



This is an official DHEC Health Update

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Reporting of all COVID-19 Laboratory Results

Summary

- All testing results (positive, negative, and indeterminate) for <u>Coronavirus</u>
 <u>Infectious Disease 2019 (COVID-19) must be reported to DHEC</u> within 24 hours.

 This includes the results of rapid tests done in any setting.
- Medical providers who order in home COVID-19 testing for patients are also required to report the results of those tests to DHEC.

Background

With increasing testing capacity throughout the state, this Health Alert is intended to provide a reminder on the required reporting of all positive, negative, and indeterminate COVID-19 test results. The public health response to COVID-19 in South Carolina depends on comprehensive testing data, as these data contribute to understanding COVID-19's impact and testing coverage.

Anyone ordering and/or performing rapid testing in any setting must report those results to DHEC within 24 hours. Medical providers ordering in home testing for patients are responsible for reporting the results of those tests.

This HAN supplements and updates previous South Carolina Department of Health and Environmental Control (DHEC) guidance provided <u>August 29th</u>, <u>2020</u>, in addition to other guidance.

Who Must Report

South Carolina Law §44-29-15 and Regulation §61-20 requires reporting of <u>all COVID-19 test results</u> (positive, negative, and indeterminate) to DHEC. This includes, but is not limited to, all laboratories, within or outside the state, which collect specimens in South Carolina, or which receive the initial order for testing from a practitioner, blood bank, plasmapheresis center, or other health care provider located in South Carolina.

COVID-19 testing sites are defined as:

- Laboratories that perform clinical diagnostic or screening testing under CLIA,
- Non-laboratory COVID-19 diagnostic or screening testing locations, and
- Other facilities or locations offering COVID-19 point-of-care diagnostic or screening tests, or in-home diagnostic or screening tests (i.e. schools, nursing homes, long-term care facilities, correctional facilities, etc.)

This requirement applies to all testing for COVID-19 including, but not limited to:

- Molecular Testing: Nucleic acid amplification test (NAAT), RT-PCR test, LAMP test
- Antigen Testing: Rapid, point-of-care diagnostic test, Saliva-based antigen test
- Antibody testing: Serology test, blood test
- Combination tests: Influenza SARS-CoV-2 Multiplex Assay

What to Report

All <u>COVID-19 test results, including positive, negative, and indeterminate must be</u> reported to DHEC. Complete test results must include the following data elements when reporting a COVID-19 case:

- Patient's full name (First, Middle, Last)
- Patient's complete address, phone number, county of residence, date of birth, race, sex, and the last five digits of social security number
- Physician's name and phone number
- Name, institution, and phone number of person reporting
- Disease or condition
- Date of diagnosis
- Symptoms
- Date of onset of symptoms
- · Lab results, specimen site, collection date
- If female, pregnancy status
- Patient status: In childcare, food-handler, health care worker, childcare worker, nursing home, prisoner/detainee, and travel in last 4 weeks

How to Report

All <u>test results</u>, including <u>positive</u>, negative, and indeterminate must be urgently reported to DHEC within 24 hours. Positive tests results must be reported by phone within 24 hours to the regional DHEC office <u>unless</u> the provider or facility has the capability to submit all test results to DHEC using an approved electronic reporting option, including Electronic Lab Reporting (ELR), DHEC's secure web-based reporting portal (SCIONx), Comma-Separated Value (CSV) file transmitted via secure FTP site.

Facilities that are not already submitting results via ELR or SCIONx should contact MUHELPDESK@dhec.sc.gov to inquire about ELR submission, or SCIONHELP@dhec.sc.gov to inquire about SCIONx and other electronic reporting options. Additional information regarding disease reporting can be found on DHEC's List of Reportable Conditions.

Considerations for Reporting

Federal Health Insurance Portability and Accountability Act (HIPAA) 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).

The Coronavirus Aid, Relief, and Economic Security (CARES) Act requires every COVID-19 testing site to report every diagnostic and screening test performed to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (e.g., molecular, antigen, antibody) to the Secretary of the U.S. Department of Health and Human Services (HHS) (See Public Law 116-136, § 18115(a)). CARES Act, requires anyone who orders a COVID-19 test, collects a specimen, or performs a laboratory test is required to collect complete demographic information. Ordering providers should make every effort to collect this critical information from patients during the specimen collection process and provide it to the laboratories performing the test.

The Secretary of HHS is requiring that all data be sent to state or local public health departments using existing reporting channels (in accordance with state law or policies) to ensure rapid initiation of case investigations by those departments, concurrent to laboratory results being shared with an ordering provider, or patient as applicable. It is also applied to point-of-care testing and at-home specimen collection (See CARES Act Section 18115).

Clinical Research Trials and Studies

For information regarding reporting of laboratory results for clinical research trials and studies, please see the Centers for Disease Control and Prevention's (CDC's) updated resource on Reporting Lab Data.

K-12 School Antigen Test Reporting

As mandated by the CARES Act, schools are required to report all diagnostic and screening tests performed to the appropriate state or local health department. In addition, school administrators should notify staff, teachers, families, and/or emergency contacts or legal guardians immediately of any case of COVID-19 while maintaining confidentiality in accordance with <u>HIPAA</u>, Americans with Disabilities Act (ADA), Family Educational Rights and Privacy Act (FERPA), and other applicable laws and regulations.

DHEC contact information for reportable diseases and reporting requirements

Reporting of <u>COVID-19 laboratory results</u> (<u>positive</u>, <u>negative</u>, <u>and</u> <u>indeterminate</u>), <u>deaths</u>, <u>and associated Multisystem Inflammatory Syndrome</u> <u>in Children (MIS-C)</u> 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	Midlands	Pee Dee	<u>Upstate</u>
4050 Bridge View Drive, Suite 600	2000 Hampton Street	1931 Industrial Park Road	200 University Ridge
N. Charleston, SC 29405	Columbia, SC 29204	Conway, SC 29526	Greenville, SC 29602
Fax: (843) 953-0051	Fax: (803) 576-2993	Fax: (843) 915-6506	Fax: (864) 282-4373
CALL TO:			
Lowcountry Allendale, Bamberg, Beaufort,	Midlands Aiken, Barnwell, Chester,	Pee Dee Clarendon, Chesterfield,	Upstate Abbeville, Anderson, Cherokee,
Berkeley, Calhoun, Charleston,	Edgefield, Fairfield, Kershaw,	Darlington, Dillon, Florence,	Greenville, Greenwood,
Colleton, Dorchester, Hampton, Jasper, Orangeburg	Lancaster, Lexington, Newberry, Richland, Saluda, York	Georgetown, Horry, Lee, Marion, Marlboro, Sumter, Williamsburg	Laurens, McCormick, Oconee, Pickens, Spartanburg, Union
Office: (843) 441-1091	Office: (888) 801-1046	Office: (843) 915-8886	Office: (864) 372-3133
Nights/Weekends: (843) 441-1091	Nights/Weekends: (888) 801-1046	Nights/Weekends: (843) 915-8845	Nights/Weekends: (864) 423-6648
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For information on reportable conditions, see https://www.scdhec.gov/ReportableConditions

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

Categories of Health Alert messages:

Health Alert Conveys the highest level of importance; warrants immediate action or attention.

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