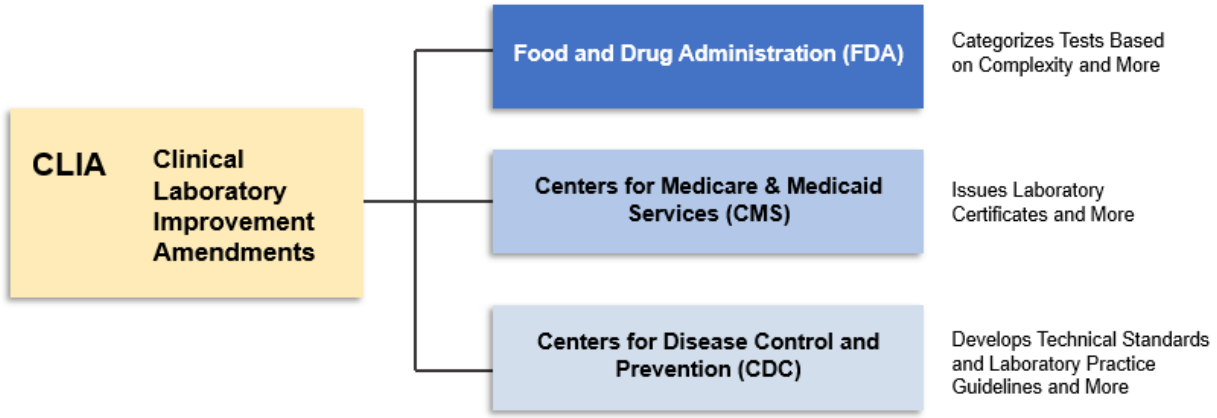
This information should not be considered to represent advice or guidance on behalf of the U.S. Department of Health and Human Services or any agency or office thereof.

CLIA Waived Tests

Context

The Clinical Laboratory Improvement Amendments (CLIA) provide the authority for certification and oversight of clinical laboratories and laboratory testing. Under the CLIA program, clinical laboratories are required to have appropriate certification before they can accept human samples for testing.[1] The U.S. Food and Drug Administration (FDA), Centers for Medicare & Medicaid Services (CMS), and Centers for Disease Control and Prevention (CDC) share non-overlapping responsibilities for oversight over CLIA.



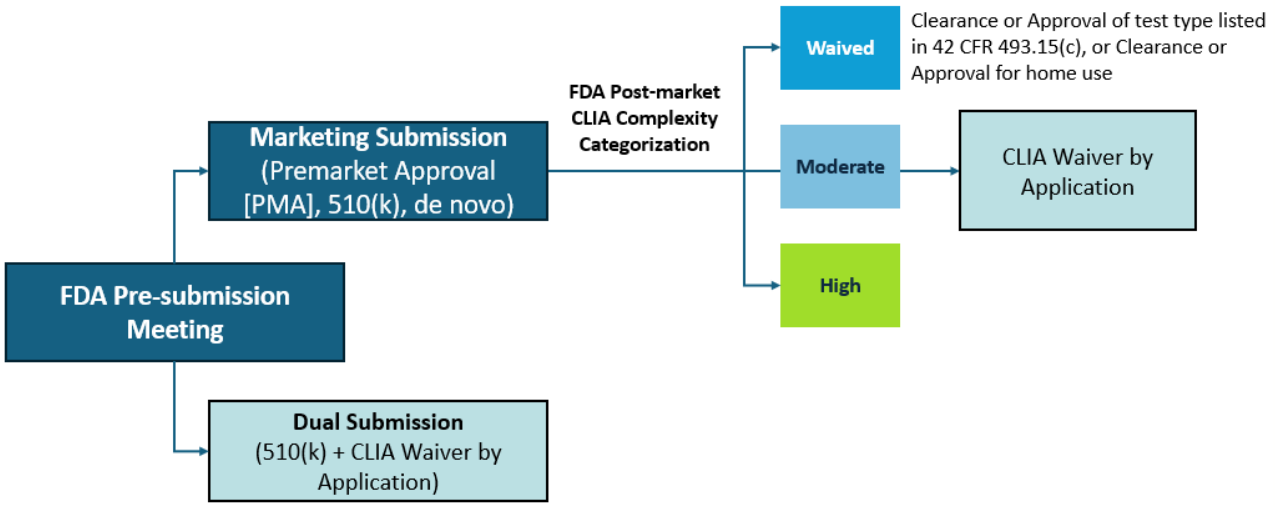
In vitro diagnostics (IVDs) that are simple to use, with a low risk of inaccurate results – i.e., waived tests – may be offered in health clinics at a school or local pharmacy, as well as for home use. Before an IVD can be "waived" FDA must evaluate a categorization request (submitted by the developer) for tests not automatically categorized as waived by regulation – a process called *CLIA complexity categorization*. This can be requested through either a CLIA Waiver by Application or Dual Submission to FDA. Only tests categorized as waived by FDA can be offered in a laboratory with a CMS CLIA Certificate of Waiver (or equivalent). This document highlights the interplay between the regulatory requirements for the IVD test itself and the setting where the waived test will be used.

FDA Regulation: CLIA Complexity Categorization of the test

CLIA categorization is determined after FDA has cleared or approved a marketing submission, or upon request for devices already legally marketed. FDA categorizes clinical laboratory tests based on their complexity—from the least to the most complex: waived, moderate complexity, and high complexity tests.
For tests not statutorily waived, FDA determines a test's complexity by reviewing the package insert instructions and using a criteria "scorecard" to define the test as moderate or high complexity (42 CFR 493.17).

[1] https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia

For more information, see Section 10.1 of the Regulatory Knowledge Guide for In Vitro Diagnostics and the CLIA Categorization Criteria and Scoring Table.



Waived Tests

Traditionally, FDA determines CLIA complexity categorizations post market approval. Tests that either are waived by regulation under 42 Code of Federal Regulations (CFR) 493.15(c) or are approved for home or over-the-counter use are automatically categorized as waived by FDA.

You can research CLIA waived tests using the following FDA Public Databases:

- CLIA Database
- Clinical Laboratory Improvement Amendments - Currently Waived Analytes
- Over The Counter Database

CLIA Waiver by Application

An FDA CLIA Waiver by Application is a request to FDA to change the categorization of a test to waived after it has already been categorized as *moderate risk* by FDA. When a test is categorized by FDA as waived, it allows that test to be performed within laboratories with a CLIA Certificate of Waiver or equivalent – this is a larger set of laboratories than those with Moderate Complexity certification.

FDA publicly posts CLIA Waiver by Application summaries; the decision summaries may provide information on the types of flex and clinical studies conducted by other companies which could be used by innovators to inform their study designs. The summaries can be found here: CLIA Waiver by Application Decision Summaries.

Dual Submission Pathway

If a test would not automatically be categorized as waived but is simple to use, with a low risk of inaccurate results, and is used at the point-of-care (which often requires waived categorization) a dual submission can be considered. This pathway involves the simultaneous submission of both a CLIA Waiver by Application (for an otherwise "moderate complexity" test) and a 510(k) premarket notification to FDA.

While the dual submission pathway can speed up the review process, FDA requests the same information and level of detail in a dual submission as would be included in separate 510(k) and CLIA Waiver applications. Some data, such as comparison and reproducibility study results may be submitted as a single set. An example of a dual application is the BIOFIRE SPOTFIRE Respiratory/Sore Throat (R/ST) Panel, a CLIA waived test which diagnoses Influenza A and Influenza B, SARS-CoV-2 and other pathogens.

CMS Regulation: CLIA Certificate of Waiver for the point of use of the test

A CMS CLIA Certificate of Waiver is a certification a clinical laboratory can obtain through CMS (or alternative, equivalent certification or accreditation bodies). The Certificate allows the lab to conduct tests that are categorized as waived by FDA; waived tests are deemed simple based on their low risk for providing inaccurate results.

		CMS Laboratory Certificates		
		CLIA Certificate of Waiver	Moderate-complexity CLIA-certified Lab	High-complexity CLIA-certified Lab
FDA CLIA Categorization	Waived	✓	✓	✓
	Moderate		✓	✓
	High			✓

Point-of-Care Testing

When people refer to point-of-care testing, they are generally referring to a test that was categorized by FDA as waived. A Point-of-Care (POC) setting, such as a school, will need to acquire a CMS CLIA Certificate of Waiver to perform FDA CLIA waived testing. The Centers for Disease Control define POC testing as: "a phrase used to describe the location where testing is performed, such as at the bedside or near the site of patient care. While some point-of-care tests are approved for a CLIA waiver, advances in technology that enhance the rapidity of testing enable more complex, nonwaived testing to be performed at or near the site of patient care."[2] An example of a waived test that can be offered in a point-of-care setting such as a doctor's office or at home is a urine pregnancy test.

[2] Test Complexities | Clinical Laboratory Improvement Amendments (CLIA) | CDC

Resources

- FDA: Clinical Laboratory Improvement Amendments (CLIA)
- FDA: CLIA Categorizations
- FDA: CLIA Waiver by Application
- FDA: Recommendations for Dual 510(k) and CLIA Waiver by Application Studies (Guidance document)

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