

Virginia Board of Dentistry

COVID-19 Screening and Testing

On May 8, 2020 the Virginia Board of Dentistry voted that screening dental patients for COVID-19 was within the scope of practice of dentistry.

Dental practices must be able to identify COVID-19 infected dental patients for the safety of all patients and staff. Dental practices performing FDA-approved and Emergency Use Authorized COVID-19 screening tests could be valuable to this effort.

What is Screening?

Screening includes intentional procedures that are designed to identify illness before symptoms are obvious. Screenings, if they are to be effective, generally have more false positives than other types of tests because a false negative carries greater consequence. Obtaining a history from a dental patient that includes exposures and symptoms is a type of screening. Taking a temperature is a form of screening. A *screening test* is a medical test or procedure performed on a dental patient to assess the likelihood of the patient having a particular disease. Screening tests do not diagnose the illness. Rather subjects who test positive require referral for further evaluation with subsequent diagnostic tests. The BOD deemed all three of these types of screening (history, temperature, and screening tests) to be within the scope of practice of dentistry.

Who can perform Screening or Screening Tests?

Dentists, dental hygienists and dental assistants under the supervision of a dentist may perform screenings with or without CLIA-waived COVID screening tests. Per CLIA requirements, training for how to collect the sample and perform the test must be documented.

What is CLIA?

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing authority to promulgate standards for certain laboratory testing to ensure the accuracy and reliability of test results regardless of where or by whom the test was performed. Under CLIA, a laboratory is a facility that performs tests on materials derived for the human body for the purpose of providing information concerning health. Hence, a dental office doing COVID-19 screening tests is a laboratory.

What is a waived test?

As defined by CLIA, waived tests are categorized as “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result.” The Food and Drug Administration (FDA) determines which tests meet these criteria when it reviews manufacturer’s applications for test system waiver. The FDA recently clarified that, when it grants an Emergency Use Authorization (EUA) for a point-of-care test, that test is deemed to be CLIA-waived.

What COVID-19 Tests are CLIA Waived?

All point-of-care testing that is CLIA-waived can be identified using the following steps:

1. Access the FDA's EUA website

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd>

2. Scroll down to find the "In Vitro Diagnostics EUAs" on the FDA's website.

3. Tests that are indicated with a "W" under the "Authorized Setting(s)" section of the list are considered CLIA-waived point-of-care tests

Is a CLIA Certificate of Waiver Required When the Dental Practice *Only Collects* Samples?

No. If the dental practice is only collecting specimen samples and sending the samples to a laboratory for performing the test, then the dental practice is not required to obtain a CLIA Certificate of Waiver. Proper training for collecting the sample or overseeing the patient's self-collection is necessary to ensure validity of the process, the accuracy of test results, and mitigation of potential exposure to the virus.

How is a CLIA Certificate of Waiver Obtained?

Dental practices that are collecting specimen samples and performing CLIA-waived tests at the practice must obtain a CLIA Certificate of Waiver. Refer to the CMS document *How to Apply for a CLIA Certificate of Waiver*.

<https://www.cms.gov/regulationguidance/legislation/clia/downloads/howobtaincertificateofwaiver.pdf>

The Virginia Department of Health – Office of Licensure and Certification (OLC) is the state agency responsible for overseeing the federal CLIA requirements. An application must be submitted to OLC for obtaining a new CLIA Certificate of Waiver or when amending a certificate to add approved tests. OLC processes applications typically within 2-3 business days. Because not all COVID-19 tests are CLIA-waived and supply challenges may exist, OLC may require information about the test method, system or device successfully obtained by the dental practice prior to awarding the Certificate of Waiver. During the state of emergency and upon application processing, patient testing can begin once OLC emails the dental practice its CLIA number. The week after the application is processed, a fee coupon is mailed out. The week after the fee is paid, the paper certificate is mailed. The fee can be paid online at pay.gov or via mail as instructed on the fee coupon. Generally, the mailed certificate is received within 10-14 business days. Fee coupons and certificates are mailed once a week by a third-party vendor for the nation. Please note that the fee is non-refundable even if the dental practice is unsuccessful in obtaining the tests due to supply challenges.

<https://www.vdh.virginia.gov/licensure-and-certification/acute-care-division/clinical-laboratory-improvement-amendments-clia/>

Is a Prescriber's Order Required to Perform a CLIA-Waived COVID-19 Test?

No. The point-of-care COVID-19 tests authorized under an EUA are deemed CLIA-waived tests and do not require a prescriber's order prior to administration. However, testing should be performed in accordance with CDC and VDH testing priorities.

Must Test Results be Reported to VDH?

Yes. If the dental office is performing the test, then the dental office should report the test results to VDH immediately utilizing the Confidentiality Morbidity Report (<https://redcap.vdh.virginia.gov/redcap/surveys/?s=NYKYR7W47M>). More information about the disease reporting requirements and the online reporting portal can be found on the VDH website. If the dentist is only collecting the specimen sample and partnering with a lab that will perform the test, then the dental office should confirm with the lab that the lab will bear responsibility for reporting test results to VDH.

Must Patients be Notified?

All patients must be notified of their test results in a timely manner that maintains patient privacy in accordance with state and federal laws, and regulations. The local health district will perform contact tracing upon notification of a positive test result.

Is Training Required for Collecting and Performing Tests? Dental practices must ensure all dentists, dental hygienists, and dental assistants collecting specimen samples and/or performing COVID-19 tests receive appropriate training to conduct the activity in a safe and effective manner. This includes adherence to the testing device manufacturer's instructions. Completion of training must be documented. For additional information, refer to the "General Guidelines" section on CDC's website. <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

Is Reimbursement Available for Dental Practices Collecting or Performing COVID-19 Testing? The Board is not in a position to offer guidance on reimbursement. Please consult with relevant insurance carriers or administrators.