



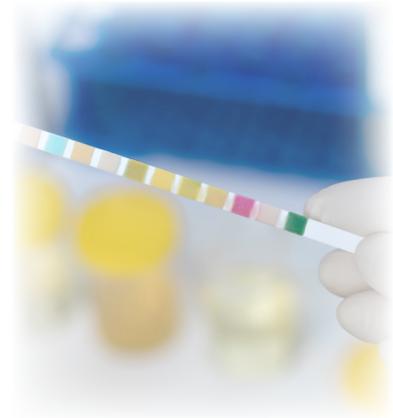
## Clinical Laboratory Improvement Amendments (CLIA)

# How to obtain a CLIA Certificate of Waiver

*NOTE: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing authority to promulgate standards for certain laboratory testing to ensure the accuracy, reliability and timeliness of test results regardless of where or by whom the test was performed. The CLIA requirements are based on the complexity of the test and the type of laboratory where the testing is performed. While every effort has been made to ensure the accuracy of this restatement, this brochure is not a legal document. The official CLIA program requirements are contained in the relevant law, regulations and rulings. Please note that state, local, and accreditation requirements may be more stringent.*

## What is a laboratory?

Under CLIA, a laboratory is defined as a facility that performs applicable testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings.



## I am a physician performing urine dip sticks and finger sticks for blood glucose in my office as part of the patient's visit. Am I considered to have a laboratory and do I need a CLIA certificate?

Generally yes, as those tests likely qualify as waived laboratory testing, you need a CLIA Certificate of Waiver and you must follow the manufacturer's instructions. This kind of testing requires a CLIA certificate regardless of how many tests you perform, even if you do not charge the patient or bill Medicare or other insurances. However, you may not need a CLIA certificate if your laboratory is located in the states of New York or Washington, as those States operate their own laboratory regulatory programs. Contact the appropriate [State Agency](#) to determine if you need a CLIA certificate.

## What is a waived test?

As defined by CLIA, waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result." The Food and Drug Administration (FDA) determines which tests meet these criteria when it reviews manufacturer's applications for test system waiver.

## Where can I find a list of waived tests?

For a list of waived tests sorted by analyte name, visit the FDA website at: [CLIA – Currently Waived Analytes](#)

## Can I perform tests other than waived tests if I have a Certificate of Waiver?

No, only those tests that are CLIA-waived can be performed by a laboratory with a Certificate of Waiver.

## How do I enroll in or apply to the CLIA program?

You can enroll your laboratory in the CLIA program by completing an application ([Form CMS-116](#)) available on the [CMS CLIA website](#) or from your local State Agency. Send your completed application to the address of the local [State Agency](#) for the State in which your laboratory is located. Additionally, check with your [State Agency](#) for any other state-specific requirements. If you do not have online access and do not have information about your [State Agency](#), you may contact the CLIA program at 410-786-3531 for the address and phone number of your [State Agency](#).

## If I have more than one office and perform waived testing at more than one site, do I need additional certificates

You will need a CLIA certificate for *each* site where you perform testing, *unless* you qualify for one of the exceptions listed below:

- If your testing location changes, such as with mobile units providing laboratory testing, health screening fairs, or other temporary testing locations, the testing may be covered under the certificate of the designated primary site or home base, using its address.
- If you are performing limited public health testing, you may file a single application to cover multiple locations. Limited public health testing is defined as not-for-profit or Federal, State or local government laboratories that engage in limited testing (not more than a combination of 15 moderately complex\* or waived tests per certificate). So you may be able to cover the waived testing you perform at more than one office if you meet this exception.
- If your testing locations are within a hospital and are located at contiguous buildings on the same campus and under common direction, you may file a single application for the laboratory sites within the same physical location or street address.

Contact your [State Agency](#) if you have questions or you are filing a single application for more than one testing site.

\* Laboratory tests regulated under CLIA are categorized by the FDA as either waived, moderate complexity or high complexity based on set criteria.

## Will I receive an identifying CLIA number?

You will receive a ten-character alpha-numeric code on the CLIA certificate. This number will be utilized to identify and track your laboratory throughout its entire history. You should use this number when making inquiries to the State Agency and CMS about your laboratory.

## When can I start performing the waived testing?

After you apply for your certificate, you will receive a fee coupon assessing a fee. Follow the instructions on the fee coupon for payment. After your payment is received, your certificate will be mailed to you. You generally may begin testing once you have received your CLIA certificate, but you also need to check with your [State Agency](#), since some states have additional state-law requirements.

## If I only perform waived tests, what does CLIA require that I do?

For waived testing, CLIA requires that you:

- Enroll in the CLIA program by obtaining a certificate;
- Pay the certificate fee every two years;
- Follow the manufacturer's instructions for the waived tests you are performing; and
- Notify your [State Agency](#) of any changes in ownership, name, address or Laboratory Director within 30 days, or if you wish to add tests that are more complex.

## How and when will I be inspected?

Laboratories with a Certificate of Waiver are not subject to a routine inspection (survey) under the CLIA Program, but may be surveyed in response to a complaint or if they are performing testing that is not waived.

## What does it mean to follow the manufacturer's instructions for performing the test?

To follow the manufacturer's instructions for performing the test means to follow *all of the instructions in the package insert from "intended use" to "limitations of the procedure."* The manufacturer's instructions can be found in the package insert for each test. It is good laboratory practice and important to read the entire package insert before you begin testing. Be sure the package insert is current for the test system in use, the correct specimen type is used, the proper reagents (testing solutions) are added in the correct order, and the test is performed according to the step by step procedure outlined in the package insert.

Some waived tests also have quick reference instructions included, which are cards or small signs containing diagrams or flow charts with essential steps for conducting the test. Be sure that quick reference instructions are current for the test system in use and are available to the individuals performing the test.

## How do I know if I have current manufacturer's instructions?

Always use the package insert or quick reference instructions that come with the test system you just opened. If you are unsure whether you have current instructions, contact the manufacturer at the telephone number listed in the package insert.

## Why is it important to follow the current manufacturer's instructions?

It is important to always follow the current test system's instructions precisely to be sure your results are accurate. This includes performing any quality control procedures that the manufacturer recommends or requires. Over time, a manufacturer may make modifications to a test system that result in changes to the instructions. Failure to use the current instructions could cause inaccurate results that may result in a misdiagnosis or delay in proper treatment of a patient.



## **Do I need to follow all the manufacturer's instructions on how to perform the test?**

Yes, *all* the information in the test package insert instructions is considered part of the manufacturer's instructions and must be followed. Some examples of this information are:

- Observing storage and handling requirements for the test system components;
- Adhering to the expiration date of the test system and reagents, as applicable;
- Performing quality control, as required by the manufacturer;
- Performing function checks and maintenance of equipment;
- Training testing personnel in the performance of the test, if required by the manufacturer;
- Reporting patients' test results in the units described in the package insert;
- Sending specimens for confirmatory tests, when required by the manufacturer; and
- Ensuring that any test system limitations are observed.

## **Can I follow the quick reference guide instead of following the package insert?**

No, the quick reference guide is only a synopsis of the entire package insert.

## **When performing waived testing, am I required to do everything in the instructions, even if some of the items are manufacturer's recommendations or suggestions?**

Yes, you must follow all instructions when such terms as "always," "require," "shall," and/or "must" are used by the manufacturer.

You have the option to follow the recommendations or suggestions of the manufacturer. However, adhering to the manufacturer's recommendations and suggestions will help ensure the accuracy and reliability of the test, and is considered good laboratory practice.

## As a laboratory director, what kinds of things can I do to help ensure the accuracy and reliability of the waived testing in my laboratory?

In order to ensure the accuracy and reliability of waived testing in your laboratory, you should develop and maintain good laboratory practices. Some examples are listed below:

- Provide specific training to the testing personnel so that you are certain they:
  - Collect specimens appropriately;
  - Label and store specimens appropriately;
  - Understand and then follow the manufacturer’s instructions for each test performed;
  - Know how to perform the testing;
  - Know how to document and communicate the test results; and
  - Are able to identify inaccurate results or test system failures.
- Observe and evaluate your testing personnel to make certain the testing is accurate.
  - Do they positively identify the patient and specimen?
  - Do they collect a proper specimen?
  - Do they know how the specimen should be preserved, if applicable?
  - If the specimen needs to be transported, do your testing personnel understand and adhere to the transport requirements?
- Check for extreme changes in such things as humidity, temperature, or lighting; as these may affect test results.
- Make sure that the patient specimen is handled properly from collection to test completion.

## Where can I find more information about good laboratory practices?

The Centers for Disease Control and Prevention has published recommendations for “[Good Laboratory Practices for Waived Testing Sites](#)” in *Morbidity and Mortality Weekly Reports (MMWR); Recommendations and Reports*. The MMWR publication provides comprehensive recommendations for facilities that are considering introducing waived testing or offering a new waived test, and good laboratory practices to be followed before, during, and after testing. You can find this article on the [CDC CLIA Waived Testing website](#).

Additionally, there are free educational materials on waived testing on the [CDC Division of Laboratory Systems website](#).

## Can I make any changes to the test system instructions?

No, it is not acceptable for you to make changes to the current instructions provided with the test system. This could change the “intended use” of the test system as approved by FDA and result in a test that is ***no longer waived***. For example, if a test specifies urine as the waived specimen type and you test a different body fluid, then you are no longer performing a waived test and your laboratory is subject to an inspection and additional CLIA requirements. You must be sure that testing personnel follow the directions exactly, and add the proper reagents in the correct order and amount given by the manufacturer to ensure correct test results.

## Where can I get additional information?

For additional information, you can email questions to the CMS Lab Excellence mailbox at: [LabExcellence@cms.hhs.gov](mailto:LabExcellence@cms.hhs.gov).

[CLIA Law & Regulations](#)

[CDC CLIA website](#)

[FDA CLIA website](#)

## Hyperlink Table

Embedded Hyperlink	Complete URL
CLIA – Currently Waived Analytes	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a>
Form CMS-116	<a href="https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf">https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf</a>
CMS CLIA website	<a href="https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/CLIA/">https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/CLIA/</a>
State Agency	<a href="https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf">https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf</a>
“Good Laboratory Practices for Waived Testing Sites”	<a href="https://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf">https://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf</a>
CDC CLIA Waived Testing website	<a href="https://wwwn.cdc.gov/clia/Resources/WaivedTests/default.aspx">https://wwwn.cdc.gov/clia/Resources/WaivedTests/default.aspx</a>
CDC Division of Laboratory Systems website	<a href="https://www.cdc.gov/csels/dls/educational-materials.html">https://www.cdc.gov/csels/dls/educational-materials.html</a>
CLIA Law and Regulations	<a href="https://wwwn.cdc.gov/clia/Regulatory/default.aspx">https://wwwn.cdc.gov/clia/Regulatory/default.aspx</a>
CDC CLIA website	<a href="https://wwwn.cdc.gov/clia/default.aspx">https://wwwn.cdc.gov/clia/default.aspx</a>
FDA CLIA website	<a href="https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm">https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm</a>