

## Q: What is the recommendation for Dentists in performing COVID-19 Testing?

From the CA Department of Public Health:

Dentists are not automatically qualified to perform COVID-19 testing. A lab performing these tests must have federal CLIA certification and California licensure or registration appropriate to the complexity of the tests being performed. Most dentists do not have lab licensure to perform moderate and high complexity testing, but some have a CLIA waived certificate and California registration that qualify them to perform waived tests.

From Los Angeles County Department of Public Health:

*"The California Dental Practice Act allows dentists to perform such a test for dental treatment decisions. There are many steps to get the approval. FDA has to approve the test. Dentists have to apply for the California Clinical Laboratory Registration and CLIA Certificate of Waiver. Before this CMS has to list the test under the waiver category."*

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On April 17, 2020, the American Dental Association (ADA) submitted a letter to HHS (see attached) urging federal recognition for licensed dentists to administer point of service tests authorized by the FDA for COVID-19 under their existing scope of practice. It was discovered that licensed dentists are eligible to administer COVID-19 diagnostic tests within their scope of practice, provided they obtain (or already have) a Certificate of Waiver from the Centers for Medicare & Medicaid Services, as may be needed. Like physicians, dentists may need the certificate to administer FDA-waived COVID-19 diagnostic tests, as required by the [Clinical Laboratory Improvement Amendments](#) (CLIA) regulation. To obtain a CLIA waiver, dentists must submit an [application](#) and pay a \$150 application fee, though the ADA is lobbying Congress to waive the certificate requirement or at least waive the application fee. I am not sure of the effectiveness of these lobbying efforts. I did a cursory search on the HHS website but found nothing.

Apparently, a certificate from the Clinical Laboratory Improvement Amendments of 1988 (CLIA) is required for any laboratory testing. There are two appropriate certificates under the current COVID-19 conditions. A Certificate of Waiver (COW) is for laboratory tests designated as waived by the FDA. A Certificate of Compliance (COC) is required for a laboratory performing moderate- or high-complexity testing. Director qualifications are minimal for a COW and the certificate is easier to obtain. To acquire this certificate, submit an FDA CLIA application to the state's department of health. They will then contact the applicant and request certain forms such as disclosure of ownership, dental license, and IRS forms with Tax ID (states vary). The requirements for a COC are much higher. For a moderately complex laboratory certificate, a physician without any prior COC experience would need to take a 20-hour course. For a high-complexity laboratory certificate, the director of the lab needs to be at an anatomical or clinical pathologist's training.

I am unfamiliar with this CLIA regulation from 1988. It is possible that DHS, as a system, already has this certificate which covers all of our physicians (and dentists) as I can't imagine that every physician who administers swabs has their own individuals' certificate of waiver within DHS. I'm not sure who to talk to about verifying this for the system – so I've hit a bit of a wall in pursuing and verifying that aspect. For your purposes with MHLA, though, you would need to work with the CHCs to determine

status of the CLIA certificate of waiver. If you can verify the status of the waiver, my thought is that having dentists administer swabs – especially the oropharyngeal testing – would absolutely be within our scope.

Another option to consider is something that has just recently been implemented across DHS – the anterior nasal swabs that the patients perform themselves – with some guidance by a nurse/dentist/physician/etc. Dr. Bolaris, the chair of our Infection Prevention Committee is a big proponent of this testing as it conserves PPE (N95s are NOT necessary for the HCW guiding the patient through the testing) and the testing is rather simple for the patient to collect the sample themselves. Specificity and sensitivity of this test has proven a little lower than nasopharyngeal and oropharyngeal, but the benefits outweigh the risks of imperfect testing.

Below are some additional references you can research for more information on the ADA's request and on the CLIA-waiver.

References:

[https://www.ada.org/~media/ADA/Advocacy/Files/200417\\_oash\\_covid19\\_testing.pdf](https://www.ada.org/~media/ADA/Advocacy/Files/200417_oash_covid19_testing.pdf)

<https://www.ada.org/en/publications/ada-news/2020-archive/april/ada-advises-dentists-to-follow-science-backed-guidance-regarding-covid-19-testing>

<https://www.ada.org/en/publications/ada-news/2020-archive/april/ada-urges-hhs-to-federally-recognize-licensed-dentists-to-administer-point-of-service-covid-19-test>

[https://www.cdc.gov/csels/dls/locs/2020/fda\\_clarifies\\_clia-waived\\_status.html](https://www.cdc.gov/csels/dls/locs/2020/fda_clarifies_clia-waived_status.html)

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