



INTRODUCTION TO CLIA-WAIVED TESTING

OVERVIEW

Any site that performs laboratory testing must follow applicable regulatory requirements including federal, state and local mandates for testing, as well as requirements for the safety and confidentiality* of personal information. The federal requirements are mandated by the Centers for Medicare & Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA) regulations. These CLIA regulations distinguish two basic types of laboratories – those that perform high and moderate complexity testing, and those that perform waived complexity testing.

Visit CMS' CLIA website for information on CLIA regulations and obtaining a CLIA certificate:

www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index

WAIVED LABORATORIES AND TESTS

Before testing patients, federal regulations require testing sites to have a CLIA certificate issued by CMS. Sites performing only waived tests must obtain a Certificate of Waiver by applying for this certification for each location performing testing.

Waived tests include test systems cleared by the Food and Drug Administration (FDA) for home use and tests approved for waiver under CLIA criteria. The FDA list of waived tests is continuously updated.

The most current information on FDA-cleared and FDA-waived tests can be found at the following website:

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm

This database is useful to verify that the test or tests performed by the laboratory are categorized as waived. The Centers for Disease Control and Prevention (CDC) has a comprehensive booklet titled *To Test or Not to Test?* that provides detailed information on waived testing. You can find it here:

www.cdc.gov/clia/docs/waived-tests/15_255581-test-or-not-test-booklet.pdf

The CDC's booklet includes a wealth of information to support waived testing, including these issues to consider¹:

- **Oversight of testing** – Someone will need to be responsible for managing testing and making decisions to assure quality testing.
- **Regulatory requirements** – Every site will need to follow applicable federal, state and/or local requirements for testing, safety, confidentiality and privacy.*
- **Location for testing** – Testing will need to be performed in a location with adequate space, an appropriate physical environment and accommodations for proper disposal of biohazardous waste.
- **Selecting tests** – Consider the test characteristics, sample requirements and costs when choosing a test.
- **Testing personnel** – Personnel who perform testing will need to be trained and periodically assessed on their ability to perform quality testing.
- **Starting to test** – Make sure that you have, understand and follow the current manufacturer's instructions.
- **Quality assessment** – Continually monitor, evaluate and look for ways to improve the quality of testing.

APPLYING FOR A CLIA CERTIFICATE OF WAIVER

To obtain a CLIA Certificate of Waiver, CMS form 116 must be completed. This form can be found at:

www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf

The completed CMS form 116 should be sent to the address of the local State Agency for the state in which your laboratory resides. This State Agency may be contacted for additional forms that may be necessary to complete the registration process. The list of CMS State Agency and Regional Office CLIA Contacts can be found at:

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/ContactInformation>

Information may also be obtained by contacting the CLIA program at 410-786-3531 for the address and phone number of your State Agency.

For additional information on how to obtain a Certificate of Waiver, refer to the CMS brochure located online at:

<https://www.cms.gov/regulations-and-guidance/legislation/cliadownloads/howobtaincertificateofwaiver.pdf>

MAINTAINING CERTIFICATION

Once your site has obtained a CLIA Certificate of Waiver, requirements for testing include the following:

- Perform only waived tests.
- Follow the current manufacturer's instructions for the waived tests you perform, without any changes.
- Pay the certificate renewal fee every two years.
- 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 not waived.
- Allow announced or unannounced on-site inspections by a CMS representative.

STATE AND LOCAL REQUIREMENTS

State and local jurisdictions vary in how they regulate laboratory testing. Some have requirements governing testing, personnel licensure or phlebotomy. Often there are specific regulations for biohazard safety or the handling and disposal of medical waste. The person overseeing testing should ensure that all state and local requirements are met. When state, local and federal requirements are not the same, the strictest requirement that applies to your site should be followed.

*SAFETY AND PRIVACY (HIPAA)

The CDC booklet includes important information for safety and requirements for confidentiality and patient privacy that are beyond the scope of this document.

1. Centers for Disease Control and Prevention. To Test or Not to Test? Considerations for Waived Testing. https://www.cdc.gov/cliadocs/waived-tests/15_255581-test-or-not-test-booklet.pdf.