NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Division of Public Health

January 15, 2021

To: All North Carolina 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

This memo provides information about SARS-CoV-2 variant viruses and guidance 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. In the United Kingdom (UK), a new variant (known as 20B/501Y.V1, VOC 202012/01, or B.1.1.7 lineage) emerged with an unusually large number of mutations. This variant seems to spread more easily and quickly than other variants. Currently, there is no evidence that it causes more severe illness or increased risk of death. This variant was first detected in September 2020 and is now highly prevalent in London and southeast England. It has since been detected in numerous countries around the world, including the United States and Canada.

In South Africa, another variant (known as 20C/501Y.V2 or B.1.351 lineage) has emerged independently of the variant detected in the UK. This variant, originally detected in early October, shares some mutations with the variant detected in the UK. There have been cases caused by this variant outside of South Africa. This variant also seems to spread more easily and quickly than other variants. Currently, there is no evidence that it causes more severe illness or increased risk of death.

While the emerging variants may have a minor impact on some SARS-CoV-2 molecular tests authorized by the U.S. Food and Drug Administration (FDA), the impact is currently low and insignificant. The FDA recently issued an alert stating that they will continue to monitor for impacts of viral mutations on diagnostic tests. 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 the following pertaining to specimens collected from a North Carolina resident. Residual specimens meeting the criteria below may be requested for submission to NS3 via NCSLPH.

NC Clinical Laboratories performing Genomic Sequencing

- Clinical laboratories conducting genomic sequencing of SARS-CoV-2 should report the identification of B.1.1.7, B.1.351, or any other newly emerging variants via this secure online reporting form.

NC Clinical Laboratories NOT performing Genomic Sequencing

- Clinical laboratories performing diagnostic testing for SARS-CoV-2 using the Thermo Fisher TaqPath COVID-19 Combo assay or the Linea COVID-19 Assay Kit should report positive specimens exhibiting spike gene target failure (SGTF) via this secure online reporting form.
- Note that SGTF can be seen with the B.1.1.7 variant but not with B.1.351 or other current emerging variants of concern.

Residual Clinical Specimen Submission Criteria

- Previously sequenced specimens must have Ct values $\leq$28.
- Positive specimens with SGTF must have Ct values $\leq$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.

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.

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 SGTF or clinical specimen submission, please contact NCSLPH at slph.covid19@dhhs.nc.gov.