



This is an official DHEC Health Update

Distributed via Health Alert Network
March 31, 2022; 10:00 AM
10511-DHU-03-31-2022-COVID-report

COVID-19 Reporting Requirements

Summary

On March 8, 2022, the U.S. Department of Health and Human Services (HHS) updated its COVID-19 [Laboratory Data Reporting Guidance](#). Based on this guidance, DHEC has updated the South Carolina reporting requirements. These requirements go into effect on April 1, 2022.

This DHEC Health Update provides reminders and updated guidance on reporting of COVID-19 laboratory results and COVID-19-associated conditions for South Carolina residents. It replaces previous reporting requirements and reflects more tailored reporting requirements that are specific to entity and test type.

Updated Reporting Guidance

In accordance with SC laws and regulations, DHEC requires reporting of COVID-19 cases and laboratory test results related to the detection or characterization of SARS-CoV-2 as follows:

- **Positive, negative, and inconclusive results for SARS-CoV-2 Nucleic Acid Amplification (NAAT) testing:** Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories that are certified to perform moderate- or high-complexity testing must report all NAAT (e.g., RT-PCR) test results (i.e., positive, negative, inconclusive) within 24 hours. This includes, but is not limited to, NAAT testing performed for SARS-CoV-2 by clinical laboratories, including public health, commercial, healthcare system, and academic laboratories.
- **Whole genome sequencing (WGS):** All patient-specific results and analyses of WGS must be reported within 24 hours, regardless of CLIA certification status of the laboratory. CDC has provided [guidance](#) for reporting these results (updated March 21, 2022). As a reminder, laboratories must meet all applicable CLIA-certifications if they intend to report these results directly to providers or patients when the result is requested to diagnose, prevent, treat, or assess health status of an individual.
- **All other SARS-CoV-2 testing (except antibody and self-administered testing):** Entities conducting all other SARS-COV-2 testing (e.g., testing conducted in a setting operating under a CLIA certificate of waiver, non-NAAT testing conducted in a facility certified under CLIA to perform moderate- or high-complexity tests) except antibody and self-administered testing, must report all positive test results. Entities should not report negative results of those tests, whether individual test results or in aggregate. This includes rapid testing conducted in many settings (e.g., screening

testing at schools, correctional facilities, employee testing programs, long-term care facilities, and point-of-care testing performed in pharmacies, medical provider offices, and drive-through testing sites.)

- **SARS-CoV-2 antibody testing:** Results from antibody tests, whether positive, negative, or inconclusive), are no longer reportable by any facility.
- **COVID-19 vaccine breakthrough cases:** Patients meeting the vaccine breakthrough case definition are no longer reportable by any healthcare provider.

Reporting Requirements of COVID-19 Test Results by Entity and Test Type

Test Type and Entity	Is Reporting Required Under this Guidance?		Examples
	Positive Results	Negative & Inconclusive Results	
NAAT-testing conducted in a facility certified under CLIA to perform moderate- or high-complexity tests	Required	Required	<ul style="list-style-type: none"> • Laboratory-based Nucleic Acid Amplification Test (NAAT) testing, including RT-PCR, TMA, LAMP, and SDA tests • See https://www.cdc.gov/coronavirus/2019-ncov/lab/naats.html for more information
Whole genome sequencing (WGS) conducted in both non CLIA and CLIA-certified facilities	Required	Required	Test performed to determine what SARS-CoV-2 variant (genetic lineage) is present in a positive specimen
All other testing	Required	Do not report	<ul style="list-style-type: none"> • Testing conducted in a setting operating under a CLIA certificate of waiver such as rapid tests used in many settings (e.g., screening testing at schools, correctional facilities, employee testing programs, long-term care facilities, and point-of-care testing performed in pharmacies, medical provider offices, and drive-through and pop-up testing sites) • Non-NAAT (e.g., high throughput antigen) testing conducted in a facility certified under CLIA to perform moderate or high-complexity tests
Antibody Testing	Do not report	Do not report	Tests used to determine previous infection with SARS-CoV-2 in any setting

Reminders

- All COVID-19 associated deaths and cases of multi-system inflammatory syndrome in children (MIS-C) must be reported within 24 hours of determination to the [regional health department](#) responsible for the county in which they occur.

- Over-the-counter (OTC) at home tests with no provider or laboratory oversight should not be reported (see [HAN](#) from May 24, 2021 for details). At home tests ordered by providers must have their results reported by the provider.

How to Report

Deaths related to COVID-19 and MIS-C cases are urgently reportable by phone to the [regional health department](#). Positive test results must be reported by phone within 24 hours to the regional DHEC office unless the provider or facility has the capability to submit all reportable 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](#).

Resources for Additional Information

SC DHEC. List of reportable conditions. Available at <https://scdhec.gov/health-professionals/south-carolina-list-reportable-conditions>

CDC. Guidance for reporting SARS-CoV-2 sequencing results. Available at <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/reporting-sequencing-guidance.html>

CDC. Genomic surveillance for SARS-CoV-2 variants. Available at <https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-surveillance.html>

SC DHEC. Coronavirus disease 2019 (COVID-19) homepage. Available at <https://scdhec.gov/covid19>

SC DHEC. South Carolina COVID-19 Data and Dashboards. Available at <https://scdhec.gov/covid19/covid-19-data>.

SC DHEC. South Carolina Health Alert Network (SC HAN). Available at <https://scdhec.gov/health-professionals/south-carolina-health-alert-network-han>

CDC. Overview of testing for SARS-CoV-2 (COVID-19). Available at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>

SC DHEC. Multisystem inflammatory syndrome in children (MIS-C). Available at <https://scdhec.gov/covid19/multisystem-inflammatory-syndrome-children-mis-c>

DHEC contact information for reportable diseases and reporting requirements

Reporting of certain SARS-CoV-2 laboratory and whole genome sequencing results, COVID-19 associated deaths, and cases of 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 2022 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 – 2022			
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) 915-6506	<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) 409-0695	<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.