Date Issued: March 23, 2022
To: All laboratories performing testing for Coronavirus Disease 2019 (COVID-19) operating under a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Compliance or Certificate of Waiver.
Regarding: Reporting of test results for all SARS-CoV-2 molecular, antigen and serological tests.

The current US Health and Human Services (HHS) reporting guidance (COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act) has been updated. The new guidance will go into effect on April 4, 2022 (COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act). Specifically, beginning April 4, 2022, COVID-19 testing facilities that test under a CLIA certificate of waiver are no longer required to report NEGATIVE results for tests authorized for use under a CLIA certificate of waiver. This includes rapid PCR and antigen tests performed for a variety of purposes including, but not limited to, screening and diagnostic testing at schools, correctional facilities, employee testing programs, long-term care facilities, and rapid testing performed in pharmacies, medical provider offices, and drive-through and pop-up testing sites.

The updated guidance still requires laboratories certified under CLIA to perform moderate- or high-complexity tests to report both POSITIVE AND NEGATIVE results for laboratory-based nucleic acid amplification tests (NAATs).

Pursuant to the authority granted to the Secretary of the Kansas Department of Health and Environment (KDHE) under K.S.A. 65-101, effective Monday April 4, 2022, KDHE will adopt the updated HHS reporting guidelines as written.

Facilities operating under a CLIA certificate of waiver, please note, under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), individuals are entitled to receive the results of their COVID-19 testing, which would include negative test results. If you are a facility that is using LabXchange to both report COVID-19 test results to KDHE and also notify patients of their results, you may continue to submit positive and negative results via LabXchange and the system will continue to notify your patients of their results. If you have another means by which patients can obtain their results, you can use LabXchange to meet your requirement to submit positive molecular and antigen results to KDHE.

Facilities operating under CLIA to perform moderate- or high-complexity tests, please continue to send all COVID-19 NAAT results to KDHE.

Janet Stanek
Secretary
Kansas Department of Health and Environment

CC: Kansas Department of Health and Environment, Kansas Health and Environmental Laboratories, Laboratory Improvement Program Office