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DATE: April 1, 2022

TO: Physician Office Clinical Laboratories

FROM: New York State Department of Health (Department)

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

Background

Governor

This health advisory is being issued to New York State (NYS) physician office 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 <u>SARS-CoV-2 laboratory data reporting requirements</u> 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 physician office laboratories will be required to follow the HHS SARS-CoV-2 laboratory data reporting requirements.

Summary of Reporting Requirements

- 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.
- 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.
- Laboratories performing waived 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. For additional information on
 the use of over the counter tests, see the <u>Over-The-Counter (OTC) Home Testing and
 CLIA Applicability Frequently Asked Questions</u> document issued by the Centers for
 Medicare and Medicaid Services.

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