



CLIA LICENSING

GUIDEBOOK

Want to offer rapid point-of-care testing at your pharmacy or lab?
First, you'll need the right license.




TABLE OF CONTENTS

The Centers for Disease Control, the Centers for Medicare and Medicaid Services (CMS) and Food and Drug Administration (FDA) support the CLIA program and set standards for clinical laboratory quality. This guidebook will provide a high-level overview of CLIA and of licensing requirements for **CardioChek Plus** and **AICNow** tests.

What is CLIA?	01
Types of licenses	02
How to apply	03
FAQs	04
Additional Resources	05

WHAT IS CLIA?

The Clinical Laboratory Improvement Amendments (CLIA) of 1988 set federal standards for regulating laboratory testing in the U.S. The aim of the CLIA program is to ensure quality laboratory testing.



Who Needs CLIA Licensing?

Any facility, site, or person that tests human specimens such as blood, urine, or saliva to assess health, or to diagnose, prevent, or treat disease is considered a laboratory under the CLIA program.

In other words, anyone who performs a diagnostic test on anyone other than themselves must be CLIA licensed.

The facility must comply with all federal, state, and local laboratory laws.



Who Issues CLIA Licenses?

CLIA licenses are *issued* by the U.S. federal government; specifically, by the Centers for Medicare and Medicaid Services (CMS). But they are *administered* through each state.

States and municipalities may impose additional requirements beyond the federal regulations.

To begin the process of applying for your CLIA license, [reach out to your state CLIA agency contact.](#)

TYPES OF CLIA LICENSES

The type of license you need is determined by the complexity of test(s) you want to offer at your facility. CMS issues CLIA licenses, but the FDA clears laboratory tests for clinical use and categorizes them based on their complexity.

Certificate of Waiver (COW)

Facilities that have a Certificate of Waiver can only perform waived tests.

Waived tests are simple and accurate. They have little risk of error when performed correctly. Personnel typically do not need clinical expertise to perform the test.*

CardioChek and A1CNow are both waived tests.

**Some states do have clinical personnel requirements for Certificate of Waiver licensees. Check with your state CLIA administrator for more information.*

Certificate of Compliance (COC) – Moderate Complexity

Facilities that have moderate complexity COCs can perform both waived and moderately complex tests.

Moderately complex tests must be performed by personnel with some clinical expertise to avoid risk of error.

Certificate of Compliance (COC) – High Complexity

Facilities that have high complexity COCs can perform waived, moderately complex, and highly complex tests.

Highly complex tests must be performed by personnel with a high level of clinical expertise to avoid risk of error.

HOW TO GET A **CLIA LICENSE**

1. Apply

Complete and send a CMS-116 application to your state contact. You can download the application and find your state contact at CMS.gov.

[CLIA Application for Certification \(CMS116\)](#)

[CLIA State Contacts](#)

2. Pay the licensing fee

Once your application is accepted, you will receive an invoice for the cost of your federal license. As of May 2023, the fee for the Certificate of Waiver at the federal level is \$180. The certificate is good for 2 years; it must be renewed before the expiration date.

3. Receive your license

Once the invoice is paid, you will receive your CLIA license.

4. Complete additional state and local requirements, where applicable.

Some states require you to submit not only CMS-116, but also their own state forms and applications. Check with your state's CLIA contact for additional information. You may also need to check with county and/or city health departments to see if there are additional local requirements. There may also be additional state and local licensing fees.



FREQUENTLY ASKED QUESTIONS

01

Are CLIA requirements the same in all U.S. states and territories?

No. Though it is a federal law, CLIA is administered through each state. States are allowed to enforce their own laboratory requirements as long as they are equally stringent or more stringent than the federal law. For example, New York, Maryland, New Jersey, Washington, California, and Pennsylvania are states that enforce additional requirements beyond the federal law.

02

Does my CLIA license allow me to test in all U.S. states?

Yes. But you must follow any additional regulations in the state in which you are testing. For example, you may be required to hire personnel who are licensed in the state in which you are testing, rather than your own personnel, due to state requirements.

03

Once we get our CLIA license, will we be subject to state inspections?

If you have a Certificate of Waiver, typically no. But states do have the right to inspect any licensed entity, and will sometimes send inspectors to health fairs, for example.

If you are operating under a Moderate or High Complexity license, your facility will be subject to routine inspections.

04

Are we allowed to interpret test results?

Only to the extent listed in the test's package insert. For example, you may provide information that lists the expected values for the test. You may not provide any medical advice. Patients should be referred to their healthcare provider for medical advice.

ADDITIONAL RESOURCES

General Information

[CLIA Brochures - CMS.gov](#)

[CLIA Categorizations - FDA.gov](#)

[CLIA Laboratory Improvement Amendments - CMS.gov](#)

[CLIA Requirements, 42CFR493 - Code of Federal Regulations](#)

[Waived Tests - CDC.gov](#)



How to Apply

[How to Apply for a CLIA Certificate - CMS.gov](#)

State Information

[CLIA Exempt States - CMS.gov](#)

[State Agency Contacts - CMS.gov](#)





Want more info about CardioChek or A1CNow?

Schedule a Phone Call

bit.ly/pts-intro

