NEW YORK STATE OF OPPORTUNITY. Department of Health

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DATE: April, 1 2022
TO: Clinical Laboratories and Limited Service Laboratories
FROM: New York State Department of Health (Department)

Health Advisory: Updated Reporting Requirements for Laboratory Results for SARS-CoV-2

Background

This health advisory is being issued to New York State (NYS) permitted clinical laboratories and limited service laboratories to provide updates on SARS-CoV-2 reporting requirements. On March 8, 2022, the U.S. Department of Health & Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) announced revisions to HHS SARS-CoV-2 laboratory data reporting requirements that will become effective on April 4, 2022. In some instances, HHS will no longer require reporting of SARS-CoV-2 test results. Effective April 4, 2022, NYS will be implementing the HHS SARS-CoV-2 laboratory data reporting requirements.

Summary of Reporting Requirements

- Clinical laboratories performing moderate or high complexity COVID-19 nucleic acid amplification tests (NAATS), such as PCR, will continue to be required to report positive, negative, and inconclusive results.
- Clinical laboratories performing moderate or high complexity COVID-19 antigen tests will be required to report positive results. Reporting of negative and inconclusive results will be optional.
- Clinical laboratories and limited service laboratories performing COVID-19 testing using waived COVID-19 rapid antigen and rapid molecular tests will be required to report positive results. Reporting of negative and inconclusive results will be optional.
- Reporting of results obtained with SARS-CoV-2 antibody tests will no longer be required.
- When reporting is required, results must be reported to the Department within 24 hours of results being known or determined, through the Electronic Clinical Laboratory Reporting System (ECLRS).
- Individuals that use home use tests that are entirely self-administered (i.e., a test that allows for self-collection and testing at home, also known as home use or over the counter tests) are not required to report their test results. In accordance with federal guidance, this includes congregate residence settings where an at home or over the counter test is used to test residents who are unable to test themselves. For additional information on the use of over the counter tests, see the Over-The-Counter (OTC) Home Testing and CLIA Applicability Frequently Asked Questions document issued by the Centers for Medicare and Medicaid Services.

Please contact clep@health.ny.gov with any questions regarding this advisory. For technical questions on how to report results, please contact (866) 325–7743 or eclrs@health.state.ny.us.