



This is an official **DHEC Health Update**

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COVID-19 Antibody Testing for Immunity & Return-to-Work Decisions

Summary

- Serologic tests should not be used to diagnose acute COVID-19 infection, nor should they be used to determine immune status to COVID-19. They may produce false negative or false positive results, the consequences of which include providing individuals incorrect guidance on preventive interventions like physical distancing or protective equipment.
- If COVID-19 is suspected as a diagnosis, DHEC recommends PCR-based testing, if
 possible. Likewise, the FDA recommends that providers not use serological (antibody)
 tests as the sole basis to diagnose COVID-19; serology results may provide information
 about whether a person may have been exposed to COVID-19 in the past.

Background

Antibody tests may have promise to inform treatments, disease surveillance, and determination of immunity after infection. Communities and employers are thus rightfully interested in the potential for antibody tests to inform status on community-wide immunity or decisions for when employees can safely return-to-work after COVID-19 infection, particularly if infection was mild or with no symptoms.

While over 90 tests exist on the market, the Food and Drug Administration (FDA) has granted emergency use authorization for COVID-19 antibody tests to very few. The following information is currently not well studied and needs to be better understood before antibody testing, even if FDA authorized, can be effectively used:

- 1. Understanding of when and for how long antibodies are produced in a person during the course of COVID-19 disease
- 2. Understanding of what antibody level, if any, confers immunity to COVID-19 disease and for how long

3. Evidence for how well a particular test detects SARS-CoV-2 antibodies consistently

The development of reliable serologic assays that accurately assess prior infection with COVID-19 will be essential in the future for epidemiologic studies, ongoing surveillance, vaccine studies, and potentially for risk assessment of health care workers. DHEC recommendations on the reliability of available serology assays for COVID-19 infection may change as more data become available, at which time further guidance will be issued.

Recommendations

- Given the current lack of evidence that detection of COVID-19 antibody on any serologic test is indicative of durable immunity, it should <u>not</u> be used to determine <u>immune status</u> or <u>return-to-work recommendations</u>, nor should it be the sole test for <u>evaluating an</u> <u>acutely ill patient</u> for COVID-19.
- Patients with <u>symptoms consistent with COVID-19</u> are recommended to have an <u>nasopharyngeal (NP) swab</u> for nucleic acid amplification testing (NAAT) to confirm infection (see reporting criteria and recommendations on evaluating for testing <u>here</u>).
- If collection of an NP swab is not possible for a <u>symptomatic patient suspected to have</u> <u>COVID-19</u>, they should be advised to complete the same isolation period a confirmed positive would regardless of serology results (guidelines to end isolation available <u>here</u>).
- If the patient has <u>no symptoms</u> but has a <u>positive immunoglobulin M (IgM)</u> (or IgM/IgG total without a separate IgM level) on a serologic test, they should be asked to isolate for seven (7) days after the specimen was collected. Although the significance of the IgM result in the tests is not known at this time, this recommendation is provided out of an abundance of caution based on the possibility that the IgM may indicate an acute infection. Any patients with symptoms should complete the same isolation period as a NAAT confirmed positive case.
- Any patients with positive lab results (serology or NAAT) suggestive of COVID-19 should be reported to the regional health department at the contact information below. As a reminder, both cases and deaths from COVID-19 are considered <u>Urgently Reportable</u> by phone within 24 hours.

DHEC contact information for reportable diseases and reporting requirements

Reporting of COVID-19 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:			
Lowcountry 4050 Bridge View Drive, Suite 600 N. Charleston, SC 29405 Fax: (843) 953-0051	Midlands 2000 Hampton Street Columbia, SC 29204 Fax: (803) 576-2993	Pee Dee 1931 Industrial Park Road Conway, SC 29526 Fax: (843) 915-6502 Fax2: (843) 915-6506	Upstate 200 University Ridge Greenville, SC 29602 Fax: (864) 282-4373
CALL TO:			
Lowcountry Allendale, Bamberg, Beaufort, Berkeley, Calhoun, Charleston, Colleton, Dorchester, Hampton, Jasper, Orangeburg Office: (843) 441-1091 Nights/Weekends: (843) 441-1091	Midlands Aiken, Barnwell, Chester, Edgefield, Fairfield, Kershaw, Lancaster, Lexington, Newberry, Richland, Saluda, York Office: (888) 801-1046 Nights/Weekends: (888) 801-1046	Pee Dee Clarendon, Chesterfield, Darlington, Dillon, Florence, Georgetown, Horry, Lee, Marion, Marlboro, Sumter, Williamsburg Office: (843) 915-8886 Nights/Weekends: (843) 915-8845	Upstate 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 <u>https://www.scdhec.gov/ReportableConditions</u>		DHEC Bureau of Communicable Disease Prevention & Control 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	

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