NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

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February 12, 2021 (replaces version dated January 15, 2021)

To: All North Carolina Clinicians and Laboratories
From: Scott Shone, PhD, HCLD (ABB), Public Health Laboratory Director
Zack Moore, MD, MPH, State Epidemiologist
Re: Detection of SARS-CoV-2 Variant Viruses (2 pages)

This memo provides updated information about SARS-CoV-2 variant viruses and guidance to laboratories and clinicians for reporting potential variants of interest to the North Carolina Division of Public Health (NC DPH).

**Background**
Multiple SARS-CoV-2 variants are circulating globally and within the United States. Several new variants emerged in the fall and winter of 2020-21, most notably:

- B.1.1.7: This variant was first detected in the United Kingdom in September 2020 and has since been detected in numerous countries around the world.
- B.1.351: This variant was first detected in South Africa in early October and has since been identified in multiple countries, including in the United States.
- P.1: This variant was first identified in January 2021 in travelers from Brazil who arrived in Japan and has since been identified in multiple countries, including in the United States.

Other variants have been identified as sequencing efforts have increased, including the CAL.20C variant that has been associated with a large proportion of recent infections in California and was subsequently identified in multiple other states. Updated information about potential implications for disease severity, transmissibility, and immunity from vaccines or previous infections is available on the CDC website.

The FDA recently issued an alert stating that they will continue to monitor for impacts of viral mutations on diagnostic test performance. At this point, the impact of currently circulating variants on diagnostic test sensitivity is believed to be low; additional information will be shared as it becomes available.

The North Carolina State Laboratory of Public Health (NCSLPH) is participating in the National SARS-CoV-2 Strain Surveillance (NS3) program, which requires regular submission of select positive SARS-CoV-2 samples to the Centers for Disease Control and Prevention for sequencing and viral characterization. NCSLPH is also developing internal capacity and plans for SARS-CoV-2 strain surveillance.

**Guidance for NC Laboratories**
In order to better identify emerging variants of concern in North Carolina, NC DPH is requesting that clinical laboratories performing genomic sequencing report the identification of B.1.1.7, B.1.351, P.1 , or any other newly emerging variants in specimens collected from North Carolina residents. Reports should be made via this secure online reporting form. Additional specimens meeting the criteria described below may also be considered for

submission to NS3 via NCSLPH. NC DPH is no longer requesting submission of specimens with s-gene target failure.

**Residual Clinical Specimen Submission Criteria**

- Previously sequenced specimens must have Ct values ≤28.
- Positive clinical specimens must have Ct values ≤30 for positive targets.
- Residual specimens in molecular transport media are not acceptable.
- Residual upper and lower respiratory specimens are acceptable.
- Residual specimens must have at least 500µL.
- Residual specimens must be frozen at -70°C within 72 hours of collection.
- Residual specimens will be shipped overnight frozen on dry ice to the NC SLPH, if requested.

**Guidance for NC Clinicians**

Clinicians should contact NC DPH for cases meeting one or more of the following criteria to discuss potential submission of specimens for sequencing:

- Persons who have a positive diagnostic test at least 14 days after completing vaccination with an FDA authorized vaccine (meaning after two doses for Pfizer and Moderna vaccines) and with no previous positive test in the preceding 45 days
- Persons with suspected re-infection, if:
    - Both the initial and subsequent positive sample are available for submission, **OR**
    - The positive test was collected at least 90 days after their initial positive and the person had new onset of COVID-19 symptoms requiring hospitalization
- Persons with severe immune compromise with prolonged infection
- Persons with international travel within 14 days before symptom onset (or before positive test if asymptomatic)
- Large or unusual outbreaks or clusters
- Pediatric deaths

Reports should be made by contacting the Epidemiologist on Call at 919-733-3419. Please note that because of limited sequencing capacity, not all specimens for which sequencing is requested may be sequenced. You will be contacted by someone from NC DPH with further information if your sample can be sequenced once your request has been reviewed. Because SARS-CoV-2 whole genome sequencing at CDC is done for surveillance purposes and is not a CLIA approved assay, results from sequencing will not be communicated back to the provider.

Additional information regarding emerging strains of SARS-CoV-2 is available at:
https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/scientific-brief-emerging-variants.html
https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html.

Specific information regarding emergence of SARS-CoV-2 B.1.1.7 lineage is available at: Emergence of SARS-CoV-2 B.1.1.7 Lineage — United States, December 29, 2020–January 12, 2021.

More information and guidance regarding strain surveillance in North Carolina will be shared when available.

For questions about the secure online reporting form, please contact the epidemiologist on call at 919-733-3419. For technical questions about clinical specimen submission, please contact NCSLPH at slph.covid19@dhhs.nc.gov.