



This is an official **DHEC Health Advisory**

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10488-DAD-05-06-2021-COVID-19

COVID-19 Vaccine Breakthrough Cases

Summary

- A COVID-19 vaccine breakthrough case is defined as a U.S. resident who has SARS-CoV-2 RNA or antigen detected in a respiratory specimen collected ≥ 14 days after completing the primary series of an FDA-authorized COVID-19 vaccine, in the absence of a positive COVID-19 test in the 45 days prior to the current positive test.
- As of May 1, 2021, the Centers for Disease Control and Prevention (CDC) transitioned from monitoring all reported COVID-19 vaccine breakthrough infections to identifying and investigating only vaccine breakthrough cases that result in hospitalization or death.
- Only report to DHEC patients meeting the above criteria and who were hospitalized or died.
- If available, send residual respiratory specimens from patients meeting above criteria to the DHEC Public Health Laboratory for whole genome sequencing.

Background

On February 22, 2021, the South Carolina Department of Health and Environment Control (DHEC) sent an initial Health Alert Network (HAN) Advisory that provided information on the definition of COVID-19 vaccine breakthrough, how to report these cases to DHEC, and how to submit patient specimens for further testing to the DHEC Public Health Laboratory (PHL). As of May 1, 2021, CDC transitioned from monitoring all reported COVID-19 vaccine breakthrough infections to identifying and investigating only vaccine breakthrough cases that result in hospitalization or death. Given the large number of people being vaccinated in the United States and the high level of ongoing SARS-CoV-2 circulation, thousands of symptomatic vaccine breakthrough cases are expected even if the vaccines remain as effective as demonstrated during the clinical trials. Focusing on hospitalized and fatal vaccine breakthrough cases will help maximize the quality of the data collected on cases of greatest clinical and public health importance. Based on the CDC transition, DHEC will also shift to identifying and investigating only vaccine breakthrough cases that result in hospitalization or death. This HAN Advisory provides updated information regarding the reporting of COVID-19 vaccine breakthrough cases to DHEC.

COVID-19 Vaccine Breakthrough Definition

COVID-19 vaccine breakthrough cases continue to be defined as a U.S. resident who has SARS-CoV-2 RNA or antigen detected in a respiratory specimen collected ≥ 14 days after completing the primary series of an FDA-authorized COVID-19 vaccine. Cases who have a positive COVID-19 test in the 45 days prior to the current positive test will not be included as meeting the definition of a vaccine breakthrough case.

Updates for Reporting COVID-19 Vaccine Breakthrough Cases

Healthcare providers who identify a patient meeting the vaccine breakthrough case definition AND was hospitalized or died should report this case to DHEC by contacting the regional health department where the patient resides. Other COVID-19 vaccine breakthrough cases who were not hospitalized or died no longer need to be reported to DHEC. See the [table below labeled as 'Regional Public Health Offices'](#) for regional health department contact information.

Specimen Submission for COVID-19 Vaccine Breakthrough Cases

After contacting the appropriate regional health department, healthcare providers and laboratories who have residual respiratory specimens from the patient's current positive test should send these specimens to the DHEC PHL for whole genome sequencing (WGS). Follow the specimen packaging and transport information listed below.

Specimen packaging information

- a. If using Fed Ex to ship, follow IATA guidelines. This sample will be considered Category B.
- b. Ship cold, but not frozen. Use cold packs around the outside of the secondary packaging in an insulated shipper. Do not use ice because it will melt and leak during shipping.
- c. If shipping through DHEC or another courier, ensure specimen is kept cold and in a biohazard bag or secondary container in the cooler.
- d. Include 2 copies of the lab requisition form (DHEC 1335) and label each specimen for each patient. Please write on the form that the specimen is being sent for WGS for vaccine breakthrough and indicate if the patient was hospitalized or died. The form can be found at: <https://scdhec.gov/sites/default/files/Library/D-1335.pdf>

Specimen transport

- a. If an established process/courier for transporting specimens to the PHL is already in place, use that system.
- b. On weekdays, facilities can courier specimens to the regional health department for transport to the PHL.
- c. If additional assistance is needed regarding specimen transport, consult with the regional health department.

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 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).

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.