
Obtaining a CLIA Waiver

A CLIA (Clinical Laboratory Improvement Amendments of 1988) Certificate of Waiver is required to perform some tests like finger sticks for blood glucose. Point-of-care testing such as the Abbott BinaxNOW test is one type of test approved by the FDA for use in RCFEs that have obtained a CLIA waiver. Each community that performs CLIA-waived tests requires their own certificate, so companies with multiple sites must have a waiver for each community that performs waived tests. Click [here](#) for the California Department of Public Health’s Guidance for COVID-19 Testing that helps entities understand the legal requirements for performing waived antigen testing.

There are two parts to the process, federal and state, which both require an application and fee. Laboratory Field Services (LFS), which is part of the California Department of Public Health, is responsible for collecting and processing the federal and state applications. LFS has opened an online application process, which can be accessed [here](#) (see below for more information on the application process). A successful submission will consist of the online application and completed forms [CMS 116](#), [LAB 182](#), and [LAB 183](#). The forms must be completed and uploaded to the application portal. The federal CLIA program will bill applicants separately for the federal CLIA certification fee.

California requires applicants to identify a laboratory director under which the overall operation and administration of the testing will occur. State law allows the following to be designated as a lab director for waived tests: physician, clinical laboratory scientist, limited clinical laboratory scientist, or naturopathic doctor. Also note that the five facility limit does not apply to CLIA waivers ([Business & Professions Code Section 1209](#)). (For more information see [ISSUES SPECIFIC TO CALIFORNIA CLINICAL LABORATORY LAW](#).)

Here’s what you need to know about the online application process:

Submitting a CLIA Waiver Application

- Go to <https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/OnlineNewApplication.aspx>. Read through the information and follow the steps on the webpage to create an account. Once you have an account you will have access to the online application. As noted above, in addition to the application process, three forms are required (one federal and two state)—[CMS 116](#), [LAB 182](#), and [LAB 183](#)—that must be completed and uploaded to the application portal. State payment of \$113 is due at the time of submission, and federal payment is collected later. The certificate will be mailed after all payments have been collected.
- Companies with more than one RCFE can submit multiple applications and pay for them all together at the payment screen. The person submitting the application should stop at the Payment Information screen, save their information, and close. They will be taken back to the dashboard that shows the option to “Start New Application.” This will allow them to add another site. Continue to add sites in this manner. When ready to pay, click through the payment screen and pay \$113 per application. Please note that you must click on “Start New Application” for each RCFE; **do not** click on “Add Secondary Site.” For additional information view the [Online User Guides](#).

Test Result Reporting Requirements

- RCFEs conducting tests on-site under a CLIA waiver are not currently required to report test results per [CDPH guidance](#).

For more information on how to obtain a CLIA [certificate of waiver](#) visit the CMS website and the [LFS](#) website; or you may send an email to LFSCC@cdph.ca.gov for additional information.