



This is an official DHEC Health Update

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COVID-19 Antibody Testing Guidance

Summary

- CDC has released additional [guidance](#) on antibody testing for COVID-19
- In general, use of serology tests should currently be limited to population-level seroprevalance study, evaluation of recovered individuals for convalescent plasma donations, and in other situations where they are used as part of a well-defined testing plan and in concert with other clinical information by physicians well-versed in interpretation of serology test results.
- Serologic testing should not be used to determine immune status in individuals until the presence, durability, and duration of immunity is established.
- Serologic testing can be offered as a method to support diagnosis of acute COVID-19 illness for persons who present late. For persons who present 9-14 days after illness onset, serologic testing can be offered in addition to recommended direct detection methods such as polymerase chain reaction. This will maximize sensitivity as the sensitivity of nucleic acid detection is decreasing and serologic testing is increasing during this time period.
- Serologic testing should be offered as a method to help establish a diagnosis when patients present with late complications of COVID-19 illness, such as multisystem inflammatory syndrome in children (MIS-C).
- Currently, there is no identified advantage of assays whether they test for IgG, IgM and IgG, or total antibody.
- It is important to minimize false positive test results by choosing an assay with high specificity and by testing populations and individuals with an elevated likelihood of previous exposure to SARS-CoV-2.
- The significance of IgA in this disease is still to be determined and testing for IgA antibodies to COVID-19 is not recommended. Serologic testing should not be used to make decisions about groupings in congregate settings like schools dormitories, or correctional facilities, and should not be used for return-to-work decisions.

Background information regarding serology-based testing

This Health Alert updates interim [guidance](#) from the Centers for Disease Control and Prevention (CDC) on antibody testing and supplements guidance provided in previous DHEC and CDC [HANS](#).

While the FDA currently requires all commercially marketed serological tests to apply for and receive an Emergency Use Authorization (EUA) to market these tests to the public, the FDA does not automatically independently verify performance of each of these tests and primarily relies on submitting manufacturers to self-validate their offerings. For tests that are not commercially marketed, such as laboratory developed tests (LDTs), FDA authorization is not required.

Recently, concern has been growing over both test performance and fraudulent labeling of a number of currently marketed tests. While many tests with FDA authorization are relatively high-performing, a number of tests currently on the market are not. Physicians should pay close attention to the regulatory status of any test offered. FDA maintains a [listing of all serological tests](#) authorized for use for COVID-19.

Limitations of serology testing

Physicians and the general public need to be aware that serology tests, in general, have several limitations that make correct interpretation of the results critical. Serological tests for SARS-CoV-2 antibodies, in particular, present even greater challenges, as much is still unknown about immune status for the novel virus. Some limitations to be aware of include:

- **False positive results:** Serological testing for disease with a low prevalence in the population presents inherent challenges with interpretation of positive results. Even high performing tests (e.g. high sensitivity and specificity) will return false positive results when disease prevalence is low, as is currently the case with COVID-19. Take, for example, a community of 100 individuals with a disease prevalence of 5%. If a serological test with a specificity of 95% was used in this population, it would be expected to return 5% false positives, so 5 out of the population of 100. Five true positives would also be expected, as the disease prevalence is 5%. Overall, this test would return 10 positive results, however, only 50% of the results would be accurate, showing the inherent limitation of these types of tests in low disease prevalence areas. Once disease prevalence is higher, the concern about false positives becomes somewhat mitigated, however, this is not the current reality with COVID-19.
- **Cross-reactivity:** While this may not be true of all serology tests for SARS-CoV-2, cross-reactivity has been a noted concern among some offered tests. Cross-reactivity occurs when a test for antibodies for SARS-CoV-2 identifies not only antibodies for this virus, but also for other coronaviruses, such as those causing the common cold. For tests where cross-reactivity is possible, antibodies for other coronaviruses may result in a positive test result for SARS-CoV-2 even when the patient in question was not infected (another example of a false positive test).
- **False negative results:** since antibodies can take weeks to develop and be detected on serology testing, individuals may falsely test negative for SARS-CoV-2 when they are acutely infected. This “window period” between infection and antibody detection also reduces the usefulness of the serology test in certain contexts.
- **Immune status:** Given that SARS-CoV-2 is a novel virus, there is much we do not know about what, if any, immunity it may confer to those exposed and recovered from infection. According to the World Health Organization (WHO), currently there is no available evidence showing immunity to COVID-19 after infection. While individuals typically develop some type of immune response after exposure to most viruses, it is not yet clear when an immune response develops after COVID-19 infection, how strong this immune response may be, and how long the immune response may last. There is also no definitive evidence what concentration of antibodies is needed to confer protection.

Resources for Additional Information

Interim Guidelines for COVID-19 Antibody Testing

<https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html>

Serological testing for SARS-CoV-2 antibodies

<https://www.ama-assn.org/delivering-care/public-health/serological-testing-sars-cov-2-antibodies>

DHEC contact information for reportable diseases and reporting requirements

Reporting of **COVID-19 cases and deaths**, including MIS-C, is consistent with South Carolina Law requiring the reporting of diseases and conditions to your state or local public health department. (State Law # 44-29-10 and Regulation # 61-20) as per the DHEC 2020 List of Reportable Conditions available at:

<https://www.scdhec.gov/sites/default/files/Library/CR-009025.pdf>

Federal HIPAA legislation allows disclosure of protected health information, without consent of the individual, to public health authorities to collect and receive such information for the purpose of preventing or controlling disease. (HIPAA 45 CFR §164.512).

Regional Public Health Offices – 2020			
Mail or call reports to the Epidemiology Office in each Public Health Region			
MAIL TO:			
<u>Lowcountry</u> 4050 Bridge View Drive, Suite 600 N. Charleston, SC 29405 Fax: (843) 953-0051	<u>Midlands</u> 2000 Hampton Street Columbia, SC 29204 Fax: (803) 576-2993	<u>Pee Dee</u> 1931 Industrial Park Road Conway, SC 29526 Fax: (843) 915-6502 Fax2: (843) 915-6506	<u>Upstate</u> 200 University Ridge Greenville, SC 29602 Fax: (864) 282-4373
CALL TO:			
<u>Lowcountry</u> Allendale, Bamberg, Beaufort, Berkeley, Calhoun, Charleston, Colleton, Dorchester, Hampton, Jasper, Orangeburg Office: (843) 441-1091 Nights/Weekends: (843) 441-1091	<u>Midlands</u> Aiken, Barnwell, Chester, Edgefield, Fairfield, Kershaw, Lancaster, Lexington, Newberry, Richland, Saluda, York Office: (888) 801-1046 Nights/Weekends: (888) 801-1046	<u>Pee Dee</u> Clarendon, Chesterfield, Darlington, Dillon, Florence, Georgetown, Horry, Lee, Marion, Marlboro, Sumter, Williamsburg Office: (843) 915-8886 Nights/Weekends: (843) 915-8845	<u>Upstate</u> Abbeville, Anderson, Cherokee, Greenville, Greenwood, Laurens, McCormick, Oconee, Pickens, Spartanburg, Union Office: (864) 372-3133 Nights/Weekends: (864) 423-6648
For information on reportable conditions, see https://www.scdhec.gov/ReportableConditions		<u>DHEC Bureau of Communicable Disease Prevention & Control</u> Division of Acute Disease Epidemiology 2100 Bull St • Columbia, SC 29201 Phone: (803) 898-0861 • Fax: (803) 898-0897 Nights / Weekends: 1-888-847-0902	

Categories of Health Alert messages:

Health Alert	Conveys the highest level of importance; warrants immediate action or attention.
Health Advisory	Provides important information for a specific incident or situation; may not require immediate action.
Health Update	Provides updated information regarding an incident or situation; unlikely to require immediate action.
Info Service	Provides general information that is not necessarily considered to be of an emergent nature.