



Clinical Laboratory Improvement Amendments (CLIA)

How to Obtain a CLIA Certificate of Waiver

When is a CLIA Certificate of Waiver Required?

NOTE: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April, 24, 2003.



WHAT IS A LABORATORY?

Under CLIA, a laboratory is defined as a facility that performs 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?

Yes, the testing you perform qualifies as waived laboratory testing and you need a CLIA Certificate of Waiver. This testing requires a CLIA certificate regardless of how many tests you perform and even if you do not charge the patient or bill Medicare or other insurances.

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 the criteria for tests being simple with a low risk of error and approves 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 <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm>.

For a list of waived tests sorted by the test categorization date and by the test system name, visit the FDA website at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm>.

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 online at www.cms.hhs.gov/clia or from your local State Agency. Forward your completed application to the address of the local State Agency for the State in which your laboratory is located. A list of State Agencies is available at the web site listed above. 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.

- Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base using its address.
- Not-for-profit or Federal, State or local government laboratories that engage in limited public health testing may file a single application.
- Laboratories within a hospital that are located at adjoining buildings on the same campus and under common direction 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.

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 CMS receives your payment, your certificate will be mailed to you. You may begin testing once you have received your certificate. You also need to check with your State Agency since some states have additional 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 manufacturers' instructions for the waived tests you are performing;
- Notify your State Agency of any changes in ownership, name, address or director within 30 days, or if you wish to add tests that are more complex; and
- Permit inspections by a CMS agent, such as a surveyor from the State Agency. However, your laboratory is not subject to a routine survey or inspection.

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 product insert from "intended use" to "limitations of the procedure."** The manufacturer's instructions can be found in the product insert for each test. It is good laboratory practice and important to read the entire product insert before you begin testing. Be sure the product 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 product 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 testing. 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 product 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 product 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 product 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 PRODUCT INSERT?

No, the quick reference guide is only a synopsis of the entire product 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 the 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 assure 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 ASSURE THE ACCURACY AND RELIABILITY OF THE WAIVED TESTING IN MY LABORATORY?

In order to assure 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 website at <http://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf>.

You may also find helpful information on the CLIA web site at www.cms.hhs.gov/clia under “Certificate of Waiver Laboratory Project.”

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 assure correct test results.

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. Also, CMS is currently conducting a project whereby a small percentage of laboratories that perform waived testing may receive an educational visit at no charge. CMS representatives provide helpful information to the waived testing sites. This project has been extremely well received by the laboratory community.

NOTE: This brochure is not a legal document. The official CLIA program provisions are contained in the relevant law, regulations and rulings.

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