



This is an official DHEC Health Update

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Reporting of At-Home COVID-19 Testing Results

Summary

- Medical providers who order at-home COVID-19 testing for patients are required to report the results of those tests to DHEC.
- At-home self-tests (over-the-counter tests) should not be reported to DHEC unless ordered, proctored, and/or performed by a medical provider.

Background

With increasing testing types for COVID-19 throughout the state, this Health Update supplements and updates previous South Carolina Department of Health and Environmental Control (DHEC) guidance provided [November 30th, 2020](#), and provides information on the type of at-home tests available and the required reporting for these types of tests. DHEC recommends caution when accepting results from at-home/over-the-counter self-tests due to the possibility of improper specimen collection and misinterpretation of the result by non-medical personnel.

There are two types of self-testing options currently authorized by the Food and Drug Administration (FDA) for testing of COVID-19 in symptomatic and asymptomatic individuals:

1. ***At-home self-collection*** devices, which allow an individual to collect a specimen at home and ship it to a certified lab for analysis.
2. ***At-home self-tests (over-the-counter tests)***, which allow an individual to test and obtain a result for a self-collected specimen at home without a prescription.

Medical providers prescribing at-home testing for patients are required to report the results of those tests to DHEC.

At-home self-tests should not be reported to DHEC unless ordered, proctored, and/or performed by a medical provider.

Who Must Report

South Carolina Law §44-29-15 and Regulation §61-20 requires reporting of all COVID-19 test results (positive, negative, and indeterminate) to the South Carolina Department of Health and Environmental Control (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 COVID-19 test results, including positive, negative, and indeterminate must be 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 test results, including positive, negative, and indeterminate must be urgently reported to DHEC within 24 hours. 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 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).

DHEC contact information for reportable diseases and reporting requirements

Reporting of **COVID-19 laboratory results (positive, negative, and indeterminate), deaths, and associated Multisystem 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 2020 List of Reportable Conditions available at:

<https://www.scdhec.gov/sites/default/files/Library/CR-009025.pdf>

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Regional Public Health Offices – 2021			
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.