

CABINET FOR HEALTH AND FAMILY SERVICES Department for Public Health

Andy Beshear Governor

Eric C. Friedlander Secretary 275 East Main Street, HS1GWA Frankfort, KY 40621 502-564-3970 Fax: 502-564-9377 www.chfs.ky.gov Steven J. Stack, MD Commissioner

September 3, 2021

Dear SARS-CoV-2 Laboratory Services Provider,

Thank you for providing testing capacity for COVID-19 and for your additional efforts to provide sequencing data to KDPH. This sequencing data enables public health to understand the spread and characteristics of SARS-CoV-2 variants inform prevention efforts. Your work has helped us to characterize both the rapid spread of B.1.617.2 (i.e., Delta Variant) in Kentucky and its increased impact on younger and more vulnerable populations. Thank you for your continued collaboration.

As sequencing has increased, more requests are being made by clinicians and patients to receive their ordered or personal sequencing results. We appreciate the limitations on laboratories providing this information due to the scope of CLIA Certification and also the lack of clinical utility for clinical patient due to the time required to produce sequencing results.

Though CDC and CLIA guidance allows for patient-specific results to be provided to healthcare providers or patients for "public health purposes," it is rare that there is any public health utility to patients or providers receiving patient-specific results. Additionally, neither our Division of Laboratory Services nor our COVID-19 Response Unit have the capacity to maintain a clearinghouse to provide sequencing results to healthcare providers and patients.

Even so, we have seen a recent trend for some providers and patients to be more insistent in their demands to receive sequencing results. In response, some laboratories referred these requests to KDPH. In a few cases, specific email addresses of our lab surveillance staff were even provided to clinicians or members of the public. Should this occur in the future, the requestor will be directed back to the laboratory that performed the testing. As noted above, we have neither the capacity nor the obligation to field these requests. Should the lab feel it is within the purview of its CLIA certification to provide those results, we encourage you to explore that or other options.



KENTUCKY CABINET FOR HEALTH AND FAMILY SERVICES KDPH has offered to send <u>aggregate</u> (not patient-specific) sequencing results to healthcare facilities and providers. This can help them to understand the distribution of variants present in their practice setting to help guide clinical decisions for their patient population. Hopefully, this will alleviate some of the burden of these requests – at least from clinicians.

No action is necessary with this communication. I just wanted to inform you of the process we will follow with requests for individual sequencing results that come to KDPH.

Thank you, again, for your continuing hard work to provide valuable diagnostic and genetic sequencing capacity to the Commonwealth. Your efforts are greatly appreciated.

Sincerely yours,

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Steven J. Stack, MD Commissioner Department for Public Health