

This is an official  
**DHEC Health Update**

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10491-DHU-06-14-2021-COVID-19

## COVID-19 Whole Genome Sequencing and Other Reporting Requirements

### Summary

- All COVID-19 laboratory results (including both positive, negative, and indeterminate results and office-based rapid tests or laboratory-based tests) should be reported to DHEC within 24 hours. This requirement applies to all present and future testing modalities related to detection or characterization of SARS-CoV-2 virus performed or ordered by those required to report to DHEC under South Carolina laws and regulations.
- Whole genome sequencing results for SARS-CoV-2 must be reported to DHEC within 24 hours of completion of the analysis in accordance with guidance provided by the CDC and DHEC for reporting as outlined below.
- Reminders:
  - All deaths in which COVID-19 is known or suspected to be a contributing factor and all cases of multisystem inflammatory syndrome in children (MIS-C) should be reported to DHEC within 24 hours of determination.
  - Vaccine breakthrough cases should only be reported when they result in hospitalization or death of the patient.
  - Providers who order at home testing are responsible for reporting those results (both positive and negative) to DHEC. The only exception to the reporting requirements is over-the-counter (OTC) tests performed without provider or laboratory oversight which should **not** be reported to DHEC. Additional information related to reporting of at-home COVID-19 testing can be found in the [SC DHEC HAN released on May 24, 2021](#).

### Background

DHEC requires reporting of all laboratory test results related to the detection or characterization of SARS-CoV-2, with the only exception being over-the-counter (OTC) at home tests performed without clinician or laboratory oversight. This includes results for [whole genome sequencing \(WGS\)](#) to detect variants of SARS-CoV-2 and any future testing modalities as they become available. All results and analyses of WGS should be reported to [DHEC](#). CDC has provided [guidance](#) for reporting these results (updated April 9, 2021). This HAN provides a reminder of reporting requirements and updated guidance on reporting of WGS results. A reminder is also provided about other reporting requirements including reporting of cases

of [multisystem inflammatory condition in children \(MIS-C\)](#). MIS-C occurs in children and is a rare condition that can cause swelling of different organ systems.

## Reporting Whole Genome Sequencing Results

The Centers for Medicare and Medicaid Services (CMS) allow for the reporting of WGS results on SARS-CoV-2 to public health authorities regardless of Clinical Laboratory Improvement Amendments (CLIA) certification status of the laboratory, and DHEC requires this reporting in accordance with SC laws and regulations. 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.

Reports may be made through the standard reporting mechanism described below. Contact the MUHELPDESK or SCIONHELP as directed below to determine the best method for reporting, and refer to the [CDC guidance](#) for some technical aspects related to reporting. Reports should include the initial positive Nucleic Acid Amplification Test (NAAT) or reverse transcription polymerase chain reaction (RT-PCR) result that led to the decision to sequence (if possible) or include the relevant patient demographics and date of initial test to allow for matching of results.

## Additional Reporting Requirements

In addition to reporting of SARS-CoV-2 laboratory and rapid test results, 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](#) in which they occur. Recently updated requirements include the reporting of vaccine breakthrough cases **only** when they result in hospitalization or death (see [HAN](#) from May 6, 2021 for details). At home tests ordered by providers must have their results reported, but 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).

## 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 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](mailto:MUHELPDESK@dhec.sc.gov) to inquire about ELR submission, or [SCIONHELP@dhec.sc.gov](mailto: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

South Carolina Department of Health and Environmental Control (SC DHEC). List of reportable conditions. Available at <https://scdhec.gov/health-professionals/south-carolina-list-reportable-conditions>

The Centers for Disease Control and Prevention (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 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>

SC DHEC. MIS-C and COVID-19 Variants Dashboard. Available at <https://scdhec.gov/covid19/mis-c-covid-19-variants>

## DHEC contact information for reportable diseases and reporting requirements

Reporting of **SARS-CoV2 laboratory results (positive, negative, and indeterminate), whole genome sequencing results, COVID-19 associated deaths, and cases of Multi-system inflammatory syndrome in children (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 2021 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).

<b>Regional Public Health Offices – 2021</b>			
Mail or call reports to the Epidemiology Office in each Public Health Region			
<b>MAIL TO:</b>			
<b><u>Lowcountry</u></b> 4050 Bridge View Drive, Suite 600 N. Charleston, SC 29405 Fax: (843) 953-0051	<b><u>Midlands</u></b> 2000 Hampton Street Columbia, SC 29204 Fax: (803) 576-2993	<b><u>Pee Dee</u></b> 1931 Industrial Park Road Conway, SC 29526 Fax: (843) 915-6506	<b><u>Upstate</u></b> 200 University Ridge Greenville, SC 29602 Fax: (864) 282-4373
<b>CALL TO:</b>			
<b><u>Lowcountry</u></b> Allendale, Bamberg, Beaufort, Berkeley, Calhoun, Charleston, Colleton, Dorchester, Hampton, Jasper, Orangeburg  Office: (843) 441-1091 Nights/Weekends: (843) 441-1091	<b><u>Midlands</u></b> Aiken, Barnwell, Chester, Edgefield, Fairfield, Kershaw, Lancaster, Lexington, Newberry, Richland, Saluda, York  Office: (888) 801-1046 Nights/Weekends: (888) 801-1046	<b><u>Pee Dee</u></b> Clarendon, Chesterfield, Darlington, Dillon, Florence, Georgetown, Horry, Lee, Marion, Marlboro, Sumter, Williamsburg  Office: (843) 915-8886 Nights/Weekends: (843) 409-0695	<b><u>Upstate</u></b> Abbeville, Anderson, Cherokee, Greenville, Greenwood, Laurens, McCormick, Oconee, Pickens, Spartanburg, Union  Office: (864) 372-3133 Nights/Weekends: (864) 423-6648
<b>For information on reportable conditions, see</b> <a href="https://www.scdhec.gov/ReportableConditions">https://www.scdhec.gov/ReportableConditions</a>		<b><u>DHEC Bureau of Communicable Disease Prevention &amp; Control</u></b> <b>Division of Acute Disease Epidemiology</b> 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:

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