NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

DATE: April 30, 2020
TO: Clinical Laboratories, Limited Service Labs, and Other Entities Supporting SAR-CoV-2 Testing
FROM: New York State Department of Health (Department)

Health Advisory: 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

Background

As the landscape of available tests for the COVID-19 infection continues to evolve, it is essential that the reporting of results for SARS-CoV-2 testing is complete, accurate, and timely. Efforts to successfully reopen businesses, schools, and other entities affected by current social distancing requirements will rely upon State and local public health officials having greatly expanded access to testing and accurate testing data. These efforts will also rely upon promptly interviewing positive cases, performing contact investigations, and issuing isolation and quarantine orders.

New York State Testing Protocol

On April 26, 2020, the Department issued *Updated Interim Guidance: Protocol for COVID-19 Testing Applicable to All Health Care Providers and Local Health Departments* which includes guidance about when diagnostic and/or serologic testing for COVID-19 shall be authorized by a health care provider and the prioritization of testing. Specifically, testing shall be authorized by a health care provider when:

- An individual is symptomatic or has a history of symptoms of COVID-19 (e.g. fever, cough, and/or trouble breathing), particularly if the individual is 70 years of age or older, the individual has a compromised immune system, or the individual has an underlying health condition; or
- An individual has had close (i.e. within six feet) or proximate contact with a person known to be positive with COVID-19; or
- An individual is subject to a precautionary or mandatory quarantine; or
- An individual is employed as a health care worker, first responder, or other essential worker who directly interacts with the public while working; or
- An individual presents with a case where the facts and circumstances – as determined by the treating clinician in consultation with state or local department of health officials – warrant testing.

All laboratories in the state, both public and private, that conduct COVID-19 diagnostic testing, must complete COVID-19 diagnostic testing in accordance with Executive Order 202.19, issued on April 17, 2020.

Reporting Requirements

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 58.14 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. These results must be reported to the Commissioner through the Electronic Clinical Laboratory Reporting System (ECLRS) on a schedule determined by the Commissioner.

Positive results for COVID-19 must be reported immediately. All other test results related to COVID-19, including the serology antibody testing, must be submitted to ECLRS four times per day at 5 am - 7 am; 11 am - 1 pm; 4 pm - 6 pm; and 8 pm - 11 pm.

Labs are required to report all molecular, antigen, and serological tests to New York State. All laboratory result reporting to New York State must be done through ECLRS.

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 address, phone, 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 (FDA) can be found at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
- 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#serology.

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