# COVID Compendium of Reporting

## Reportable COVID-19 data

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** | • Laboratory-based Nucleic Acid Amplification Test (NAAT) testing, including RT-PCR, TMA, LAMP, and SDA tests<br>• 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** | • 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)<br>• 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.

## Statutes Applicable to Reporting

Federal Regulations

The Coronavirus Aid, Relief, and Economic Security (CARES) Act and its March 8, 2022 laboratory reporting guidance require 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, WGS) to the appropriate state or local public health department, based on the individual's residence.

**Antibody testing is no longer reportable based on this new guidance**. The CARES Act acknowledged that the data elements requested go above and beyond what has been historically requested, but that this information should be made available in all reporting to state and local public health departments and subsequently the CDC as soon as possible, but no later than August 1, 2020.

The Centers for Medicare and Medicaid Services (CMS) published information that allows both non Clinical Laboratory Improvement Amendments (CLIA) and CLIA-certified facilities that perform SARSCoV-2 genetic sequencing on identified specimens to report patient-specific results to state, local, tribal, or territorial public health departments. Any sequencing data can be reported to public health.

S.C Laws and Regulations

Reporting of COVID-19 cases, deaths, and associated Multisystem Inflammatory Syndrome in Children (MIS-C) is consistent with South Carolina Law §44-29-10 and Regulation §61-20 requiring the reporting of diseases and conditions to your state or local public health department, as per the DHEC List of Reportable Conditions available at: https://www.scdhec.gov/sites/default/files/Library/CR-009025.pdf.

South Carolina Law §44-29-15 requires reporting of all COVID-19 test results (positive, negative, indeterminate, and WGS) **performed under CLIA certification 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.

Positive results of tests performed in ***settings 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) are reportable.

## How to report

Typically, urgently reportable conditions, like cases of COVID-19, are to be reported by phone within 24 hours. However, other options are available for COVID-19 reporting, particularly for providers and facilities that have or can develop the capability to report to DHEC using an approved electronic reporting option.

- 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.

## Data to report for COVID-19 cases, deaths, associated MIS-C, lab, and WGS results

DHEC requires certain data elements be reported with each case. These data allow DHEC to quickly start COVID-19 case investigations and initiate public health interventions as necessary.

- Patient Information
  - Name (First, Middle, Last)
  - Complete address
  - Phone number
  - County of residence
  - Date of birth
  - Race
  - Sex
- Physician's name and phone number
- Name, institution, and phone number of person reporting
- Disease or condition
- Date of diagnosis
- Patient's symptoms
- Date of onset of symptoms
- Lab results, specimen source and collection date
- If female, pregnancy status
- Patient status: In childcare, food-handler, health care worker, childcare worker, nursing home, prisoner/detainee, travel in last 4 weeks

The reporting of the sequencing data should include all the original patient demographic data, along with both the viral test report content and the second test with viral genetic lineage identified.

## Frequently Asked Questions (FAQs)

**Q1: COVID-19 is an urgently reportable (call within 24 hours) condition. Are commercial labs (who may be processing thousands of specimens per day) required to call all results to DHEC?**

**A1:** No. Commercial labs processing large numbers of COVID-19 specimens do not have to call all results to DHEC if they utilize ELR or another electronic reporting mechanism to submit all COVID-19 results (positive, negative, indeterminate, and WGS results) to DHEC. Commercial labs not utilizing ELR should email MUHELPDESK@dhec.sc.gov for more information about ELR submissions or SCIONHelp@dhec.sc.gov for more information about other electronic reporting options.

**Q2: Are providers and healthcare facilities that are performing large numbers of COVID-19 point-ofcare testing required to call all COVID-19 results to DHEC?**

**A2:** In-house laboratories and providers/healthcare facilities performing point-of-care tests are required to report all COVID-19 test results to DHEC within 24 hours. Positive COVID-19 results should be called to the regional public health office where the patient resides or the facility is located unless the provider or facility has the capability to submit all test results to DHEC using an approved electronic reporting

option (ELR, SCIONx or other electronic reporting options). Contact information for the regional public health offices can be found on DHEC's List of Reportable Conditions. For inquiries about electronic reporting, please contact MUHELPDESK@dhec.sc.gov to inquire about ELR submission, or call 1-800917-2093 or email SCIONHelp@dhec.sc.gov for more information about SCIONx and other electronic reporting options.

**Q3: I understand why positive antigen or molecular tests should be called in to DHEC since they may indicate an active infection. Does this time requirement also apply to positive antibody test results that may indicate a recent or past infection?**

**A3**: Antibody results (positive, negative, or inconclusive) are no longer reportable.

**Q4: My lab doesn't have the ability to send Electronic Lab Reports (ELRs) yet but we cannot keep up with the amount of calling or faxing we need to do. How can I speed up my reporting process?**

**A4:** Please call 1-800-917-2093 or email SCIONHelp@dhec.sc.gov to find out if other reporting options are available.