

Virginia Board of Pharmacy

COVID-19 TESTING

On April 8, 2020, the United States Department of Health and Human Services (HHS) [announced](#) that it had published [guidance](#) to authorize licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) has authorized. A list of FDA authorized tests under emergency use authorization (EUA) to diagnose and respond to public health emergencies is found [here](#).

The FDA has clearly articulated which point of care tests for COVID-19 are considered CLIA-waived according to an EUA. As defined by CLIA, waived tests are categorized as “simple laboratory examinations and procedures that have an insignificant risk of erroneous result.” The FDA is the agency which determines which tests meet these criteria when it reviews a device manufacturer’s application for a waiver.

On October 20, 2020, under the Secretary’s PREP Act Declaration, the Office of the Assistant Secretary for Health (OASH) issued additional [guidance](#) authorizing qualified pharmacy technicians and State-authorized pharmacy interns to administer COVID-19 tests, including serology tests, that the FDA has approved, cleared, or authorized. By doing so, such qualified pharmacy technicians and State-authorized pharmacy interns will qualify as “covered persons” under the PREP Act. And they may receive immunity under the PREP Act with respect to all claims for loss caused by, arising out of, relating to, or resulting from, the administration or use of FDA-authorized COVID-19 tests.

May CLIA-Waived Tests be Performed at a Pharmacy in Virginia?

The Virginia Board of Pharmacy has a longstanding position that the performing of CLIA-waived tests is within the scope of practice of pharmacy. Tests must be administered in accordance with FDA’s CLIA requirements.

Who Can Perform Testing?

Pharmacists, along with pharmacy technicians and pharmacy interns under the supervision of a pharmacist may perform CLIA-waived tests. Per CLIA requirements, training for how to collect the sample and perform the test must be documented.

Is a CLIA Certificate of Waiver Required When Only Collecting Samples?

No. If the pharmacy is only collecting specimen samples and sending the samples to a laboratory for performing the test, then the pharmacy 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 impacting the accuracy of test results and mitigating potential exposure to the virus.

How is a CLIA Certificate of Waiver Obtained?

Pharmacies that are collecting specimen samples and performing the CLIA-waived test at the pharmacy must obtain a CLIA Certificate of Waiver. Refer to the CMS document [How to Apply](#)

for a [CLIA Certificate of Waiver](#). The [Virginia Department of Health – Office of Licensure and Certification](#) (OLC) is the state agency responsible for overseeing the federal CLIA requirements. 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 pharmacy prior to awarding the Certificate of Waiver. During the state of emergency and upon application processing, patient testing can begin once OLC emails the pharmacy 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 pharmacy is unsuccessful in obtaining the tests due to supply challenges.

Which COVID-19 Tests are CLIA-Waived?

There are two main types of tests for COVID-19: diagnostic (molecular) tests for current infection and serologic (antibody) tests for past infection. Information regarding these two types of tests may be accessed on the [Virginia Department of Health website](#) (VDH) and clicking on “Information for Healthcare Professionals”.

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.

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

1. Access the [FDA’s EUA website](#)
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

Technology	Authorized Setting(s) ¹	Authorization Documents ²
Molecular	H, M, W	HCP, Patients, IFU

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 a 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](#) and therefore, patients must currently be screened for eligibility.

Is there a Pharmacy Checklist for Performing COVID-19 Diagnostic Tests?

Yes. VDH has developed a [Pharmacy Checklist](#) to assists pharmacists collecting specimen samples and performing COVID-19 Diagnostic (Molecular) tests.

Must Test Results be Reported to VDH?

Yes. If the pharmacy is performing the test, then the pharmacy should report the test results to VDH immediately utilizing the [Confidentiality Morbidity Report](#). More information about the disease reporting requirements and the online reporting portal can be found on the [VDH website](#). If the pharmacy is only collecting the specimen sample and partnering with a lab that will perform the test, then the pharmacy should confirm with the lab that it will bear responsibility for reporting test results to VDH. If the pharmacy has questions regarding reporting, they should contact the [local health district](#).

How 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?

Pharmacies must ensure all pharmacists, pharmacy interns, and pharmacy technicians collecting specimen samples and 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](#).

Where Can Information on Personal Protective Equipment (PPE) and Infection Control Measures be Accessed?

Information on PPE to be worn when collecting or handling a patient's self-collected sample may be accessed on [CDC's website](#).

May a Pharmacy Obtain PPE from VDH?

Challenges in obtaining PPE currently remain and are sporadic. Pharmacies that are experiencing difficulty in obtaining PPE may [contact their local health department](#) to assess opportunities for either obtaining PPE or partnering with VDH to increase access to COVID-19 testing. Until the supply of PPE increases, healthcare, testing sites, public health and first responders are being prioritized.

Is There a Map of Testing Sites?

Yes. VDH has developed a [locator map of COVID-19 testing sites](#). To be included on the map, pharmacies should submit their testing location using the link found on the locator map webpage.

Is Reimbursement Available for Pharmacies 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.