

Tutorial: Basic California State Laboratory Law

This document is meant to cover basic elements of state laboratory law and should not be relied upon in place of legal advice or the official codes of California.

1. What laboratories need to be licensed or registered? What is the difference?

Any time a sample from a human is tested in California to diagnose a disease, or to monitor treatment or the physiological condition of a person, this is considered a clinical lab test and is subject to laboratory law. State law requires a lab to be licensed or registered, based on their type of testing. Federal law also requires them to have a Clinical Laboratory Improvement Amendments (CLIA) certification.

A few types of labs don't need to be licensed, such as those doing testing for research, teaching, forensic, veterinary purposes, or those owned and operated by the US government. Labs outside California doing testing on specimens sent from California on residents here must also be licensed or registered.

Lab doing only simple waived tests or provider performed microscopy (PPMP) tests must be registered. These labs are not routinely inspected and must follow the manufacturer's instructions for performing the test. Proficiency testing and routine inspections are not required for waived labs.

The requirements for labs doing non-waived tests, classified as moderate or high complexity, are more comprehensive. Licensed labs doing non-waived tests must participate in proficiency testing and must be inspected before they can be licensed, and then are subject to inspections every other year.

Generally, as the test complexity increases, the requirements for who can do the testing also increase. To do high complexity testing in California, a baccalaureate degree, advanced training and a California personnel license is required. However, persons doing high complexity testing in a physician office laboratory do not need to meet these requirements.

2. What about laboratory test complexity?

The US Food and Drug Administration (FDA) classifies tests as waived (simple), provider performed microscopy procedures (PPMP), moderate or high complexity, depending on how difficult the tests are. Labs doing moderate or high complexity tests (also called "non-waived tests") must be licensed and inspected every 2 years. Labs doing waived or PPMP tests must be registered with the state and are not routinely inspected.

Tests that are not classified by the FDA are automatically considered high complexity. Many of these tests are developed by the laboratory itself. For non-

FDA classified tests, or FDA tests that have been modified, the laboratory must verify and establish the tests performance specifications of these tests since there is no manufacturer to do that.

In California, the complexity of tests determines who can do the test. Only licensed baccalaureate- or doctorate-level people (as clinical lab scientists or physicians) can do high complexity tests in licensed clinical & hospital laboratories, while lesser qualified people are authorized to do the simpler tests. For example, Associate-level Medical Laboratory Technicians and Registered Nurses are authorized to perform moderate complexity, but not high complexity tests. Many waived tests are performed in physician offices by the physician's staff. They must possess as a minimum requirement, a high school diploma and have competency assessment before performing the test.

3. Who can direct a clinical laboratory in California?

Only a licensed physician and surgeon, a licensed osteopath, or a licensed doctoral scientist can direct a laboratory in California. However, the director of the laboratory of an acute care hospital must be a board certified pathologist. A bioanalyst may direct a hospital lab if a pathologist is not available, but the pathologist must be accessible.

The laboratory director is responsible for all the operations of a laboratory. If there is any problem with a lab, the director and owner are mutually and equally responsible. The lab director has many responsibilities including signing all the procedure manuals, and making sure the testing people are competent, and the testing facilities are adequate.

A laboratory director can serve as clinical consultant, technical supervisor, technical consultant, general supervisor, or testing person in California. A laboratory director must be actively involved in the lab he/she is directing.

A lab director cannot direct more than 5 non-waived, licensed labs at the same time.

4. What are proficiency testing, procedure manual, and report requirements?

Proficiency testing is blind testing required by labs performing non-waived (moderate and high) complexity testing. Samples are sent to laboratories for testing and their results are graded for closeness to an expected value.

Regulated analytes are those tests (such as glucose) for which proficiency testing is required. Non-regulated analytes are those tests (such as fructosamine) for which proficiency testing is not required. When proficiency testing is not required, a laboratory must have a method of verifying test results twice a year.

Proficiency testing is generally performed 3 times a year for regulated analytes on 5 specimens for each analyte. A passing score is 80% or better, except in immunohematology in which only a 100% score is passing. Unsatisfactory proficiency testing performance is failing one testing event for an analyte. Unsuccessful performance is failing 2 testing events in a row, or 2 out of 3 for the same analyte. In such a case, a laboratory is required to stop testing until they can get a passing score on 2 more successive proficiency tests. Corrective action must be taken and documented any time there is a proficiency testing failure.

A lab cannot share, discuss or copy proficiency testing done at another lab, and all proficiency testing results must be signed by the lab director. The testing personnel must attest that the testing was performed the same way that patient tests are performed.

The procedure manual gives all the important information about a test. It gives the name of the test, specimen requirements, reagents, instrumentation, quality control, corrective actions to take, panic values, reference values. The procedure manual must be signed and dated by the lab director annually or any time the procedure is changed. The procedure manual must be available to the testing personnel.

A test result may be reported by a licensed person with documented competency in the test being performed. The laboratory shall establish critical or "panic" values which require the physician to be contacted immediately.

The test report must identify the person tested, give his/her age and gender, date blood was drawn and date reported, name of test, reference range, name of lab performing test, name of director of lab, and any other information necessary for the referring physician to understand the result.

5. What are some Quality Control requirements in state law?

Quality control procedures are taken to assure that laboratory tests are accurate, reliable and reproducible. Controls are run with known answers at normal and abnormal levels. This helps assess that the testing is producing accurate results.

For waived tests, the laboratory must comply with the manufacturer's directions for quality control as approved by the FDA.

For moderate and high complexity tests at least 2 controls are to be run each day, but laboratories can perform more. The controls have established acceptable limits, and if the values are outside these limits corrective action must be taken to bring them back into control. Test results cannot be reported when the controls are outside their acceptable ranges.

The persons who are qualified to perform quality control procedures are those persons specified in the procedure manual for the test. When using a kit method, quality control should be performed according to the manufacturer's instructions. When using a method that has been developed by the laboratory itself, the laboratory director is responsible for establishing quality control parameters and test performance specifications.

An instrument is calibrated with standards of known levels. An instrument should be calibrated at a frequency specified by the manufacturer, at least every six months, whenever the instrument is serviced, or there is a major part change or reagent change.

6. What are basic personnel license requirements?

People doing testing in California must be licensed, or must work under supervision of licensed people. Licensure requirements are based on complexity of testing performed. Before any person works in a laboratory, licensed or not, their competency to do the job must be documented by the lab director or technical supervisor.

Doctoral-level people can be licensed as bioanalysts, chemists, microbiologists, toxicologists, bioanalysts, or genetic molecular biologists. These people can direct a lab in these specialties, if also licensed by the state as a director, or be technical supervisors or technical consultants.

Baccalaureate-level people can be licensed as clinical lab scientists, chemistry scientists, microbiology scientists, hematology scientists, histocompatibility scientists, genetic molecular biologists scientists, cytogenetic scientists, and cytotechnologists. These people can work as general supervisors or testing personnel. A licensed clinical lab scientist can perform tests in all specialties except cytology or pathology. They can perform phlebotomy and supervise phlebotomists. Clinical lab specialists, as a clinical hematologist scientist, can perform testing in all waived and moderate complexity specialties, but can only perform high complexity testing in their specialty, such as hematology. A cytotechnologist can only perform cytology testing.

Associate-level people can be licensed as Medical Lab Technicians. MLTs can perform waived testing without supervision in California and can perform moderate complexity testing in chemistry, hematology, immunology and microbiology with supervision. They cannot work in immunohematology (blood bank) or perform microscopic analyses.

High school-level people can be certified as phlebotomy technicians. Certified phlebotomists can draw and process blood from patients, but cannot do any testing.

Unlicensed lab aides are limited as to what they can do in a laboratory, and must have at least a high school education. Unlicensed lab aides can assist in testing but cannot perform testing themselves. They can prepare media and reagents, assist in preventive maintenance and quality control, but cannot calibrate an instrument.

When people apply for licensure or certification in California, they must apply, pay a fee, document that they meet education and training requirements, provide a social security number, attest to any criminal convictions, and pass an examination. If a person lies on their application, their license can be denied, revoked, or suspended.

If a licensed or certified person moves, they must notify Lab Field Services within 30 days.

Licensed people can let their license go inactive for up to 5 years. They do not have to pay any fees during that time, but they cannot work when their license is inactive. In order to reactivate the license, people need to take 12 hours of continuing education in the year before the license is activated, pay all back fees, and notify Lab Field Services that they want their licenses re-activated. If people let their license stay inactive more than 5 years, the licenses are lapsed and the people need to re-apply for licensure.

The laboratory where licensed people work needs to post the licenses prominently. Duplicate licenses issued by the state must can be posted by people with 2 jobs.

7. What are continuing education requirements for licensed lab people?

In order to maintain licensure or certification, people must complete continuing education courses. Doctorate-, baccalaureate- and associate-degreed licensees must complete 12 hours of continuing education from an approved provider each year. People with 2-year licenses must complete 24 hours of continuing education in that 2-year period. Phlebotomists have a 2-year certificate and must complete 3 hours of continuing education each year or 6 hours of continuing education in that 2-year period in order to renew their certificate.

Documentation of continuing education is submitted when the license or certificate is renewed. A licensed person must keep documentation of their continuing education courses for a minimum of 4 years in case they are audited.

A person can ask that their license be put in inactive status for up to 4 years. During the fourth year, they must complete 12 hours of continuing education in order to re-activate their license in the fifth year. If a license is kept inactive for

more than 5 years, it is lapsed and the person must reapply and retake the examination.

Licensed people can ask for a waiver from the continuing education requirement if they live outside the US for more than half their license period, they are in the military outside California more than half the license period, or have documented illness that prevents their taking continuing education.

8. What is phlebotomy law in California?

Only people who are authorized can perform phlebotomy in California. Generally those authorized are licensed physicians, registered nurses, licensed vocational nurses, licensed clinical lab scientists and certified phlebotomists. Medical assistants can perform phlebotomy only in a physician's office or clinic.

There are 3 kinds of phlebotomy certificates in California. Limited Phlebotomy Technicians (LPT) can perform capillary (fingerstick) blood draws only. Certified Phlebotomy Technician-1 (CPT-1) can do perform capillary or venipuncture, and CPT-2 can perform capillary, venipuncture and arterial blood collections. A certified phlebotomist is not authorized to do any testing. For example, they cannot do point-of-care tests for glucose, and cannot do urine glucose testing or breath testing. A phlebotomist can only draw blood on a doctor's order. A phlebotomist must be employed by a laboratory and be supervised. A phlebotomist's supervisor must assure a phlebotomist is competent before they start drawing blood, and then must check their competency annually. A phlebotomist cannot be self employed.

9. What is cytology and who can perform cytology tests?

Cytology is the study of cells. People that analyze cells microscopically are called cytotechnologists. Only licensed cytotechnologists or cytopathologists can perform cytology. The most common test that cytotechnologists perform is Pap smears (gynecological cytology), but they are trained to look for abnormalities in other cells, too (non-gynecological cytology).

Licensed cytotechnologists are limited to microscopic reading of no more than 80 manual Pap smears in a day or 200 a day using semi-automated or automated screening instruments. Cytotechnologists that work at 2 laboratories must keep track of the number of Pap smears they read and not exceed the daily limit. All abnormal Pap smears and 10 percent of all normal Pap smears must be reviewed by a cytopathologist.