



DATE: May 15, 2020
TO: Pharmacies and Local Health Departments
FROM: New York State Department of Health

Health Advisory: Authorization of Licensed Pharmacists to order COVID-19 Tests

Background

[Executive Order 202.24](#), issued on April 25, 2020, authorizes licensed pharmacists to order COVID-19 tests, approved by the Food and Drug Administration (FDA), to detect SARS-CoV-2 or its antibodies. Executive Order 202.24 also allowed pharmacists to administer COVID-19 tests subject to subdivision 579(3) of the Public Health Law, in patients suspected of a COVID-19 infection, or suspected of having recovered from COVID-19 infection, subject to completion of appropriate training developed by the Department of Health (NYSDOH). In addition, it permits NYS licensed pharmacists to be designated as a qualified healthcare professional for the purpose of directing a limited service laboratory, pursuant to subdivision 579(3) of the Public Health Law, to test patients suspected of a COVID-19 infection or its antibodies, provided that such test is FDA-approved and waived for use in a limited service laboratory.

Overview of Requirements for Pharmacist Ordered COVID-19 Test

- New York State licensed pharmacists may order a COVID-19 test when:
 - The pharmacist/pharmacy has notified the State that they will be ordering COVID-19 tests, providing the name and address of the laboratory that will be performing the test; AND
 - The test is ordered in accordance with NYS Protocol for COVID-19 Testing, set forth below; AND
 - Specimens are either:
 - Sent to a clinical laboratory permitted by NYS and the result, as reported back to the pharmacist by the laboratory, as well as to DOH through the Electronic Clinical Laboratory Reporting System (ECLRS) is provided directly to:
 - The patient, with appropriate education and counseling about the result; and
 - The patient's primary care health provider; or
 - Tested within a limited service laboratory and results are reported to:
 - The patient, with appropriate education and counseling about the result; and
 - The patient's primary care health provider; and
 - The Department, through ECLRS, within 24 hours of test completion.

Process for State Notification of Specimen Collection Site

Pharmacists intending to order COVID-19 tests and establish a collection site must email PharmacyTestReporting@health.ny.gov with the following information: the site name and address, the name and address of the laboratory where specimens will be sent for testing, or, in the alternative, indication that the pharmacists will be conducting testing as a limited service laboratory.

Testing Site Considerations:

On April 19, 2020, the Department issued [Guidance for Private Physician Practices Operating Specimen Collection Sites](#), describing the site requirements when operating large-scale specimen collection sites for submission to laboratories for COVID-19 testing. Pharmacies ordering COVID-19 tests and operating specimen collection sites must follow this guidance.

Pharmacies intending to order and collect COVID-19 tests should contract with a private laboratory and follow that laboratory's instructions for proper collection, handling, and transport. The private laboratory must be a [NYS permitted laboratory](#) qualified to perform COVID-19 testing in New York State. Pharmacies intending to order and perform a COVID-19 waived test as a limited service laboratory should follow instructions for specimen collection testing provided by the test manufacturer.

Since collection of nasopharyngeal specimens for COVID-19 testing is not within a pharmacist's normal scope of practice, if this type of specimen is intended to be collected, pharmacists must complete training authorized by the Commissioner of the New York State Department of Health, in accordance with [Executive Order 202](#). A Health Advisory regarding this training is available on the [Health Commerce System](#).

Personal Protective Equipment

Pharmacists ordering COVID-19 tests are responsible for ensuring that proper safety and infection prevention protocols are followed during specimen collection process.

- All personnel collecting specimens must have training regarding COVID-19 and appropriate personal protective equipment (PPE).
- All personnel must be provided PPE appropriate for the task they are performing, to protect against the transmission of the virus. Pharmacies are expected to supply their personnel with appropriate PPE. If unable to obtain PPE, pharmacists should request it through their local county [Office of Emergency Management](#).

NYS Testing Protocol

On April 26, 2020, the Department issued [Updated Interim Guidance on the Protocol for COVID-19 Testing Applicable to All Health Care Providers and Local Health Departments](#). This guidance describes when diagnostic and/or serologic testing for COVID-19 shall be authorized by a health care provider, and the prioritization that should be followed when conducting COVID-19 testing, in accordance with the [Executive Order 202.19](#), issued on April 17, 2020. Pharmacies intending to order COVID-19 tests should review and must follow this guidance before providing COVID-19 testing.

Patient Counseling

Patients must be counseled at the time of their test, to follow all [quarantine instructions](#) if they are a contact to a confirmed or suspected case, until the results are known. Additional resources are available from the NYSDOH website, including [Next Steps](#) and [Contact Tracing Tool](#) flyers.

When ordering a COVID-19 test, the ordering provider has an obligation to report the results of the tests to the patient in a timely fashion. When communicating results to a patient, pharmacists must provide basic patient counseling. This must include:

- Information on the meaning of the test result ([Diagnostic Testing](#) and [Antibody Testing](#));
- In accordance with current [guidance on quarantine and isolation](#), the need to:
 - Self-quarantine if test result is positive; or
 - Maintain isolation if result is negative and an exposure to the virus occurred less than 14 days ago;
- Referring further questions about individual health to their healthcare provider; AND
- Notice that their local health department will be contacting them about the need for isolation or quarantine.

Reporting Requirements to Healthcare Providers

Pharmacists must directly report the result of the test to the patient's primary healthcare provider via mail, fax, or phone. If patients do not have a primary healthcare provider, the pharmacist should assist the patient in finding a healthcare provider, including consideration of a referral to a [Federally Qualified Health Center](#).

State Reporting Requirements

All COVID-19 laboratory results must be reported to the local health department where the patient resides, as well as the State. 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)***.

- Pharmacists ordering AND performing a COVID-19 waived test as a limited service laboratory, must follow the above guidance for reporting to ECLRS.
- Pharmacists sending specimens to a clinical laboratory do not need to report results to the State, as this will be done by the laboratory conducting testing.
- All results are sent by the State to the local health department where the patient resides.

Performing Testing as a Limited Service Laboratory

Pharmacies wanting to perform COVID-19 testing, must apply and be approved as a limited service laboratory (LSL). LSL application materials for pharmacies can be found at: <https://www.wadsworth.org/regulatory/clep/limited-service-lab-certs>. Under an LSL approval,

pharmacies can only use tests that have FDA Emergency Use Authorization (EUA) and have been deemed to be a “waived” test. A list of FDA EUA approved COVID-19 waived tests can be found at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>. This website includes a table entitled “Test Kit Manufacturers and Commercial Laboratories Table” and waived tests are designated as “W” under the “Authorized Setting” column.

On April 30, 2020, the Department issued a [Health Advisory on COVID-19 Serology Testing](#) which includes information regarding serological tests now available from commercial manufacturers, used to determine the presence of antibodies against SARS-CoV-2. This advisory should be reviewed since it has information describing the setting where COVID-19 serology tests can be used (i.e., in a laboratory approved to do high complexity, moderate complexity, or waived testing).

For Questions Regarding:

- Operating a specimen collection site, contact icp@health.ny.gov.
- Laboratory testing contact clepltd@health.ny.gov.