



Complying with CLIA Regulations for Laboratory Testing



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This document has been provided to help you understand the CLIA regulations for laboratory testing. This document is a summary of the CLIA regulations which may apply to your facility regarding the EZ Chem product and is not intended as a substitute for a complete review of the CLIA regulations or the steps necessary to become CLIA compliant. CLIA regulations, inspections and associated fees may vary by State. Each facility must review the CLIA regulations, including all amendments relating thereto, in their entirety and insure that their facility fully understands the requirements and will comply with the CLIA regulations as they relate to the EZ Chem product. This document is not intended to act as legal, medical or regulatory advice. CLIA regulations may be amended from time to time. E-Z-EM makes no representations or warranties with respect to the accuracy or completeness of this document.

Overview of Laboratory Regulations

“CLIA” is the acronym for the Clinical Laboratory Improvement Amendments (CLIA) of 1988, Public Law 100-578. On February 28, 1992, the *Federal Register* published the CLIA regulation that set forth uniform quality standards for laboratories. Since that time, the CLIA regulation has been updated and modified several times.

The CLIA program is administered by the Centers for Medicare and Medicaid Services (CMS).

All facilities that test human specimens for the purpose of diagnosis, treatment or monitoring are subject to the CLIA regulations, regardless of who (or whether) the laboratory receives payment from Medicare, Medicaid or another third-party payer.

Each location where testing is performed, regardless of ownership, must possess a valid CLIA identification number. If testing is performed under the same roof or on the same campus of a contiguous medical facility, one CLIA certificate may suffice.

CLIA Test Classification

The CLIA requirements are based on the complexity of tests (waived, moderate and high) and not the type of entity where the testing is performed.

CLIA classifies all tests into the following categories:

- Waived
- Provider Performed Microscopy Procedures (PPMP), technically a subspecialty of the Moderate Complexity category
- Moderate Complexity
- High Complexity

CLIA requirements for personnel and quality measures range from onerous for very complicated tests (termed highly complex) to virtually nonexistent for the simplest tests (CLIA-waived). (Table 1) EZ Chem creatinine testing is classified under CLIA '88 as moderately complex.

**Table 1
CLIA Requirements by Test Complexity**

CLIA Category	Test Examples	Fees*	Inspections	Personnel Requirements
Waived	Urine dip strips, fecal occult blood, Strep A kits, pregnancy tests, small instruments for urinalysis, blood chemistry	\$150	No	None
PPMP**	Microscopic: urinalysis KOH preps, semen detection	\$200	No	Provider (MD, DO, PA, NP) must perform
Moderate Complexity***	Creatinine on EZ Chem, CBC, large chemistry, immunoassay analyzers	Varies by test volume	Yes	Testing Personnel - HS grad Lab Director - MD with 1-year experience
High Complexity***	Cultures and sensitivities, pathology, histology	Varies by test volume	Yes	Testing Personnel - Lab tech Lab Director - MD or board-certified PhD

* Assessed every other year

** Provider Performed Microscopy Procedures

*** Proficiency Testing

Types of CLIA Certificates

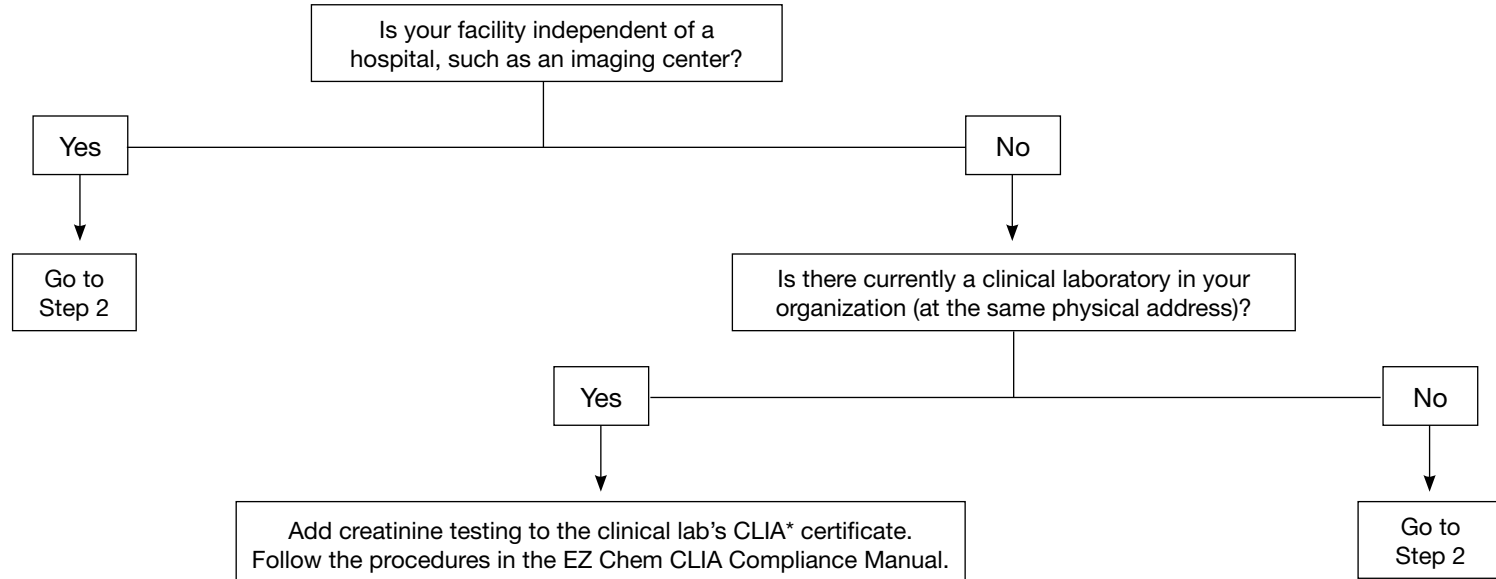
- **Certificate of Waiver** - for facilities that perform only CLIA-waived tests.
- **Certificate for Provider Performed Microscopy Procedures (PPMP)** - physician or mid-level provider performs simple microscopic exams, such as skin scrapings and wet preps. PPMP facilities may also perform CLIA-waived tests.

Facilities that perform moderate (EZ Chem creatinine) and/or high complexity tests may have either of the following types of CLIA certificates:

- **Certificate of Compliance** - indicates that CMS state surveyors will inspect the laboratory.
- **Certificate of Accreditation** - instead of applying for a Certificate of Compliance, laboratories may voluntarily enroll in an accreditation program, such as COLA, JCAHO, AOA, or CAP, if they wish to be inspected by surveyors from the accrediting agency, not state CLIA inspectors. Quality requirements are similar for both certified and accredited facilities.

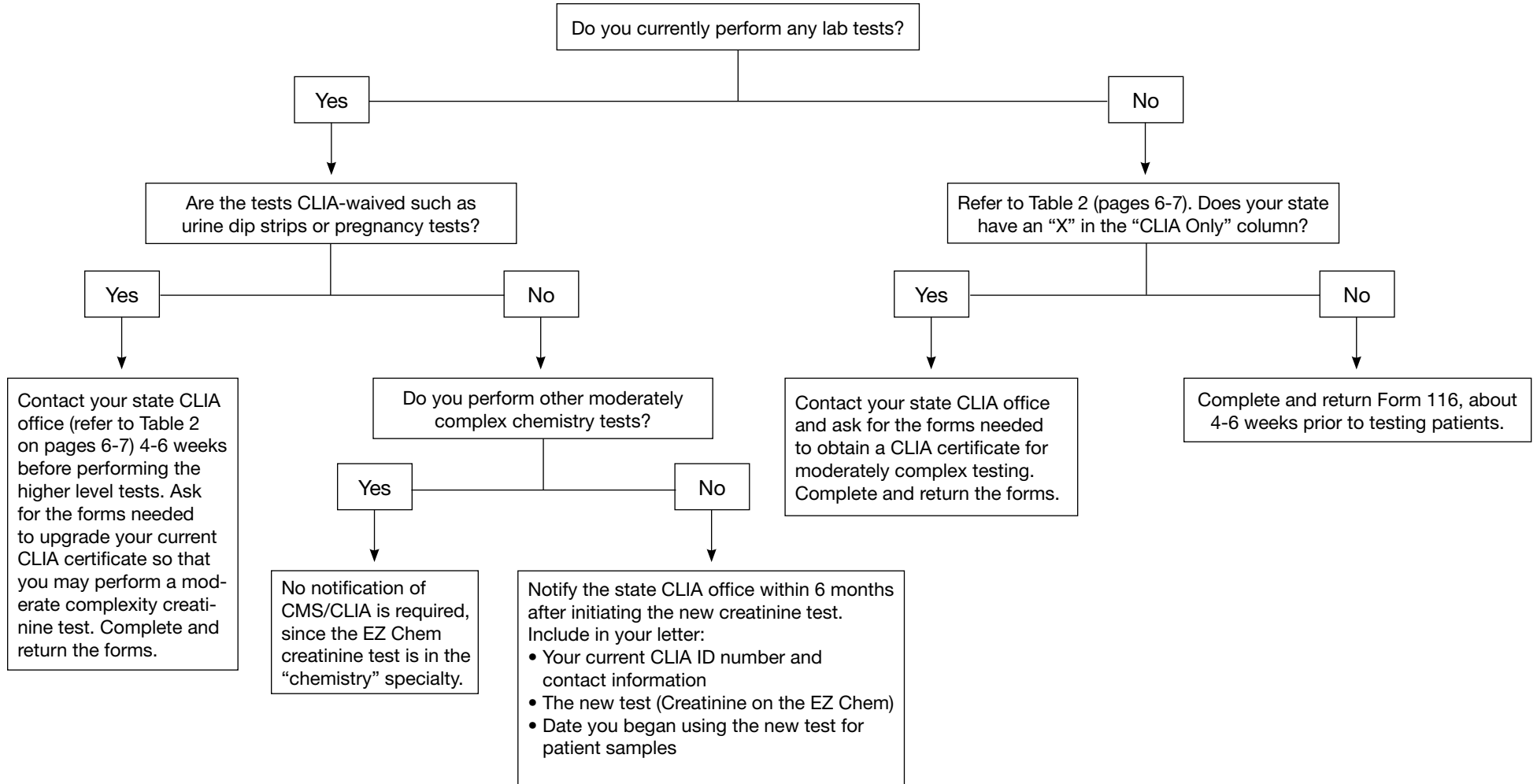
How to Enroll in the CLIA Program in Three Easy Steps

Step 1. Determine If You Need to Register for a CLIA Certificate



*If the clinical lab is accredited by the College of American Pathologists (CAP), all testing in the facility/institution must be under the direction of the clinical lab.

Step 2. Register For a New CLIA Certificate or Notify CMS of a New Test



**Table 2
State CLIA Requirements**

State	Telephone	CLIA only	CLIA + State Cert	Add'l State Fees	Add'l State Regs	Extra Pers Regs	Comments
AL	334-206-5120	X					
AK	907-334-2491	X					
AZ	602-364-0741	X					
AR	501-661-2201	X					
CA	213-620-6160 (South) 510-620-3800 (North)		X	\$978 annual	X	X	California state licensing is required for all clinical laboratories. If the imaging center has 5 or less physicians, there are no CA personnel licensure requirements, but they must still be registered in California (i.e., pay additional state fees) and also comply with federal CLIA regulation. These facilities are free to employ unlicensed personnel as long as the federal CLIA personnel requirements are met and personnel are supervised by a physician. If there are more than 5 physicians, they are subject to licensure requirements.
CO	303-692-3291	X					
CT	860-509-7400		X	\$100 applic			All non-waived labs must be state certified, except for labs owned by the Federal government. Connecticut regulations are identical to the federal CLIA regulations.
DE	302-653-2870	X					
DC	202-442-4706	X					
FL	850-487-3109		X	\$400 or more biennially		X	All non-waived labs must be state certified but quality requirements are same as CLIA regulations. Application must be notarized; application has an extensive test menu section (including instrumentation). Lab Director and CEO must undergo background screening (incl. fingerprinting) every 5 years. Personnel must be licensed by the state, but includes only filling out the form. No educational or experiential requirements that exceed CLIA. Labs are inspected before performing patient tests.
GA	404-657-5558	x					
HI	808-692-7420		X			X	Labs must be licensed, but regulations are identical to CLIA.
ID	208-334-2235 x245		X				New laboratories must fill out a state Laboratory Registration Form in addition to Form 116.
IL	217-782-7412	X					
IN	317-233-7502	X					
IA	319-335-4500	X					
KS	785-296-3811	X					
KY	502-564-2800	X					
LA	225-342-9324	X		\$25 pers license		X	Personnel licensure form must be filled out and submitted to the state with a \$25 fee. No educational or experiential requirements exceeding CLIA, but personnel must earn 12 CEU/year. Lab director's one-year experience must be attached to Form 116.
ME	207-287-9339	X					
MD	410-402-8025		X	\$100 annual		X	State certification is required for all laboratories. Additional forms for registering laboratory and personnel are required and payments for these are above and beyond federal CLIA payments. Similar quality and personnel requirements as federal regulations.
MA	617-983-6739	X if < 3 MDs	X if 3 or >3 MDs	\$300 biennially			State lab certification and additional state fees apply when there are 3 or more radiologists in an imaging center. Lab quality and personnel requirements equivalent to CLIA.
MI	517-241-0821	X					
MN	651-215-8704	X					
MS	601-576-7300	X					

**Table 2 (cont)
State CLIA Requirements**

State	Telephone	CLIA only	CLIA + State Cert	Add'l State Fees	Add'l State Regs	Extra Pers Regs	Comments
MO	573-751-6318	X					
MT	406-444-1451	X					
NE	402-471-4363	X					
NV	775-687-4475		X		X		Imaging centers that perform non-waived tests are considered "Registered laboratories" and must fill out a separate state form. Unlicensed personnel pay \$40 per year. Other requirements identical to CLIA.
NH	603-271-4832	X					
NJ	609-292-0016	X if ≤ 5 MDs	X if > 5 MDs				Imaging centers owned by a physician radiologist with 5 or fewer physicians are exempt from state regulations.
NM	505-841-4524	X					
NY	518-485-5378	X					POs and imaging centers exempt from NY state laboratory regulations and follow federal CLIA.
NC	919-733-1610	X					
ND	701-328-2352	X				X	Testing personnel licensure is required EXCEPT for MDs, licensed nurses and phlebotomists. Testing personnel may be exempt from licensure if they are supervised by MD, licensed nurses or phlebotomists.
OH	614-644-1845	X					
OK	405-271-6576	X					
OR	503-229-5853	X				X	Must complete Director Qualification Appraisal Form.
PA	610-280-3464		X	\$25 applic \$100/test category	X	X	All labs must be state certified. PA has 3-level system applying to certain tests that it may perform. Creatinine falls into level 3. Lab director needs to be present during all hours of testing. Labs are inspected before they can begin testing. Once application is received by PA, they send a pre-licensure packet and a PT sample. Need to send a completed training log for each testing person and an attestation from lab director that there is a procedure manual. Then an on-site inspection is inspected, after passing inspection, a license is issued.
RI	401-222-4526	X					Imaging centers testing their own patients are exempt from state regulations.
SC	803-545-4205	X					
SD	605-773-3694	X					
TN	615-741-7023	X					
TX	512-834-6650	X					
UT	801-584-8471	X					
VT	802-652-4145	X					
VA	804-367-2107	X					
WA	206-418-5418		X	\$450	X		Washington is CLIA-exempt. All labs need state certification, but regulations identical to federal CLIA. Fees vary depending on number of tests performed, but are \$450 for less than 2000 tests/year and are assessed biennially. Fill out separate form if changing test menu.
WV	304-558-3530 x2103	X		\$25/year/pers		X	Phlebotomists and lab personnel who perform moderate-complexity testing must pay \$25/year to be licensed. No educational or experiential requirements exceeding CLIA.
WI	608-243-2023	X					
WY	307-777-6057	X					

*Telephone numbers are current as of 11/22/06, but are subject to change. If necessary, visit <http://www.cms.hhs.gov/CLIA/downloads/CLIA.SA.pdf> for the latest CMS state contact information, or call the CMS CLIA Central Office at 410-786-3531.

Step 3. Anticipate Approximate CLIA Fees

If your state has no additional fees (refer to Table 1 on page 3), your laboratory will be assessed the following fees in two separate payments.

Type of Lab	Annual Test Volume	Number of Specialties*	Biennial Certificate Fee	Biennial Inspection (Compliance) Fee
A (Low Volume)	≤ 2000	Not specified	\$150	\$300
A	2,001-10,000	3 or less	\$150	\$840
B	2,001-10,000	4 or more	\$150	\$1,120
C	10,001-25,000	3 or less	\$430	\$1,400
D	10,001-25,000	4 or more	\$440	\$1,645
E	25,001-50,000	Not specified	\$650	\$1,890
F	50,001-75,000	Not specified	\$1,100	\$2,135
G	75,001-100,000	Not specified	\$1,550	\$2,380
H	100,001-500,000	Not specified	\$2,040	\$2,625
I	500,001-1,000,000	Not specified	\$6,220	\$2,870
J	> 1,000,000	Not specified	\$7,940	Calculation required

NOTE: A one-time fee of \$100 is assessed when initially enrolling in the CLIA program. The above fees vary by ±15% by state, so if exact fees are required, contact the state CMS office.

***Specialties:** Microbiology, Serology, Chemistry (creatinine), Hematology, Immunohematology

Overview of Quality Requirements for Moderately Complex Testing (EZ Chem™ Creatinine Meter)

A list of the quality measures required for tests classified by the CLIA regulation as moderately complex are shown in Table 3.

Table 3
Overview of CLIA Quality Requirements for Moderately Complex Tests (EZ Chem Creatinine Meter)

CLIA/JCAHO/CAP Quality Requirement	E-Z-EM Provides
Follow manufacturer's instructions.	Yes
Follow a written procedure manual for pre-analytic, analytic and post-analytic policies and procedures.	Yes
Test at least two levels of QC material on each day of patient testing.	Yes
Document personnel training and evaluation.	Yes
Perform proficiency testing three times per year.	No*
Perform method validation once before starting a new testing program.	Yes
Perform calibration verification (linearity) at least once every 6 months.	Yes

*The CLIA regulation requires that independent PT providers be used.

Personnel Requirements

CLIA specifies that a physician (MD or DO) laboratory director must have at least 1 year of experience supervising moderately complex testing OR must have completed a 20-credit educational course. Two possible avenues to obtain these credits are:

- A 2.5-day workshop provided once/year by COLA. For further information about this program, call 800-981-9883.
- Online Laboratory Director Programs at www.COLA.org or at <http://lib.cpums.edu.cn/jjepou/tupu/atlas/www.vh.org/adult/provider/pathology/CLIA/CLIAHP.html>

In addition, individuals with a bachelor's degree and 2 years of laboratory experience plus 2 years of supervisory experience (total 4 years) or a master's degree and 1 year's experience plus one year of supervisory experience (total 2 years) qualify to direct a moderately complex laboratory under CLIA '88.

Besides the laboratory director, three other positions are specified by CLIA for a moderately complex laboratory:

1. Clinical consultant (MD or DO who qualifies as laboratory director),
2. Technical consultant (MD or DO with 1 year's experience, MS with 1 year's experience or BS with 2 year's experience), and
3. Testing analyst (high school diploma or GRE with documented training).

A single person may fill these positions, and in the outpatient setting, many physicians designate themselves to be the laboratory director, clinical consultant and technical consultant. Those who perform moderately complex tests are referred to as testing analysts by CLIA and must have at least a high school diploma and documented training for tests performed.

Proficiency Testing

CLIA regulations require successful participation in proficiency testing (PT) for moderately complex tests such as creatinine. Enroll annually in a CMS-approved program to provide an external evaluation of the quality of testing.

PT is a means to demonstrate the reliability of test results. Once enrolled in a PT program, each facility will be sent five “unknown” samples three times per year. A minimum of four out of five correct results is required to pass.

Some approved PT programs are:

American Proficiency Institute

800-333-0958

www.api-pt.com

Wisconsin Laboratory of Hygiene

800-462-5261

www.slh.wisc.edu/cpt.html

American Association of Bioanalysts

800-234-5315

www.aab.org

External Comparative Evaluation for Laboratories (EXCEL)

College of American Pathologists

800-323-4040

www.cap.org

CLIA Inspections

Laboratories are inspected every other year. Generally, CMS inspectors (also called “surveyors”) telephone to schedule an on-site visit two weeks prior to the inspection. A typical inspection takes as little as two hours, but can take an entire day, depending on the extent and types of non-waived testing performed in your lab.

The inspector will ask to see evidence that you have performed proficiency testing, quality control, and quality assessment.

CLIA inspections are educational in nature, not punitive. If the inspector finds that your testing program is out of compliance with one or more CLIA requirements, you will receive a written report within two weeks of the inspection explaining the “deficiency(s)” found. You will be asked to submit a written “Plan of Correction,” explaining action taken to correct each deficiency. If the inspector is satisfied that the corrective action is sufficient, no further action is required. You will be inspected again in about two years.

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