



Executive Office

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

MEMORANDUM

DATE	May 12, 2020
TO	Pharmacists
FROM	Kimberly Kirchmeyer, Director, Department of Consumer Affairs Anne Sodergren, Executive Officer, California State Board of Pharmacy
SUBJECT	Important Information for California State Board of Pharmacy Licensees Related to COVID-19 Testing¹

The California Department of Consumer Affairs (DCA) and the California State Board of Pharmacy (Board) received inquiries regarding a pharmacist's authority to order and administer COVID-19 tests in California. In short, a pharmacist may, under the circumstances specified below, order and collect specimens for authorized COVID-19 tests. Pharmacists may also serve as qualified laboratory testing personnel to perform COVID-19 tests, but only in an appropriately licensed or registered laboratory, and only under the direction of a laboratory director.

Ordering and Collecting Specimens for COVID-19 Tests

Effective May 12, 2020, pursuant to the waiver order issued by the Director of the Department of Consumer Affairs, pharmacists may now order tests for the presence of the virus SARS-CoV-2 ("COVID 19 tests") in individual patients, and without coordination with the patient's primary care provider or diagnosing prescriber. Pharmacists may also collect test specimens (such as through the use of nasopharyngeal swabs or other means) necessary to allow for analysis and interpretation of such COVID-19 tests.

The test must be authorized by the United States Food and Drug Administration (FDA), the pharmacist must be competent and trained to collect the specimen needed for the particular test, and the specimen must be collected consistent with the provisions of an Emergency Use Authorization issued by the FDA.

The waiver order does not, however, authorize the analysis or testing of samples collected, to the extent such analysis or testing is not otherwise authorized by law. This must be done by a public health, commercial, or clinical laboratory

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

pursuant to state and federal rules, which are enforced by the California Department of Public Health (CDPH).

The DCA and Board encourage pharmacists to contact their partner laboratories to obtain information about reporting requirements, specimen handling, transportation requirements, and reimbursement.

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 CDPH'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.

Although pharmacists are not specifically included in the referenced section of the CFR, in the Board's view, a pharmacist would satisfy those requirements by virtue of the education required for licensure. Accordingly, pharmacists may serve as laboratory personnel and perform COVID-19 testing under the guidelines issued by the LFS. However, the LFS guidance also makes clear that the facilities at which such testing may occur, the qualifications for a laboratory director, clinical consultant, technical consultant, and technical supervisor, and the supervision requirements **remain in effect**. Consequently, a pharmacist performing a test for COVID-19 (beyond specimen collection) must perform such tests in a facility with the applicable state and federal clinical laboratory license, under an appropriately-qualified laboratory director.

According to the CDPH, there are currently two types of COVID-19 tests that a pharmacist may perform as laboratory testing personnel: serological (antibody) tests and molecular (RNA) tests. The FDA has issued only a few Emergency Use Authorizations (EUA) for serological (antibody) tests intended for use by clinical laboratories. These EUAs limit the actual performance of serological tests to clinical laboratories with a federal CLIA certificate of compliance or certification of accreditation and a California clinical laboratory license.

Regarding molecular (RNA) tests, the FDA has approved numerous tests that include three molecular (RNA) tests for testing in a laboratory with a federal CLIA certificate of waiver and a California clinical laboratory registration.

For more information on the current list of COVID-19 tests receiving FDA EUA approval, please see the Internet link below. For further information on the circumstances under which a test can be performed, please refer to the appropriate FDA-EUA approved manufacturer test kit's "Instructions for Use" literature.

For questions about personnel or laboratory testing related to COVID-19, please contact LFS at LFSCOVID@cdph.ca.gov. LFS has also posted FAQs for laboratories: <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:

- [FAQs](#) provided for "Laboratory Questions" and "Resources for Laboratories".
- CDC's Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19): <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.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://ems.ca.gov/covid19/>

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

The Board does not have the authority to waive provisions of California law related to clinical laboratory licensing and testing requirements, including the provisions detailed in the LFS guidance.