DSHS Coronavirus Disease 2019 (COVID-19) SARS-CoV-2 Variant Case Guidance

Updated: November 1, 2021

Guidance Updates

- The CDC has updated their COVID-19 variant classification system to include Variants Being Monitored (VBM), Variants of Interest (VOI), Variants of Concern (VOC) and Variants of High Consequence (VOHC) as of September (see Table 1 for details).
- Texas Department of State Health Services (DSHS) should receive report forms for sequence confirmed cases where a whole genome sequencing result is available for VOHC/VOC/VOI only. Texas DSHS is collecting data about these variants because they carry genetic changes that may affect transmissibility and impact antigenic profile, which could impact the ability of antibodies generated through a previous natural infection with SARS-CoV-2 or vaccination to recognize and neutralize the virus. Report forms may be submitted either as fillable PDFs or using the .csv template (see pg. 3 for details under Variant Case Reporting Process).
- There is no need to submit report forms for VBM or other lineages at this time.

Interpreting Variant Classification Guidance Updates

- Determination of variant classification under which a sequence confirmed variant case falls should be based on lab report date and date of CDC guidance update.
- Whole genome sequencing (WGS) results where lab report date occurred on or after September 20, 2021 should be handled under the current CDC variant classification system outlined in Table 1 below.
- For example:
    - A B.1.1.7 variant with a lab report date of September 19th, 2021 should have a case investigation form completed, as it was a Variant of Concern at the time the lab was reported.
    - However, a lab report date of September 21st, 2021 or later does not need to have a form completed as it falls under the variant being monitored classification.

Table 1: CDC Classification of COVID-19 Variants as of September 20, 2021

Classification	WHO Labels	PANGO Lineages
Variant of High Consequence (VOHC)*	None designated	None designated
Variant of Concern (VOC)*	Delta	B.1.617.2 and AY sub-lineages
Variant of Interest (VOI)*	None currently designated	None currently designated
Variant Being Monitored (VBM)*	Alpha	B.1.1.7, and sub-lineages Q.1-Q.8
	Beta	B.1.351.2, B.1.351.3
	Gamma	P.1, and sub-lineages P.1.1, P.1.2
	Epsilon	B.1.427, B.1.429
	Iota	B.1.526
	Eta	B.1.525
	Kappa	B.1.617.1
	Mu	B.1.621, B.1.621.1
	Zeta	P.2
	B.1.617.3	B.1.617.3

*See Appendix 1 for additional details.

Requesting Whole Genome Sequencing from Texas DSHS Austin Laboratory

- To request additional support with packing and shipping samples for whole genome sequencing at DSHS Austin Laboratory, please contact the DSHS Laboratory courier services coordinator (LabCourier@dshs.texas.gov).
- DSHS Austin Lab will accept PCR-positive samples with a Ct value<30 from cases in which a variant is likely to be present. These include the following:
    - Cases of reinfection
    - Vaccine breakthroughs
    - COVID-19 cases who were close contacts of a sequence confirmed variant of high consequence (VOHC)/variant of concern (VOC)/variant of interest (VOI) case.
    - Cases with a travel history to a location where there is a known or suspected VOHC/VOC/VOI circulation
    - Cases with extremely severe or unusual clinical presentations
    - Pediatric fatalities
    - Outbreak cases that occur in congregate settings that meet certain requirements (see Sequencing Submission Guidance for details)
- Please send requests for genomic sequencing to the DSHS EAIDU Coronavirus Epidemiology team (EAIDU-coronavirus@dshs.texas.gov), with

the subject line "Requesting Whole Genome Sequencing Approval", tagged with High Importance (the red exclamation mark "!").

- Results for samples sequenced at Texas DSHS Austin Laboratory will be directly uploaded into NEDSS. Results reported after October 4, 2021 from samples sequenced at the Texas DSHS Austin Laboratory may be shared with submitters and providers as they have completed the CLIA review process for this test. Submitters will also be notified of results directly by the DSHS Austin Laboratory.

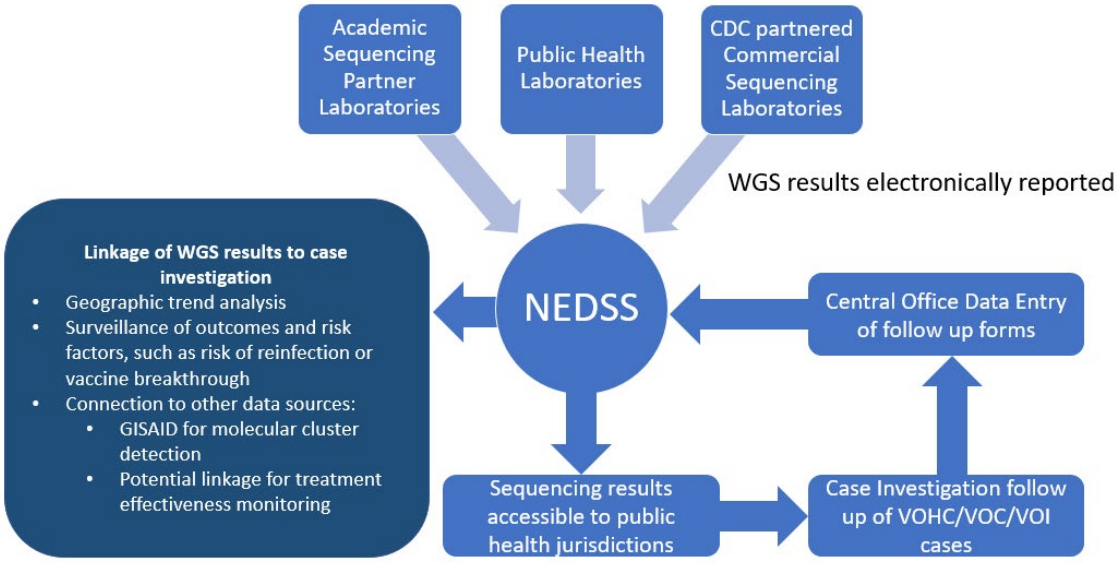
Accessing and Sharing Electronically Reported Sequencing Results in NEDSS

1. Open a web browser and log into NEDSS using your DSHS username and password.
2. Click on *Reports* located on the upper, left-hand side of the screen.
3. Expand *Public Reports*, by clicking the "+" sign to its left. Then, expand *COVID-19 Reports*, by clicking the "+" sign to its left.
4. Locate *COVID-19 Whole Genome Sequencing Lab Results* under *Report Title* and select the blue *Run* hyperlink.
5. Users can modify the range of dates as desired and select *Export* in the lower, right-hand corner for the data to download .csv file using the *Basic Filter*. A csv file labeled *ReportOutput.csv* will be downloaded to your computer.

Variant Case Reporting Process

- Please download electronically reported WGS results directly from NEDSS report as described above. The DSHS Central Office Coronavirus Epidemiology Team may additionally email WGS results for VOHC/VOC/VOI cases that have not been electronically reported directly to PHRs.
- Please request that the local health entity fill out a variant surveillance worksheet for each VOHC/VOC/VOI case reported.
    - Please use the following naming convention, NEDSS PatientID_Variant Name_COVID-19 Variant Surveillance Worksheet.pdf (i.e. 48648802_B.1.1.7_COVID-19 Variant Surveillance Worksheet.pdf), and return to the PHR and EAIDU-coronavirus@dshs.texas.gov via encrypted email.
    - Alternatively, a line list of several variant cases can be submitted using the variant reporting .csv template using the naming convention VariantInvestigations_Jurisdiction_date (i.e. VariantInvstigations_PHR1_10.5.21).
- Please notify DSHS Central Office at EAIDU-coronavirus@dshs.texas.gov if sequence confirmed variants of interest, variants of concern, or variants of high consequence cases reported to you directly from a sequencing laboratory and are not included in the report available in NEDSS as they may not have been reported previously via electronic means.

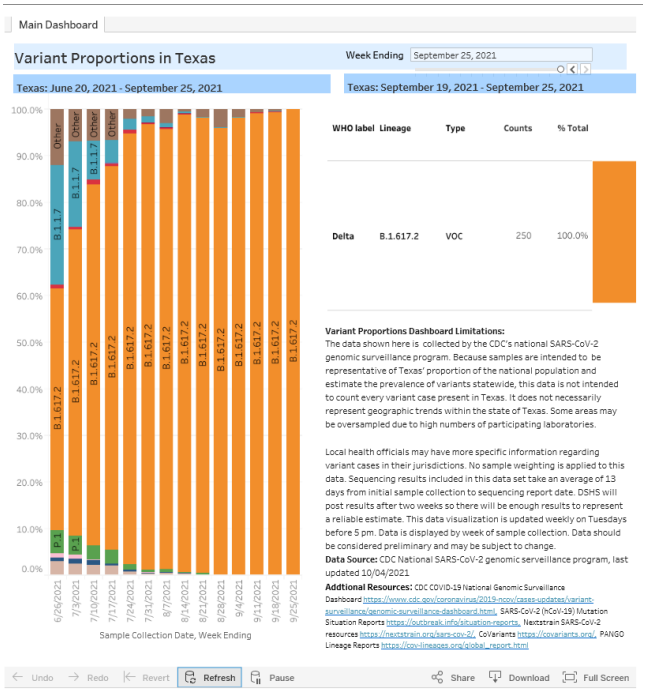
Figure 1: Sequencing/Variant Reporting Process



Accessing Variant Information in Tableau Dashboard

Each week, DSHS updates its variant dashboard with data provided by the CDC's national SARS-CoV-2 genomic surveillance program, which sequences thousands of COVID-19 cases each week to identify and track SARS-CoV-2 variants circulating in the United States.

The dashboard can be viewed here: https://www.dshs.texas.gov/coronavirus/variants-data/ (Ctrl+Click to follow the link).



Appendix 1: Variants of High Consequence (VOHC), Variants of Concern (VOC), Variant Being Monitored (VBM) and Variants of Interest (VOI) Definitions as of September 20, 2021

Variant of High Consequence (VOHC)

A variant of high consequence has clear evidence that prevention measures or medical countermeasures (MCMs) have significantly reduced effectiveness relative to previously circulating variants of SARS-CoV-2.[1]

Possible attributes of a variant of high consequence[1]:

- Evidence of impact on diagnostics, treatments, or vaccines
- Widespread interference with diagnostic test targets
- Evidence of substantially decreased susceptibility to one or more class of therapies
- Evidence of significant decreased neutralization by antibodies generated during previous infection or vaccination
- Evidence of reduced vaccine-induced protection from severe disease
- Evidence of increased transmissibility
- Evidence of increased disease severity
- Impact on Medical Countermeasures (MCM)
  - Demonstrated failure of diagnostics

- Evidence to suggest a significantly reduction in vaccine effectiveness, a disproportionately high number of vaccine breakthrough cases, or very low vaccine-induced protection against severe disease
- Significantly reduced susceptibility to multiple Emergency Use Authorization (EUA) or approved therapeutics
- More severe clinical disease and increased hospitalizations
- A variant of high consequence would require notification to WHO under the International Health Regulations, reporting to CDC, an announcement of strategies to prevent or contain transmission, and recommendations to update treatments and vaccines.

To date, CDC has not designated any SARS-CoV-2 variants rising to the level of high consequence

Variants of Concern (VOC)

A variant for which there is evidence of an increase in transmissibility, more severe disease (e.g., increased hospitalizations or deaths), significant reduction in neutralization by antibodies generated during previous infection or vaccination, reduced effectiveness of treatments or vaccines, or diagnostic detection failures. [1]

Possible attributes of a variant of concern[1]:
In addition to the possible attributes of a variant of interest

- Evidence of impact on diagnostics, treatments, or vaccines
  - Widespread interference with diagnostic test targets
  - Evidence of substantially decreased susceptibility to one or more class of therapies
  - Evidence of significant decreased neutralization by antibodies generated during previous infection or vaccination
  - Evidence of reduced vaccine-induced protection from severe disease
- Evidence of increased transmissibility
- Evidence of increased disease severity

Variants of concern might require one or more appropriate public health actions, such as notification to WHO under the International Health Regulations, reporting to CDC, local or regional efforts to control spread, increased testing, or research to determine the effectiveness of vaccines and treatments against the variant. Based on the characteristics of the variant, additional considerations may include the development of new diagnostics or the modification of vaccines or treatments[1]. Current variants of concern in the United States that are being closely monitored and characterized by federal agencies are included below.

Variant of Interest (VOI)

A variant with specific genetic markers that have been associated with changes to receptor binding, reduced neutralization by antibodies generated against previous

infection or vaccination, reduced efficacy of treatments, potential diagnostic impact, or predicted increase in transmissibility or disease severity[1].

Possible attributes of a variant of interest[1]:

- Specific genetic markers predicting to affect transmission, diagnostics, therapeutics, or immune escape
- Evidence that it is the cause of an increased proportion of cases or unique outbreak clusters
- Limited prevalence or expansion in the US or in other countries
- A variant of interest might require one or more appropriate public health actions, including enhanced sequence surveillance, enhanced laboratory characterization, or epidemiological investigations to assess how easily the virus spreads to others, the severity of disease, the efficacy of therapeutics and whether currently authorized vaccines offer protection.

Currently CDC is not designating any SARS-CoV-2 VOI

Variant Being Monitored (VBM)

The variants designated as VBM include variants for which there are data indicating a potential or clear impact on approved or authorized medical countermeasures or that have been associated with more severe disease or increased transmission (such as VOC or VOI) but are no longer detected or are circulating at low levels in the United States, and as such, do not pose a significant and imminent risk to public health in the US.

Attributes of a variant being monitored:

A variant of interest or a variant of concern may be downgraded to this list when there has been a significant and sustained reduction in its national and regional proportions over time, or other evidence indicates that a variant does not pose significant risk to public health in the United States.

These variants continue to be closely monitored to identify changes in their proportions and new data is continually being analyzed. If the data indicate that a VBM warrants more concern, the classification will be changed based on the SIG assessment of the attributes of the variant and the risk to public health in the United States.