
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 for COVID-19 is being developed and—once approved by the FDA—should allow for fast, on-demand testing that is also significantly cheaper than current testing. The Abbott BinaxNOW test is one such point-of-care test that has been approved by the FDA and is being shipped to some RCFEs that have already obtained a CLIA waiver courtesy of the federal Department of Health and Human Services (HHS). RCFEs need a CLIA waiver to perform the testing on-site. 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.

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](#).) If you need a lab director, we can help (see below).

Under a [Temporary Allowance](#) the state is allowing waived testing to be conducted in the community as soon as the RCFE has submitted a complete application and received an acknowledgement of receipt from LFS. Waived laboratories are not generally inspected but may be surveyed in response to a complaint.

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. For more information see [Congregate Living Facility Guidance](#).
- 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](#).

Need a Lab Director?

- If you need a lab director for your CLIA waiver application, let us know by filling out the information on [RCFEs in Need of CLIA Waiver Lab Directors](#) and we will match you with a CALTCM physician who will contract with you for this role. CALA has created a [contract template](#) that can be used for this purpose. Please review with your own legal counsel.

How do you receive the Abbott BinaxNOW tests once you have a CLIA waiver number?

- HHS works with CMS to ensure distribution includes all eligible communities. This process occurs on a bi-weekly basis as CMS updates laboratory designations and as COVID-19 epidemiology changes across the country. RCFEs are automatically added to and removed from the distribution during this data refresh based on eligibility, while the program is in effect.
- The state has tests that can be accessed by RCFEs. Contact your [Medical Health Operational Area Coordinator \(MHOAC\)](#) once you have submitted a complete application and received an acknowledgement of receipt from LFS to see if they have tests to distribute.

Test Result Reporting Requirements

- RCFEs conducting Abbott BinaxNOW tests on-site will have [additional reporting requirements](#). [Click here](#) for information on creating a [CalREDIE](#) account for reporting purposes. ***Please note that RCFEs in Los Angeles and San Diego counties do not report through CalREDIE and should contact their local health department for reporting requirements.***
- [CDPH guidance](#) on reporting positive tests through CalREDIE and aggregated test results for all non-positive tests through a daily survey.
- [CalREDIE Manual Lab Reporting Module](#): A one-page document that describes reporting requirements for antigen tests.
- [Manual Lab Reporting Quick Start Guide](#): Provides steps and screenshots to help users go through the CalREDIE Manual Lab Reporting Module.
- [Manual Lab Reporting Account Request Form](#): Form to be completed and submitted for CalREDIE Manual Lab Reporting users.

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 LFS@cdph.ca.gov for additional information. Click [here](#) to access several resources, including tutorials and manuals to help with the application process.