

Pharmacists' Guide to Authorized COVID-19 Tests and the CLIA Waiver Process

This list of frequently asked questions covers the Food and Drug Administration's (FDA) approval process for COVID-19 tests, how pharmacists can determine which tests are approved for their pharmacy setting, and how pharmacies can obtain a Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver.

How does FDA authorize COVID-19 tests?

The FDA's [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency](#) describes three main pathways for COVID-19 tests to be "approved" for use:

- Obtaining an Emergency Use Authorization (EUA) from the FDA.
- Developing the test under the [authorities of the State](#) in which the laboratory operates, where the State takes responsibility for COVID-19 testing by laboratories in its State. All such tests must be validated by the developer prior to being offered for clinical use.
- CLIA-certified high complexity laboratories may develop serology tests, considered Laboratory-Developed Tests (LDTs), by submitting notification of validation and labeling to FDA.

On August 19, the U.S. Department of Health and Human Services ([HHS](#)) [announced](#) that FDA will no longer require premarket review of laboratory-developed tests (LDTs) until FDA goes through a lengthy rulemaking process. LDT developers can still voluntarily request FDA reviews. As a result, substandard COVID-19 tests could be in the marketplace. The action appears to revoke previous FDA guidance used to remove 27 faulty COVID-19 serology tests from the marketplace and require testing manufacturers to submit applications for EUAs in 10 days.

The policies and guidance above do not apply to [home-based tests](#) and self-collection of samples to be sent to laboratories. Manufacturers of those tests need to work directly with FDA early in the development process.



What is an EUA?

During times of emergency, the FDA is authorized to grant [Emergency Use Authorizations](#) (EUAs), which "allow unapproved medical products or unapproved uses of approved medical products to be used ... to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives." COVID-19 tests that are considered in vitro diagnostics must receive an EUA to be considered approved for use in COVID-19, and the FDA provides an EUA template indicating required information for test kit manufacturers to facilitate the process.

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Which tests have EUA?

The full and current list of COVID-19 tests with an FDA EUA is available on the FDA's [In Vitro Diagnostics EUA page](#).

Which COVID-19 tests with EUAs can be provided in a pharmacy?

As new tests are authorized and added to the FDA's [list of tests with EUAs](#), pharmacists can determine the approved testing locations by reviewing the first page of a test's Letter of Authorization. If the "Authorized Laboratories and Other Authorized Testing Locations" section indicates "patient care settings," the test may be provided in pharmacies that have CLIA Certificates of Waiver. Point-of-care tests are indicated under the "Authorized Setting" category with a "W."

Pharmacists can partner with CLIA-certified high or moderate complexity laboratories to collect respiratory specimens for FDA EUA COVID-19 tests. If a pharmacy chooses this type of testing model, the pharmacy will not need a CLIA Certificate of Waiver to collect specimens on behalf of the certified laboratory. Pharmacy Models for COVID-19 Testing provides an overview of the necessary steps a pharmacy must take to provide COVID-19 testing either in partnership with a laboratory or as the point of care. This resource can be found in [APhA's COVID-19 Resources: Know the Facts library](#).

What is CLIA? How does CLIA normally affect tests provided in pharmacies?

The [FDA notes](#) that "the Clinical Laboratory Improvement Amendments (CLIA) regulate laboratory testing and require clinical laboratories to be certified by the Centers for Medicare and Medicaid Services (CMS) before they can accept human samples for diagnostic testing." The [CDC expands](#) on this explanation, stating that "the CLIA regulations establish quality standards for laboratory testing performed on specimens from humans, such as blood, body fluid, and tissue, for the purpose of diagnosis, prevention, or treatment of disease, or assessment of health." The FDA, CMS, and CDC are jointly responsible for CLIA tests, and each has a [specific role](#).

When diagnostic tests receive full FDA approval, they are [categorized](#) based on complexity as high complexity, moderate complexity, or waived, which determines where the tests can be analyzed. High and moderate complexity tests can only be analyzed in laboratories certified under CLIA. When a diagnostic test is granted a CLIA waiver, analysis can be done in other settings able to provide CLIA-waived tests with an EUA, such as pharmacies. CMS and state authorities are responsible for enforcement of CLIA requirements.

How can a pharmacy obtain a CLIA Certificate of Waiver?

CMS manages the process to obtain a CLIA Certificate of Waiver, and some states have additional regulations or guidance related to the process. CMS's [Quick Start Guide](#) details the process and includes helpful graphics and links. More information is also available on the agency's [CLIA webpage](#) as well as in its [How to Obtain a CLIA Certificate of Waiver](#) resource.



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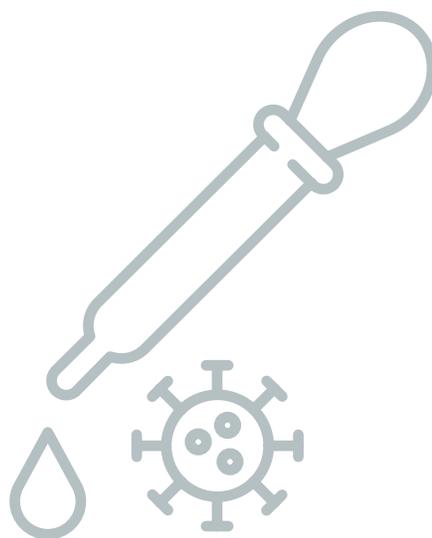


Can pharmacists order and administer COVID-19 tests?

HHS authorized “licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) has authorized.” For more information about testing authority, view [Authority to Test for COVID-19](#) resource. This resource can be found in [APhA's COVID-19 Resources: Know the Facts](#) library.

Can a pharmacist be held liable for any loss related to COVID-19 testing?

The HHS guidance notes that pharmacists ordering and administering tests “will qualify as ‘covered persons’ under the [PREP Act](#),” which provides liability immunity for any loss related to countermeasures to COVID-19. Most pharmacists administer point-of-care tests developed by manufacturers that still need an EUA. Community pharmacists do not administer LDTs. However, pharmacists may partner with labs that have an LDT for the specimen collection for the test. Pharmacists should know that they may not be covered under federal immunity protections if they provide specimen collection for a lab using LDTs that have not been approved or authorized. Pharmacists should confirm that any test performed in the pharmacy or by a laboratory partner is an FDA-authorized COVID-19 test to ensure they are not acting outside authority given by HHS to administer and order tests and that they are covered under federal immunity protections.



***Disclaimer:** Information related to the COVID-19 pandemic is changing rapidly and continuously. The material and information contained in this publication is believed to be current as of the date included on this document. The American Pharmacists Association assumes no responsibility for the accuracy, timeliness, errors or omission contained herein. Links to any sources do not constitute any endorsement of, validity, or warranty of the information contained on any site. The user of these materials should not under any circumstances solely rely on, or act based on this publication. Pharmacy professionals retain the responsibility for using their own professional judgment and practicing in accordance with all rules, regulations, and laws governing the pharmacy practice within their jurisdiction.*