

HOW TO GET A CLIA WAIVER

The steps below will help you complete a CMS-166 form to obtain a CLIA waiver for the first time

STEP 1

Complete the 4 page application using the CMS-116 form <https://bit.ly/CLIAApplication>

Section I. General Information

- Check initial application and leave the CLIA identification number blank
- Complete this section providing your pharmacy's specific information

Section II. Type of Certificate Requested

- Only check the first box, certificate of waiver

Section III. Type of Laboratory

- Check box 20: Pharmacy

Section IV. Hours of Laboratory Testing

- Indicate the times your pharmacy will provide testing

Section V. Multiple Sites

- Check no if you are only applying for one pharmacy
- Check yes if you are offering testing at more than one pharmacy. If you will have multiple sites,

provide the number of sites, and complete the remainder of this section.

Section VI. Waived Testing

- List the tests you will be performing. Refer here to review the list of approved CLIA WAIVED tests
- Estimate number of tests you'll be performing annually

Skip: Section VII. PPM Testing & VII. Non-waived testing

Section IX. Type of Control

- Check the box that best describes your pharmacy

Section X. Director Affiliation with other Laboratories

- If you have no other pharmacies with a CLIA waiver, leave this blank. If you have others with an existing CLIA Waiver, list those here.

STEP 2

Submit the application to your state agency. Your Pharmacy's Certificate of Waiver application should be forwarded to the address of the local state agency of the state in which the testing will be performed. View CLIA contacts for all states. You can also contact your local state agency for assistance in filling out the application.

The Certificate of Waiver is valid for two years. A renewal application will need to be completed and sent to the state agency not less than 9 months before the certificate's expiration date. There is a fee for a Certificate of waiver (\$150).

For additional information or assistance in filling out the CLIA waiver application, please call CMS Toll-Free: 877-267-2323; Local: 410-786-3000; TTY Toll-Free: 866-226-1819; TTY Local: 410-786-0727. Or visit the [CLIA Website](#).

Regulatory Oversight of Laboratory Testing: Clinical Laboratory Improvement Amendments (CLIA)

- [Application for CLIA Certificates and General Information on CLIA](#)

CEImpact Point of Care Testing Course Available - <https://bit.ly/CEImpactPOCT>

1. <https://www.cdc.gov/hiv/testing/nonclinical/clia.html>
2. <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/HowObtainCertificateofWaiver.pdf>