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PUBLIC HEALTH ADVISORY

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Subject: **Testing for COVID-19 – Antibody Testing**
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Testing for COVID-19 – Antibody Testing

Summary: Antibody-based tests for the detection of antibodies against coronaviruses are now available through commercial laboratories. Only a select few of these tests are specific for SARS-CoV-2, the virus that causes COVID-19. Providers should review the COVID-19 Antibody Testing Primer from the Infectious Disease Society of America (IDSA) about serology-based tests for COVID-19.

In general, two kinds of tests are available for COVID-19: **viral tests** and **antibody tests**.

A **viral test,** such as the current PCR test used in Maine's reference laboratories and the Health and Environmental Testing Laboratory (HETL), indicates a current infection.

1. A "positive" viral test indicates that the test has detected viral RNA and the person is infected. A person can continue to shed inactive virus after initial illness.
2. A "negative" test means that the person was probably not infected at the time the sample was collected. However, the person could still become ill in the future.

An **antibody test** looks to see if the person had a previous infection. There are many different antibody tests for COVID-19 with variable performance. The antibody response in COVID-infected patients is not yet known, and the clinical value of antibody testing has not been fully demonstrated. At this time, no antibody test is validated for diagnosis of COVID-19 infection.

1. A "positive" antibody test is difficult to interpret because the performance of these tests is not well characterized. It likely indicates prior infection with SARS-CoV-2 or a related coronavirus.
    - It is unclear if those antibodies can provide protection (immunity) against getting infected again.
2. A "negative" antibody test indicates that the person probably did not have a previous infection.
    - The person could have a current infection.

- Antibodies do not appear for 1 to 3 weeks after infection. Some people may take even longer to develop antibodies, and some people may not develop antibodies. Thus, a person could have been infected and still spread the virus before antibodies are detected.

Important things to note about antibody testing:

1. All SARS-CoV-2 antibody tests must be reported to Maine CDC under the notifiable conditions rule. Individuals who are antibody positive may meet the Probable case definition for COVID-19, and all antibody positive results will be investigated by Maine CDC.

2. An antibody test alone cannot tell if someone has COVID-19. Antibody testing should not be used as the sole test for diagnostic decisions. It can take 1-3 weeks after infection for antibodies to be detectable. If a patient is symptomatic, collect an upper respiratory tract specimen for testing by PCR.

3. Providers should be acquainted with the characteristics of the various antibody tests, noting the possibility of false-negative results (especially from use too early following symptoms) and false-positive results (especially from cross-reactivity to commonly circulating coronaviruses such as HKU1, NL63, OC43, or 229E). These would be noted in the product insert for the test and may be noted in the laboratory report.

4. A positive antibody test should not be used to make decisions about a person's potential to infect others, nor should it be used to make decisions about a person's immune status.

    - Until there is more evidence about protective immunity, serology results should not be used to make staffing decisions or decisions regarding the need for personal protective equipment.
    - Health care workers with positive serology should still use personal protective equipment in the care of suspect or confirmed COVID-19 patients.

5. It is not known how a positive test, or specific antibody levels, correlate with a person's immunity, nor is it known how long protection may last.

6. Whether a patient tests positive or negative for COVID-19 by a viral test or an antibody test, the patient should continue to take preventive measures to protect themselves and continue to practice physical distancing.

References

Federal Centers for Disease Control and Prevention: https://www.cdc.gov/coronavirus/2019-ncov/testing/index.html

Infectious Diseases Society of America (IDSA) COVID-19 Antibody Testing Primer https://www.idsociety.org/globalassets/idsa/public-health/covid-19/idsa-covid-19-antibody-testing-primer.pdf

Food and Drug Administration (FDA): https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#sarscov2antibody and https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#serology.

Maine Center for Disease Control and Prevention (Maine CDC) www.maine.gov/dhhs/coronavirus