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ISSUES SPECIFIC TO CALIFORNIA CLINICAL LABORATORY LAW  
California Department of Public Health  
Laboratory Field Services

2017

California has the following specific requirements that are unique to State law.

*This information is given solely to provide guidance about California clinical laboratory laws. Laboratory Field Services (LFS) in the California Department of Public Health does not provide its approval for other content. Please note that LFS does not approve written material that is not endorsed, signed, and published by LFS staff.*

I. LABORATORY DIRECTOR REQUIREMENTS AND RESPONSIBILITIES

- A. A California clinical laboratory may have multiple laboratory directors. The person serving as the CLIA laboratory director must qualify under CLIA. This includes both licensed and registered clinical laboratories performing non-waived testing. (BPC § 1209(b))
- B. A clinical laboratory must have a laboratory director who is a California-licensed physician and surgeon, master's- or doctoral-degree<sup>1</sup> scientist, or master's- or doctoral-degree bioanalyst. This includes registered laboratories performing waived tests. (Business and Professions Code (BPC) § 1209(a))
  1. A clinical laboratory registered by the California Department of Public Health must hold either a valid CLIA Certificate of Waiver or a valid CLIA Certificate of Provider-Performed Microscopy. California-registered laboratories with a

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<sup>1</sup> In this document “associate-degree license” refers to any license that requires at least an associate degree, for example, medical laboratory technician. “Baccalaureate-degree license” refers to any license that requires at least a baccalaureate degree, for example, clinical laboratory scientist and clinical laboratory scientist limited to a specialty. “Master’s or doctoral-degree license” refers to any license that requires at least a master’s or doctoral degree, for example, bioanalyst or director licenses limited to a specialty.



CLIA Certificate of Waiver that are not part of an acute care hospital may be directed by a California-licensed clinical laboratory scientist or clinical laboratory scientist limited to a specialty, a California-licensed naturopathic doctor, a California-licensed optometrist in a laboratory performing only CLIA-waived tests necessary for the diagnosis of conditions and diseases of the eye or adnexa, or the California-licensed pharmacist in-charge, responsible for directing and supervising testing oversight and decision-making in the course of pharmacist-performed routine patient assessment procedures. (BPC §§ 1206.6, 1209(a), 1265, 4036, 4052.4)

2. A licensed or registered clinical laboratory performing tests or examinations in a single specialty may be directed by a California-licensed master's or doctoral-degree scientist licensed to direct a clinical laboratory in his/her specialty, provided the tests and examinations performed by the laboratory are limited to the clinical laboratory specialty of the laboratory director. (BPC § 1264)
- C. The laboratory director of a general acute care hospital must be a board-certified pathologist. A licensed physician and surgeon or bioanalyst may serve in the absence of a pathologist, but a pathologist must be available. (BPC § 1209 (h)) Other non-pathologist physician section directors can serve as technical supervisors in general acute care hospitals even though they may not qualify as laboratory directors. (Title 17, California Code of Regulations (17 CCR § 1036.4)
- D. A licensed doctoral-degree scientist, for example, a clinical chemist, clinical microbiologist, or clinical toxicologist, may serve as a laboratory director limited to his or her specialty. If he or she is serving as the CLIA laboratory director, the qualifications specified in CLIA also apply. (BPC §§ 1207, 1209 (b), (f), (h), 1264)
- E. A licensed bioanalyst may serve as laboratory director of an acute care hospital laboratory if a qualified pathologist is not available, but a pathologist must be available for consultation. If he or she is serving as the CLIA laboratory director, the qualifications specified in CLIA also apply. (BPC §§ 1207, 1209 (b), (f), (h), 1264)
- F. A director of a histocompatibility laboratory must be a licensed physician and surgeon, a bioanalyst, or a doctoral-degree scientist who has four years of experience in immunology, two of which must have been in histocompatibility testing. (BPC § 1209.1)

- G. An interim laboratory director must be appointed within five days of a major change of director if a laboratory is left without a director. (BPC § 1265 (e)(2))
- H. The owner and director of a laboratory must notify the Department within 30 days of a major change in laboratory director. (BPC § 1265 (g))
- I. A clinical laboratory performing tests in the specialty of cytogenetics must have a director licensed as a clinical cytogeneticist, pathologist, or bioanalyst who meets CLIA requirements for laboratory director. If he or she is serving as the CLIA laboratory director, the qualifications specified in CLIA also apply. (BPC § 1209 (b), 17 CCR §§ 1030.6, 1030.7)
- J. A laboratory performing tests in genetic molecular biology must have a director licensed as a clinical genetic molecular biologist, pathologist, or bioanalyst who meets CLIA requirements for laboratory director. (17 CCR § 1030.7)
- K. An oral pathology laboratory director must be a board-certified pathologist or a dentist licensed by the Department as an oral pathology laboratory director. (17 CCR § 1030.8)
- L. A laboratory director may serve as the director of up to the maximum number of laboratories stipulated by CLIA. The director must sign all abnormal reports and all non-gynecological reports, and must be available daily. (BPC § 1209 (j))
- M. A laboratory director may direct no more than five non-waived laboratories, but is not limited in the number of waived laboratories he or she can direct. (BPC § 1209 (j))
- N. A laboratory director is excluded from directing another laboratory for two years when he or she has been the owner, operator, or director of a laboratory that has had its license revoked. (17 CCR § 1065.30)

## II. LABORATORY SUPERVISORS AND CONSULTANTS

- A. A general supervisor must be licensed to perform high complexity tests or must be a California-licensed physician and surgeon, and must have two years of experience in high-complexity testing in the specialty or specialties he or she is supervising. The general supervisor must provide day-to-day supervision and must be accessible. (17 CCR § 1036.1)

- B. A technical supervisor must be licensed to perform high complexity testing or practice medicine in California. A physician and surgeon or doctoral-level scientist must have one year of experience, a master's-level scientist, two years, and a baccalaureate-level scientist, four years of experience. (17 CCR § 1036.4)
- C. A clinical consultant must be licensed to direct a clinical laboratory in California or to practice medicine. (17 CCR § 1036)
- D. A moderate complexity technical consultant must be licensed to perform high complexity testing in California or to practice medicine and must have two years of experience in moderate or high complexity testing in the specialty or specialties for which he or she is consulting. (17 CCR § 1036.2)
- E. A waived laboratory technical supervisor or technical consultant must be qualified as a testing person authorized under BPC § 1206.5 (a), must have a baccalaureate degree, must be a licensed healthcare professional, must have one year of experience in clinical laboratory testing in those tests or examinations that he or she will be supervising, and must document competency in the tests he or she will be supervising. (17 CCR § 1036.3)

### III. TESTING PERSONNEL

- A. Testing personnel approved to perform each complexity test are listed at BPC § 1206.5.
- B. A person performing moderate complexity testing must have at least an associate degree license. (BPC § 1260.3)
- C. A person with an associate degree licensed as a medical laboratory technician may perform waived and moderate complexity tests and report the results, but must perform testing under the supervision of a licensed physician and surgeon or a person with a baccalaureate, masters, or doctoral level license. (BPC § 1260.3)
- D. A person performing high complexity testing must have a baccalaureate-level license, with exceptions for persons with military laboratory training and experience. (BPC § 1261)

- E. A person with a baccalaureate-degree license may serve as technical consultant, technical supervisor, and general supervisor when the person has adequate experience or training. (BPC § 1210)
- F. A person with a baccalaureate-level license in a specialty may perform waived or moderate complexity testing in any other specialty. (BPC § 1210).
- G. A technical supervisor must be licensed to perform high complexity testing or practice medicine in California. A physician and surgeon or doctoral level scientist must have one year of experience, a master's level scientist, two years, and a baccalaureate-level scientist, four years of experience. (17 CCR § 1036.4)
- H. A licensed baccalaureate-degree scientist may perform high, moderate, and waived-complexity tests in any specialty or subspecialty, with the exception of cytology. (BPC § 1204)
- I. A licensed clinical chemist scientist may perform high complexity tests in chemistry, including routine chemistry, clinical microscopy, endocrinology, toxicology; immunology, including diagnostic immunology and serology, and molecular biology. (17 CCR § 1031(b)(1))
- J. A licensed clinical microbiologist scientist may perform high complexity tests in microbiology including bacteriology, mycobacteriology, mycology, parasitology, and virology, immunology, including diagnostic immunology and syphilis serology, and molecular biology. (17 CCR § 1031(b)(2))
- K. A licensed clinical immunohematologist scientist may perform high complexity tests in immunohematology including ABO/Rh blood grouping and typing, unexpected antibody detection, compatibility testing and antibody identification. (17 CCR § 1031(b)(3))
- L. A licensed clinical toxicologist scientist may perform high complexity tests in the specialty of toxicology. (17 CCR § 1031(b)(4))
- M. A licensed clinical hematologist scientist may perform high complexity tests in hematology including routine hematology and coagulation. (17 CCR § 1031(b)(5))
- N. A physician office laboratory (five or fewer physicians performing tests only on their own patients) may employ any person to perform testing, but a supervising

physician must be present onsite when high complexity tests are performed. (BPC § 1206.5 (c)) A person performing high-complexity tests must have at least an associate degree in science. (Title 42, Code of Federal Regulations § 493.1489)

#### IV. UNLICENSED LABORATORY PERSONNEL

- A. There are limitations on what activities an unlicensed laboratory personnel can perform in a laboratory. (BPC § 1269)
- B. Unlicensed laboratory personnel may only perform duties in a licensed clinical laboratory. Unlicensed laboratory personnel may not perform duties in a registered clinical laboratory. (BPC § 1269)
- C. Unlicensed laboratory personnel ("aides") cannot perform tests in a laboratory that is not a physician office laboratory. (BPC § 1212, BPC § 1206.5)
- D. Unlicensed laboratory personnel require direct and constant supervision during the entire time they are assisting in the activities specified in BPC § 1269 (b). (BPC § 1206 (a) (9), 1269 (a))
- E. Unlicensed laboratory personnel require the supervision and control of a licensed person when performing pre-analytical and post-analytical procedures such as specimen preparation. (BPC § 1269 (c))

#### V. LABORATORY OWNERS

- A. Anyone with a 5% or more interest in a laboratory is considered an owner. (BPC § 1211)
- B. If the laboratory director is not the laboratory owner, then both are jointly and severally responsible for the laboratory. (BPC § 1265 (b))
- C. A laboratory owner is excluded from owning another laboratory for two years when he or she has been the owner, operator, or director of a laboratory that has had its license or registration revoked. (17 CCR § 1065.30)
- D. A major change of ownership is one that involves a change in 50 percent or more of ownership control. (BPC § 1211)

- E. A laboratory's owners and directors must notify the Department within 30 days of a change of ownership, directorship, and name, or location, including addition or deletion of owners or directors. (BPC § 1265 (g))
- F. A laboratory owner must state the name(s) and address(es) of owners and directors on the application for licensure or registration of the facility. (BPC § 1265 (b))

## VI. PHLEBOTOMY

- A. Phlebotomy can be performed by persons licensed under BPC chapter 3. (BPC § 1242)
- B. Phlebotomy can be performed by a licensed registered nurse, licensed vocational nurse, or licensed respiratory care practitioner. (BPC § 1242.6)
- C. Phlebotomy can be performed as part of a necessary training program by a student enrolled in an accredited college or university or a school approved by the department for training purposes. (BPC § 1243)
- D. Phlebotomy can be performed by a certified phlebotomy technician, who must
  - a. Be employed by a clinical laboratory (BPC § 1246); or
  - b. Perform phlebotomy for non-diagnostic (insurance) purposes or for forensic purposes outside a clinical laboratory, when the certified phlebotomy technician follows policy and procedures established by a physician and is supervised by a physician, nurse, or a person licensed under BPC Chapter 3 including a medical laboratory technician. (BPC § 1246 (c))
- E. Certification requirements and scopes of practice for phlebotomy technicians are listed in California law. (17 CCR § 1034)
- F. Instruction and training in phlebotomy for certification purposes must be obtained in a training school or program approved by the department. (17 CCR §§ 1034 and 1035.1)

## VII. TRAINEES

- A. A training program must be approved by the Department. (BPC § 1286 and 17 CCR §§ 1035, 1035.1, and 1035.3)
- B. A trainee must train in a program approved for this purpose by the Department. (BPC § 1205)
- C. A trainee must work under the direct and responsible supervision of the laboratory director or a person other than a trainee licensed under BPC chapter 3. (BPC § 1205)
- D. The ratio of licensed persons to trainees must not exceed two licensed persons to one trainee. (17 CCR § 1035 (d))

## VIII. APPLICATION OF CLINICAL LABORATORY LAW

- A. California law is broadly applied to include all facilities providing analyses of all human body specimens including blood, urine, feces, hair, breath, saliva, and body fluids. (BPC § 1206)
- B. A laboratory located outside California performing tests on specimens originating in California must be licensed or registered by the Department. (BPC § 1241)
- C. Exempt from California laboratory law are laboratories owned by the US government, public health laboratories, forensic laboratories, research and teaching laboratories, SAMSHA laboratories, childcare centers performing glucose testing on diabetic children, persons performing over-the-counter purchased home test kits, and emergency medical technicians and paramedics en route to a hospital performing glucose testing. (BPC § 1241(b))
- D. A separate license is not needed for mobile laboratories, not-for-profit or government laboratories performing fewer than 15 moderately complex or waived tests, laboratories within a hospital operating under a single license, or laboratories at a single address operating under common ownership. (BPC § 1265 (d))
- E. Laboratory licenses and personnel licenses must be posted in plain view in the laboratory. (BPC § 1266)



- F. A laboratory must notify the Department of Consumer Affairs when a specimen storage box has been improperly secured. (BPC § 1220.5)
- G. A laboratory or a person licensed, registered, or certified by the Department under Chapter 3 of the BPC must notify the Department within 30 days of any change of name or address. (BPC § 1227)
- H. A laboratory must report infectious diseases to the appropriate county health officer. (17 CCR § 2505)
- I. A laboratory must keep all records for three years, cytology records for five years, and cytology reports and histopathology reports for ten years. (BPC §§ 1265(j)(2)(A) and 1271)
- J. All clinical laboratory results must be reviewed and released by authorized persons (BPC §§ 1206.5 and 1269(d)), except those released by autoverification using a computer algorithm in conjunction with automated clinical laboratory instrumentation (BPC § 1209.5), to the healthcare provider who ordered the tests. (BPC § 1288)
- K. A patient may request from his or her physician to receive test results by internet or other electronic means. (Health and Safety Code (HSC) § 123148)
- L. A laboratory may accept self-ordered tests only for tests that are approved by the FDA for over-the-counter purchase for home testing. (BPC § 1246.5)
- M. A report of results from a clinical laboratory must show clearly the name and address of the laboratory and the name of the laboratory director. (BPC § 1288)
- N. Blood banks (HSC § 1600.2) and tissue banks (HSC § 1635) must be licensed separately from clinical laboratories. (HSC § 1635.1)
- O. A laboratory does not need proof of written consent to perform HIV screening tests. (HSC § 120990)

## IX. PROFICIENCY TESTING

- A. A laboratory must authorize its PT provider to release results to the Department in an electronic format compatible with the State's monitoring system. (BPC § 1220(a)(1)(B) and 17 CCR § 1066(d)(2))
- B. A laboratory must enroll with a State-approved PT provider. (BPC § 1272)
- C. A Laboratory must follow all CLIA PT requirements. (BPC § 1220)
- D. A laboratory license is subject to revocation for referring PT to another laboratory. (17 CCR § 1065.45)

X. CYTOLOGY

- A. A laboratory performing cytology must be licensed by the Department. (BPC § 1265)
- B. A cytotechnologist cannot perform more than 80 manual Pap smears or 100 automated or semi-automated Pap smears in a 24-hour period. If the cytotechnologist has other duties, these limits must be reduced appropriately. (BPC § 1271)
- C. A licensed cytotechnologist may perform all tests and procedures pertaining to cytology, including, but not limited to, microscopic and nonmicroscopic methodologies and tests and procedures that utilize molecular or genetic methodologies, that are performed on cytologic specimens related to infectious disease or cancer diagnosis, under the overall operation and administration of a laboratory director, who shall be a qualified pathologist. (BPC § 1270)
- D. Any tests or procedures performed by a licensed cytotechnologist must be performed in a licensed clinical laboratory certified in the subspecialty of diagnostic cytology. (BPC § 1270)
- E. A cytotechnologist must record the number of cases performed each day at each location where he or she works, and the location where the work was performed must be identified in the report. (BPC § 1271)
- F. Ten percent of all normal and all abnormal cytology cases must be reviewed by a pathologist or supervising cytotechnologist. (BPC § 1271)

- G. A cytology laboratory must send quarterly reports of all dysplasia to doctors submitting cytologic samples and review previous normal slides of the affected patients. (BPC § 1274)
- H. Anyone who reviews or who performs testing on a cytology case must sign the worksheet or report, even if he or she disagrees with the final report. (42 CFR § 1274(e) and § 493.1283(a))

XI. IT IS UNLAWFUL UNDER CALIFORNIA LAW TO:

- A. Pose as a licensed person when not licensed. (BPC § 1280)
- B. Operate a laboratory without a license, registration, or certificate of deemed status issued by a State-approved accrediting organization. (BPC § 1281)
- C. Buy or sell blood for diagnostic purposes. (BPC § 1281.1)
- D. Engage in clinical laboratory practice unless licensed as a physician, licensed by the Department, or otherwise authorized. (BPC § 1282)
- E. Perform phlebotomy unless authorized. (BPC § 1282.2)
- F. Adversely impact the integrity of a specimen. (BPC § 1282.3)
- G. Serve as a "nominal" laboratory director. (BPC § 1284)
- H. Perform clinical laboratory tests or examinations unless licensed or authorized. (BPC § 1285)
- I. Perform tests or examinations outside the scope of the laboratory's approval or outside the specialty of the testing person's authorization. (BPC § 1288.5)
- J. Operate a school or conduct a training program for clinical laboratory personnel without State approval. (BPC § 1286)
- K. Accept a test without a physician referral. (BPC § 1288)