Updated Guidelines for SARS-CoV-2 Variant Strain Surveillance and Submission

Date: June 30, 2021

Public Health Message Type: ☐ Alert ☐ Advisory ☒ Update ☐ Information

Intended Audience: ☒ All public health partners ☒ Healthcare providers ☒ Infection preventionists ☒ Local health departments ☐ Schools/Childcare centers ☐ ACOs ☐ Animal health professionals ☒ Other: Clinical laboratories

Key Points:

- Multiple variants of the virus that cause COVID-19 have been circulating both in the United States and globally during this pandemic.
- In collaboration with the SARS-CoV-2 Interagency Group (SIG) established by the Department of Health and Human Services (HHS), CDC has developed a classification scheme for variants of SARS-CoV2:
    - Variants of Interest
    - Variants of Concern
    - Variants of High Consequence
- Currently there are no SARS-CoV-2 variants that rise to the level of high consequence, however variant status might escalate or deescalate and further information on each class can be found at: https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html
- Routine collection of standardized epidemiologic and clinical data from cases as well as linking this data with associated virus sequences, can help characterize clusters of COVID-19 cases and better understand transmissibility, pathogenicity, and re-infection.
- NJDOH requests specimens for sequencing that meet the following criteria, and for which a variant strain is suspected:
    - SARS-CoV-2 -positive specimens (**RT-PCR CT values ≤28** preferred if available) collected within the 7 days prior to shipment AND
        1. Recent travel to and/or from South Africa, Brazil, India, or countries outside the United States that have reported the B.1.351, P.1 or the B.1.617 Sars-CoV-2 variant or close contacts of cases with such travel, OR
        2. Suspected reinfection (recurrence of symptoms) and positive test result ≥90 days after the initial RT-PCR positive test result (not antigen or serology), OR
        3. Cases associated with an outbreak or cluster of concern, OR
        4. Vaccine breakthrough case defined as a U.S. resident who has SARS-CoV-2 RNA or antigen detected on a respiratory specimen collected ≥14 days after completing the primary series of an FDA-authorized COVID-19 vaccine, OR
        5. COVID-related hospitalization or death in a fully vaccinated person.
- This testing is being performed at the Division of Public Health and Environmental Laboratories (PHEL) for epidemiological surveillance purposes; results will not be reported to submitters. Due to limited sequencing capacity, only a subset of the submitted specimens may be sequenced. If a variant of concern is identified, additional guidance will be provided as appropriate.

Action Items:

- To submit specimens meeting criteria #1 and #2, clinicians and laboratory partners can send specimens to PHEL with no prior approval needed.
- For persons meeting criteria #3 - 5 (associated with an outbreak/cluster or suspect vaccine failure), clinicians should consult their local health department. A directory of local health departments is available at www.localhealth.nj.gov.
    - After consultation with clinicians, local health departments can approve specimens for sequencing and should provide the CDRSS Case ID# to the clinician to be included in the "CDS Approval Number" box on the SRD-1 form. The LHD must enter the following information (as applicable) in CDRSS for these cases and email the case IDs to their Communicable Disease Service (CDS) COVID Epidemiologist:
        - Outbreak (E#) or investigation number (I#)
        - Signs/symptoms, hospitalization status and if patient died
        - Vaccination status (vaccine manufacturer and date of administration)
        - Additional applicable information and note in Comments that the specimen will be sent to PHEL for sequencing
- Providers and laboratories performing sequencing **should report** all sequencing results to NJDOH via secure email to CDS.COV.DM@doh.nj.gov or fax to (609) 826-5972.

How to submit specimens for sequencing to PHEL:

- Refer to the PHEL Technical Bulletin below for general guidance on specimen submission and acceptable specimen types.
- Store respiratory specimens at 2-8°C for up to 72 hours after collection. If a delay in testing or shipping is expected, specimens must be stored at -70°C or below and shipped on dry ice.
    - If samples have been refrigerated for greater than 72 hours after time of collection, consider collecting a new specimen for submission.
    - Samples not on dry ice received more than 72 hours after collection will be rejected.
- Please alert SARS.sequencing@doh.nj.gov upon shipping a specimen for sequencing with the number of samples being shipped, reason for shipping and estimated date/time of delivery.
- For sequencing requests, on the SRD-1 form, check 'other' category and write-in "SARS-CoV-2 RNA Sequencing" for the test requested.
    - Include information related to sequencing approval criteria (#1-5 above) in the Pertinent Clinical Information box on the SRD-1 form. If the sequencing criteria are not indicated on the submission form, the sample may not be considered for sequencing.

References and Resources:

- https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html (CDC guidance)
- https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html (Variant Cases)
- https://www.nj.gov/health/phel/documents/Bulletins/Supplemental%20Bulletin%2021.1.1%20SARS-CoV-2%20Testing%20at%20PHEL%20V3.pdf (NJPHEL specimen submission guidance – updated: 5/1/21)