



**Executive Office**

1625 North Market Blvd., Suite S-308, Sacramento, CA 95834  
P (916) 574-8200 F (916) 574-8613 | [www.dca.ca.gov](http://www.dca.ca.gov)

## MEMORANDUM

<b>DATE</b>	August 25, 2020
<b>TO</b>	Pharmacies, Pharmacists and Pharmacy Technicians
<b>FROM</b>	Kimberly Kirchmeyer, Director, Department of Consumer Affairs Anne Sodergren, Executive Officer, California State Board of Pharmacy
<b>SUBJECT</b>	<b>Guidance on COVID-19 Testing Under Executive Orders N-25-20, N-39-20 and N-75-20, and DCA Waiver DCA-20-45<sup>1</sup></b>

This guidance describes the authority and permissible practices of pharmacies, pharmacists and pharmacy technicians to order, collect specimens for, perform, and interpret results for authorized COVID-19 tests, pursuant to the Governor's Executive Orders N-25-20, N-39-20 and N-75-20, and the Department of Consumer Affairs' waiver DCA-20-45.

### Background

On March 4, 2020, the Governor proclaimed a State of Emergency to exist in California as a result of the impacts of COVID-19 to make additional resources available, formalize emergency actions already underway across multiple state agencies and departments, and help the state prepare to respond to an increasing number of individuals requiring medical care and hospitalization as a result of a broader spread of COVID-19.

Pursuant to the Governor's Executive Order N-39-20, during the State of Emergency, the Director of the California Department of Consumer Affairs may waive any statutory or regulatory professional licensing requirements and amend scopes of practice pertaining to individuals licensed pursuant to Division 2 of the Business and Professions Code, including pharmacists and pharmacy technicians. This authority allows the Director to waive restrictions on the practice of licensees and the activities that licensees may undertake.

Pursuant to the Governor's Executive Order N-75-20, the Department of Consumer Affairs, in consultation with the Department of Public Health, may amend scopes of

<sup>1</sup> This guidance was developed by the California Department of Consumer Affairs, Department of Public Health, and State Board of Pharmacy.

practice to allow pharmacists and pharmacy technicians to conduct any aspect of any point-of-care test for the presence of SARS-CoV-2 that is deemed or classified as CLIA waived and, to that end, may waive any provision of the Business and Professions Code, or any other provision of law, to the extent that provision would prevent or in any way restrict any pharmacist or pharmacy technician from conducting any aspect of any such test.

### **Performing Point-Of-Care CLIA-Waived Tests For The Presence Of SARS-CoV-2 Without A Laboratory Director**

Pursuant to the Governor's Executive Orders and the applicable DCA waiver, and as discussed in more detail below, pharmacists and pharmacy technicians may perform on individual patients point-of-care clinical laboratory tests or examinations for the presence of the virus SARS-CoV-2 that are deemed or classified as waived pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA), in settings without a laboratory director, including a pharmacy.

Such tests are limited to tests authorized by the United States Food and Drug Administration (FDA) and performed consistent with the provisions of any applicable Emergency Use Authorization.

Pharmacies where tests are performed must still comply with any other applicable federal requirements, including CLIA certificate of waiver requirements. For purposes of CLIA, the person identified as responsible for directing and supervising testing oversight and decision making is the pharmacist-in-charge.

Pharmacies where tests are performed must also register with the Department of Public Health to perform waived tests, but need not identify a laboratory director. Such pharmacies must also comply with disease reporting requirements applicable to laboratories.

There are currently several waived tests for the presence of SARS-CoV-2 that may be performed in a clinical laboratory with a federal CLIA certificate of waiver and a California clinical laboratory registration. More information about the current list of available tests receiving FDA Emergency Use Authorization is available here:

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices>

For further information about the circumstances under which a test can be performed, please refer to the appropriate FDA-EUA approved manufacturers test kit's "Instructions for Use" literature.

### **Pharmacists May Order And Collect Specimens For All CLIA Categories Of Authorized COVID-19 Tests, And They May Perform and Interpret the Results for Authorized CLIA-Waived COVID-19 Tests**

Pursuant to the Governor's Executive Orders and the applicable DCA waiver, pharmacists may order and collect specimens for all CLIA categories of tests for the presence of SARS-CoV-2 in individual patients, including waived, moderate- and high-complexity tests.

Pharmacists may also perform and interpret results for point-of-care tests for the presence of SARS-CoV-2 that are deemed or classified as CLIA waived. The DCA waiver does not, however, authorize pharmacists to perform and interpret results for moderate- or high-complexity tests.

Pharmacists must be competent and trained to collect the particular specimen and perform the particular test, and the specimen must be collected, and the test performed, consistent with any applicable Emergency Use Authorization. Pharmacists that supervise pharmacy technicians are responsible for the testing duties the pharmacy technicians perform under their supervision. Pharmacists must also comply with disease reporting requirements applicable to health care providers.

### **Pharmacy Technicians In Pharmacies May Collect Specimens And Perform Authorized CLIA-Waived COVID-19 Tests**

Pursuant to the Governor's Executive Orders and the applicable DCA waiver, pharmacy technicians in a pharmacy may collect specimens through the use of nasal, nasopharyngeal, or throat swabs, and perform, point-of-care tests for the presence of SARS-CoV-2 that are deemed or classified as CLIA waived. Pharmacy technicians must be competent and trained to collect the particular specimen and perform the particular test, and the specimen must be collected, and the test performed, consistent with any applicable Emergency Use Authorization. Pharmacy technicians collecting specimens and performing tests, as specified, must remain under the direct supervision and control of a pharmacist.

### **Pharmacists Serving As Laboratory Personnel Performing COVID-19 Tests In A Licensed Laboratory**

Separately, on March 12, 2020, the Governor issued Executive Order N-25-20, which suspended certification and licensure requirements for persons performing COVID-19 tests in licensed clinical laboratories.

On April 8, 2020, the Department of Public Health's Laboratory Field Services (LFS) released guidelines on the qualifications of testing personnel based, in part, on Executive Order N-25-20. As explained in the guidance, for the duration of the COVID-19 emergency, persons may perform testing for SARS-CoV-2, the virus that causes COVID-19, without holding a California license to perform such testing, if they meet the requirements specified in federal regulations at 42 CFR 493.1489 for high-complexity testing personnel.

Pharmacists are not specifically included in the referenced section of the Code of Federal Regulations, but in the Board of Pharmacy's view, a pharmacist would satisfy those requirements by virtue of the education required for licensure. Accordingly, Executive Order N-25-20 and LFS's guidelines separately enable pharmacists to serve as laboratory personnel and perform COVID-19 testing under the guidelines issued by the LFS.

For questions about laboratory personnel or laboratory testing pursuant to Executive Order N-25-20 and related LFS guidance, please contact LFS at LFSCOVID@cdph.ca.gov. LFS has also posted helpful information for laboratories here: <https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/COVID-19.aspx>.

## Resources

For additional information, the DCA and the Board recommend that any licensee interested in ordering COVID-19 tests, collecting specimens, and performing tests in laboratory settings review the following information:

- Guidance for COVID-19 Collection and Testing Sites:  
<https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/COVID-19Guidance.aspx>
- CDC's Information for Laboratories About Coronavirus (COVID-19):  
<https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html>
- Guidance on COVID-19 for Pharmacy Personnel:  
<https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/GuidanceforPharmacies.aspx>
- Guidance on Resource Requests for Health Care Providers:  
<https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/ResourceRequestingforHealthCareProviders.aspx>

- Guidance on Expanded Access to Testing:  
<https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Expanding-Access-to-Testing-Updated-Interim-Guidance-on-Prioritization-for-COVID-19-Laboratory-Testing-0501.aspx>
- Guidance on Medical Waste Management:  
<https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/MedicalWasteManagementInterimGuidelines.aspx>

Information about FDA-authorized COVID-19 tests can be found on FDA's website under Emergency Use Authorizations: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>.

Information on the Coronavirus Disease 2019 (COVID-19) from California Emergency Medical Authority can be found on its website under: <https://emsa.ca.gov/covid19/>

Resources to determine pharmacies' ability to be registered as a clinical laboratory can be found on CDPH's website here: <https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/ClinicalLaboratoryFacilities.aspx>.