contact with a person known to be positive with COVID-19; or
- An individual is subject to a precautionary or mandatory quarantine; or
- An individual is employed as a health care worker, first responder, or other essential worker who directly interacts with the public while working; or
- An individual presents with a case where the facts and circumstances – as determined by the treating clinician in consultation with state or local department of health officials – warrant testing.

All laboratories in the state, both public and private, that conduct COVID-19 diagnostic testing, must complete COVID-19 diagnostic testing in accordance with [Executive Order 202.19](#), issued on April 17, 2020.

To assist healthcare providers in their discussions with patients about what their test result may mean for them, the following questions and answers (Q&A's) are provided:

Q: What is SARS-CoV-2?

A: SARS-CoV-2 is the name for the virus that causes COVID-19. It is part of a large family of coronaviruses, all of which typically cause respiratory disease in humans.

Q: What are antibodies?

A: Antibodies are proteins that develop when the immune system responds to a pathogen, such as a virus. There are different types of antibodies, including ones called IgM and IgG. IgM is the first antibody that develops after someone has an acute viral infection. This is followed by the development of IgG antibodies. Once IgG antibodies have been developed, if a person comes into contact with the same virus again, the IgG antibodies help the immune system respond faster and more effectively than it did the first time and may prevent illness.

Q: If a serology test for SARS-CoV-2 antibodies is negative, does this mean I do not have the virus?

A: No. A serology test looks for the presence of proteins, called antibodies, which can be used to help understand if you were exposed to the virus recently or in the past. A person with a negative serology test could have the SARS-CoV-2 virus, but it is too early to detect the antibodies on the serology test. Only a molecular diagnostic test can be used to determine the presence or absence of the virus. Results from a serology test should not be used as the sole basis for diagnosing if someone had COVID-19.

Q: If a serology test for SARS-CoV-2 antibodies is negative, but I had a molecular test that said I was infected with the virus, what does this mean?

A: A person with a negative serology test could have the SARS-CoV-2 virus, but the serology test is negative because it is too early to detect the antibodies since these take time for the body to develop. A person can also have a negative serology test because their immune system did not make enough of the antibodies to be detected by the test after they were infected. Your healthcare provider will talk with you about what the next steps should be, which may include repeating the serology test in the future.

Q: If the serology test is positive, does that mean that I have antibodies to the SARS-CoV-2 virus?

A: If the test used is only able to detect antibodies to SARS-CoV-2, then yes, a positive test would indicate that you have antibodies to the SARS-CoV-2 virus. However, some tests that detect antibodies to SARS-CoV-2 can yield false positive results due to infection from other related coronaviruses; for these tests, a positive result may indicate a previous exposure to a related virus and/or exposure to SARS-CoV-2. Your healthcare

provider will talk with you about what a positive serology test may mean for you based on the kind of test that was used.

Q: If the serology test is positive and shows that I have antibodies to SARS-CoV-2, does that mean I am immune to the virus?

A: Based on our knowledge of how the body reacts to an infection, we presume that the presence of IgG antibodies could mean that you have some level of immunity to a virus. However, at this time, it is unclear whether the presence of SARS-CoV-2 IgG antibodies will result in immunity to prevent future COVID-19 infections. We will better understand immunity to SARS-CoV-2 as we study what happens to people who test positive for SARS-CoV-2 IgG antibodies and are again exposed to SARS-CoV-2, to determine if any of them are confirmed to have new infections.

Q: If the serology test is positive and shows that I only have IgM antibodies to SARS-CoV-2, does that mean I currently have COVID-19?

A: No, only a molecular diagnostic test can be used to determine the presence or absence of the virus. Results from a serology test should not be used as the sole basis for diagnosing if someone has or recently had COVID-19, but it can be used to screen individuals who should receive molecular testing.