



DSHS Coronavirus Disease 2019 (COVID-19) Vaccine Breakthrough Case Guidance

The Centers for Disease Control and Prevention (CDC) and Texas Department of State Health Services (DSHS) would like to learn as much as possible about vaccine breakthrough cases, including epidemiological information on the clinical severity of cases, and to evaluate the potential for vaccine breakthrough caused by new or emerging COVID-19 variant strains.

Case definition

U.S. resident who has SARS-CoV-2 RNA or antigen detected on respiratory specimen collected ≥ 14 days after completing the primary series of an FDA-authorized COVID-19 vaccine.

Exclusion criteria

SARS-CoV-2 RNA or antigen detected on a respiratory specimen collected < 45 days before the most recent positive test.

Steps for reporting vaccine breakthrough cases:

1. If a potential vaccine breakthrough case is identified, please contact the laboratory and ask them to hold any residual specimens from the positive test (respiratory specimen, RNA extract, or viral isolate). If this person qualifies as a true breakthrough case, we would like to perform further analysis of the virus in the sample.
2. Notify DSHS Central Office (EAIDU-coronavirus@dshs.texas.gov) with the following information: date of first dose, date of second dose, vaccine manufacturer, date of collection for recent specimen, test type, test result, and if residual specimen is still available. DSHS Central office will classify the case as confirmed if it meets criteria.
3. If confirmed, reach out to the local public health entity and ask them to complete the vaccine breakthrough case investigation form sections: Patient Information, Additional Identification Numbers, Health department contact, Eligibility, Case Status, Details of COVID-19 Testing, Details of Vaccination, Underlying Conditions, Clinical Presentation for each confirmed vaccine breakthrough case and send it back to the PHR and EAIDU-coronavirus@dshs.texas.gov via encrypted email with the naming convention NEDSS PatientID_COVID-19 Vaccine breakthrough Worksheet.pdf (i.e. 48648802_COVID-19 Vaccine breakthrough Worksheet.pdf). If sample from the positive PCR test remains for

submission, please also fill out the Sequencing and Additional Samples section of the form.

4. If residual sample remains for a confirmed vaccine breakthrough case, submit it for sequencing at CDC. DSHS Central Office will email out sequencing submission information and forms for CDC submission when cases are confirmed.