NEW YORK STATE OF OPPORTUNITY. Department of Health

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From: Office of the Commissioner

**INTERIM GUIDANCE FOR LABORATORY REPORTING OF COVID-19 TEST RESULTS AND DATA COLLECTION**

## Purpose

New Yorkers have successfully reduced the spread of COVID-19 to one of the lowest rates in the nation. Efforts to successfully reopen businesses, schools, and other entities affected by current social distancing requirements rely upon State and local public health officials having greatly expanded access to testing and accurate testing data. These efforts also rely upon promptly interviewing positive cases, performing contact investigations, and issuing isolation and quarantine orders. It is essential to these efforts that the reporting of results for SARS-CoV-2 testing is complete, accurate, and timely.

## Background

On March 9, 2020, the Department adopted emergency regulations to improve the State and local health departments' ability to respond to the COVID-19 outbreak. As part of these emergency regulations, Title 10 of the New York Codes, Rules, and Regulations was amended to include a new Section 58-1.14 that, along with Section 576-c of the Public Health Law (PHL), requires laboratories that perform tests for screening, diagnosis, or monitoring of those communicable diseases that require prompt action, as designated by the Commissioner, to report all results, including positive, negative, and indeterminate results, related to such communicable diseases.

On April 30, 2020, the Department issued a Health Advisory on Reporting Requirements for all Laboratory Results for SARS-CoV-2, including all Molecular, Antigen, and Serological Tests (including "Rapid" Tests) and Ensuring Complete Reporting of Patient Demographics, which describes the requirement for all labs to report all molecular, antigen, and serological tests to New York State, and that all laboratory result reporting to New York State must be done through Electronic Clinical Laboratory Reporting System (ECLRS).

Pursuant to Section 576-c of NYS PHL, the Commissioner can add new reporting requirements at any time and under Section 577(1)(f) laboratories can be subject to penalties, including revocation of a permit, for failure to file such reports.

## Reporting Requirements

Labs are required to report all COVID-19 molecular, antigen, and serological tests to New York State. All laboratory result reporting to New York State must be done through ECLRS four times per day according to the schedule delineated below. **Failure to report COVID-19 test results may result in revocation, suspension or limitation of a lab's permit, and both the owner and the director of the lab could be found guilty of a class A misdemeanor.**

Laboratories reporting COVID-19 results should adhere to the following guidance:

- Labs must only submit results if they are the site performing the test. Labs may not submit results on referred specimens.
- Labs are required to report test type, specimen source, **full patient residential address and phone number**, **occupation, employer name, work address,** employer phone number, sex, race, and ethnicity. Large commercial labs must instruct their clients that patient demographic information is required in the order request.
- Labs that send files and that perform molecular, antigen, and serological tests should create **different orderable tests** in their lab system so that the proper LOINC codes for each test can be reported to ECLRS.
- Proper SNOMED codes must be used for reporting results.
- All labs must contact the ECLRS Help Desk for guidance on sending test files to the ECLRS test system, in order to validate codes and results.
- Any changes to testing practices must be communicated to the ECLRS Help Desk so that we can make sure that the reporting does not change or get disrupted.
- Labs unable to submit via HL7, including limited service labs, can perform manual entry into ECLRS. Please contact the ECLRS Help Desk for instructions.
- As new tests become available, please make sure that you are using the correct LOINC code. SARS-CoV-2 LOINC codes can be found at www.loinc.org.
- Tests that have Emergency Use Authorization from the Food and Drug Administration can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidinvitrodev
- Information on serological tests for SARS-CoV-2 antibodies can be found at: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2

**Reporting Schedule**

As part of the emergency regulations adopted on March 9, 2020, DOH directed laboratories to submit **test results related to COVID-19 to ECLRS four times per day** during the following time frames:

- 5 am - 7 am
- 11 am - 1 pm
- 4 pm - 6 pm
- 8 pm - 11 pm

**The emergency regulations and this directive remain in effect. Adherence to this schedule is required.**

Please contact (866) 325–7743 or eclrs@health.state.ny.us with any technical questions regarding this advisory.