BUSINESS AND PROFESSIONS CODE - BPC

DIVISION 2. HEALING ARTS [500 - 4999.129] *(Division 2 enacted by Stats. 1937, Ch. 399.)*

CHAPTER 3. Clinical Laboratory Technology [1200 - 1327] *(Chapter 3 repealed and added by Stats. 1951, Ch. 1727.)*

ARTICLE 1. Definitions [1200 - 1214] *(Article 1 added by Stats. 1951, Ch. 1727.)*

1200. Every provision of this chapter shall be liberally construed to protect the interests of all persons affected.

(Repealed and added by Stats. 1951, Ch. 1727.)

1201. As used in this chapter, “person” includes firm, association, partnership, individual, limited liability company, and corporation.

(Amended by Stats. 1994, Ch. 1010, Sec. 4. Effective January 1, 1995.)

1202. As used in this chapter, “department” means the State Department of Public Health.

(Amended by Stats. 2013, Ch. 76, Sec. 1. (AB 383) Effective January 1, 2014.)

1202.5. (a) For purposes of this chapter “CLIA” means the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a; P.L. 100-578) and the regulations adopted thereunder by the federal Health Care Financing Administration and effective on January 1, 1994, or any later date, when adopted in California pursuant to subdivision (b) of Section 1208.

(b) For purposes of this chapter “HCFA” means the Health Care Financing Administration of the federal Department of Health and Human Services.

(Added by Stats. 1995, Ch. 510, Sec. 2. Effective January 1, 1996.)

1203. As used in this chapter, “clinical laboratory bioanalyst” or “bioanalyst” means a person licensed under Section 1260 to engage in clinical laboratory practice and direction of a clinical laboratory.

(a) A person licensed as a clinical laboratory bioanalyst or bioanalyst and qualified under CLIA, who is not the CLIA laboratory director, may perform clinical laboratory tests or examinations classified as of high complexity under CLIA and the duties and responsibilities of a laboratory director in the specialties of histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, genetics, reproductive biology, or other specialty or subspecialty specified in regulations adopted by the department.

(b) A person licensed as a clinical laboratory bioanalyst or bioanalyst and qualified under CLIA may perform the duties and responsibilities of a CLIA laboratory director, technical consultant, clinical consultant, technical supervisor, and general supervisor, as specified under CLIA, in the specialties of histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, genetics, reproductive biology, or other specialty or subspecialty specified in regulations adopted by the department.

(c) A person licensed as a clinical laboratory bioanalyst or bioanalyst may perform any clinical laboratory test or examination classified as waived or of moderate complexity under CLIA.

(Amended by Stats. 2022, Ch. 473, Sec. 1. (SB 1267) Effective January 1, 2023.)

1204. As used in this chapter, “clinical laboratory scientist” means a person, other than a licensed clinical laboratory bioanalyst or trainee, who is licensed under Sections 1261 and 1262 to engage in clinical laboratory practice under the overall operation and administration of a laboratory director, unless serving as a director of a waived laboratory as provided in Section 1209. A person licensed as a clinical laboratory scientist and qualified under CLIA may perform clinical laboratory tests or examinations classified as of high complexity under CLIA and the duties and responsibilities of a waived laboratory director, as specified under CLIA, technical consultant, clinical consultant, technical supervisor, and general supervisor, as specified under CLIA, in the specialties of

histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, reproductive biology, genetics, or other specialty or subspecialty specified by regulation adopted by the department. A person licensed as a “clinical laboratory scientist” may perform any clinical laboratory test or examination classified as waived or of moderate complexity under CLIA.

(Amended by Stats. 2022, Ch. 473, Sec. 2. (SB 1267) Effective January 1, 2023.)

1205. As used in this chapter, “trainee” means a person licensed under this chapter for the purpose of receiving comprehensive practical experience and instruction in clinical laboratory procedures in one of the sciences or in general clinical laboratory science under the direct and responsible supervision of a person authorized to direct a laboratory under the provisions of this chapter, clinical laboratory scientist, clinical chemist scientist, clinical microbiologist scientist, clinical toxicologist scientist, clinical immunohematologist scientist, clinical genetic molecular biologist scientist, clinical cytogeneticist scientist, clinical histocompatibility scientist, clinical laboratory geneticist scientist, clinical reproductive biologist scientist, or other equivalent licensee in the science or specialty or subspecialty for which the person is licensed in a clinical laboratory certified for this purpose by the department under this chapter.

(Amended by Stats. 2022, Ch. 473, Sec. 3. (SB 1267) Effective January 1, 2023.)

1206. (a) For the purposes of this chapter the following definitions are applicable:

(1) “Analyte” means the substance or constituent being measured, including, but not limited to, glucose, sodium, or theophyline, or any substance or property whose presence or absence, concentration, activity, intensity, or other characteristics are to be determined.

(2) “Biological specimen” means any material that is derived from the human body.

(3) “Blood electrolyte analysis” means the measurement of electrolytes in a blood specimen by means of ion selective electrodes on instruments specifically designed and manufactured for blood gas and acid-base analysis.

(4) “Blood gas analysis” means a clinical laboratory test or examination that deals with the uptake, transport, and metabolism of oxygen and carbon dioxide in the human body.

(5) “Clinical laboratory test or examination” means the detection, identification, measurement, evaluation, correlation, monitoring, and reporting of any particular analyte, entity, or substance within a biological specimen for the purpose of obtaining scientific data that may be used as an aid to ascertain the presence, progress, and source of a disease or physiological condition in a human being, or used as an aid in the prevention, prognosis, monitoring, or treatment of a physiological or pathological condition in a human being, or for the performance of nondiagnostic tests for assessing the health of an individual.

(6) “Clinical laboratory science” means any of the sciences or scientific disciplines used to perform a clinical laboratory test or examination.

(7) “Clinical laboratory practice” means the application of clinical laboratory sciences or the use of any means that applies the clinical laboratory sciences within or outside of a licensed or registered clinical laboratory. Clinical laboratory practice includes consultation, advisory, and other activities inherent to the profession.

(8) “Clinical laboratory” means a place used, or an establishment or institution organized or operated, for the performance of clinical laboratory tests or examinations or the practical application of the clinical laboratory sciences. That application may include any means that applies the clinical laboratory sciences.

(9) “Direct and constant supervision” means personal observation and critical evaluation of the activity of unlicensed laboratory personnel by a physician and surgeon, or by a person licensed under this chapter other than a trainee, during the entire time that the unlicensed laboratory personnel are engaged in the duties specified in Section 1269.

(10) “Direct and responsible supervision” means both of the following:

(A) Personal observation and critical evaluation of the activity of a trainee by a physician and surgeon, or by a person licensed under this chapter other than a trainee, during the entire time that the trainee is performing clinical laboratory tests or examinations.

(B) Personal review by the physician and surgeon or the licensed person of all results of clinical laboratory testing or examination performed by the trainee for accuracy, reliability, and validity before the results are reported from the laboratory.

(11) “Licensed laboratory” means a clinical laboratory licensed pursuant to paragraph (1) of subdivision (a) of Section 1265.

(12) “Location” means either a street and city address, or a site or place within a street and city address, where any of the clinical laboratory sciences or scientific disciplines are practiced or applied, or where any clinical laboratory tests or examinations are performed.

(13) “Physician office laboratory” means a clinical laboratory that is licensed or registered under Section 1265, and that is either: (A) a clinical laboratory that is owned and operated by a partnership or professional corporation that performs clinical laboratory tests or examinations only for patients of five or fewer physicians and surgeons or podiatrists who are shareholders, partners, or employees of the partnership or professional corporation that owns and operates the clinical laboratory; or (B) a clinical laboratory that is owned and operated by an individual licensed physician and surgeon or a podiatrist, and that performs clinical laboratory tests or examinations only for patients of the physician and surgeon or podiatrist who owns and operates the clinical laboratory.

(14) “Point-of-care laboratory testing device” means a portable laboratory testing instrument to which the following applies:

(A) It is used within the proximity of the patient for whom the test or examination is being conducted.

(B) It is used in accordance with the patient test management system, the quality control program, and the comprehensive quality assurance program established and maintained by the laboratory pursuant to paragraph (2) of subdivision (d) of Section 1220.

(C) It meets the following criteria:

(i) Performs clinical laboratory tests or examinations classified as waived or of moderate complexity under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. Sec. 263a).

(ii) Performs clinical laboratory tests or examinations on biological specimens that require no preparation after collection.

(iii) Provides clinical laboratory tests or examination results without calculation or discretionary intervention by the testing personnel.

(iv) Performs clinical laboratory tests or examinations without the necessity for testing personnel to perform calibration or maintenance, except resetting pursuant to the manufacturer’s instructions or basic cleaning.

(15) “Public health laboratory” means a laboratory that is operated by a city or county in conformity with Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code and the regulations adopted thereunder.

(16) “Registered laboratory” means a clinical laboratory registered pursuant to paragraph (2) of subdivision (a) of Section 1265.

(17) “Specialty” means histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, pathology, genetics, reproductive biology, or other specialty specified by regulation adopted by the department.

(18) “Subspecialty” means all of the following:

(A) For purposes of microbiology, means bacteriology, mycobacteriology, mycology, parasitology, virology, molecular biology, and serology for diagnosis of infectious diseases, or other subspecialty specified by regulation adopted by the department.

(B) For purposes of diagnostic immunology, means syphilis serology, general immunology, or other subspecialty specified by regulation adopted by the department.

(C) For purposes of chemistry, means routine chemistry, clinical microscopy, endocrinology, toxicology, or other subspecialty specified by regulation adopted by the department.

(D) For purposes of immunohematology, means ABO/Rh Type and Group, antibody detection for transfusion, antibody detection nontransfusion, antibody identification, compatibility, or other subspecialty specified by regulation adopted by the department.

(E) For pathology, means tissue pathology, oral pathology, diagnostic cytology, or other subspecialty specified by regulation adopted by the department.

(F) For purposes of genetics, means molecular biology related to the diagnosis of human genetic abnormalities, cytogenetics, biochemical genetics, laboratory genetics, or other subspecialty specified by regulation adopted by the department.

(G) For purposes of reproductive biology, means andrology and embryology, including diagnostic testing for management of primary and secondary infertility, fertility assessment, and fertility preservation, as well as the evaluation and assessment of

gametes and embryos and their associated fluids and tissues, or other subspecialty specified by regulation adopted by the department. Reproductive biology does not include the qualitative assessment of sperm in preparation for intrauterine insemination.

(b) This chapter does not restrict, limit, or prevent a person licensed to provide health care services under the laws of this state, including, but not limited to, licensed physicians and surgeons and registered nurses, from practicing the profession or occupation for which the person is licensed.

(c) This chapter does not authorize a person to perform or order health care services, or utilize the results of the clinical laboratory test or examination, unless the person is otherwise authorized to provide that care or utilize the results. The inclusion of a person in Section 1206.5 for purposes of performing a clinical laboratory test or examination does not authorize a person, who is not otherwise authorized, to perform venipuncture, arterial puncture, or skin puncture.

(Amended by Stats. 2022, Ch. 473, Sec. 4. (SB 1267) Effective January 1, 2023.)

1206.5. (a) Notwithstanding subdivision (b) of Section 1206 and except as otherwise provided in Sections 1206.6 and 1241, no person shall perform a clinical laboratory test or examination classified as waived under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist, a licensed dentist, or a licensed naturopathic doctor, if the results of the tests can be lawfully utilized within their practice.

(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.

(5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.

(6) A person licensed under Chapter 6 (commencing with Section 2700).

(7) A person licensed under Chapter 6.5 (commencing with Section 2840).

(8) A perfusionist if authorized by and performed in compliance with Section 2590.

(9) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(10) A medical assistant, as defined in Section 2069, if the waived test is performed pursuant to a specific authorization meeting the requirements of Section 2069.

(11) A pharmacist, as defined in Section 4036, if ordering drug therapy-related laboratory tests in compliance with paragraph (2) of subdivision (a) of Section 4052.1 or paragraph (2) of subdivision (a) of Section 4052.2, if performing skin puncture in the course of performing routine patient assessment procedures in compliance with Section 4052.1, or if performing testing as authorized in Section 4052.4.

(12) A naturopathic assistant, as defined in Sections 3613 and 3640.2, if the waived test is performed pursuant to a specific authorization meeting the requirements of Sections 3613 and 3640.2.

(13) A licensed optometrist as authorized under Chapter 7 (commencing with Section 3000).

(14) Other health care personnel providing direct patient care.

(15) Any other person performing nondiagnostic testing pursuant to Section 1244.

(b) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of moderate complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory

director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within their practice.

(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.

(5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.

(6) A person licensed under Chapter 6 (commencing with Section 2700).

(7) A perfusionist if authorized by and performed in compliance with Section 2590.

(8) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(9) A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107150) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.

(10) Any person if performing blood gas analysis in compliance with Section 1245.

(11) (A) A person certified or licensed as an “Emergency Medical Technician II” or paramedic pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code while providing prehospital medical care, a person licensed as a psychiatric technician under Chapter 10 (commencing with Section 4500) of Division 2, as a vocational nurse pursuant to Chapter 6.5 (commencing with Section 2840), or as a midwife licensed pursuant to Article 24 (commencing with Section 2505) of Chapter 5, or certified by the department pursuant to Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations as a nurse assistant or a home health aide, who provides direct patient care, if the person is performing the test as an adjunct to the provision of direct patient care by the person, is utilizing a point-of-care laboratory testing device at a site for which a laboratory license or registration has been issued, meets the minimum clinical laboratory education, training, and experience requirements set forth in regulations adopted by the department, and has demonstrated to the satisfaction of the laboratory director that the person is competent in the operation of the point-of-care laboratory testing device for each analyte to be reported.

(B) Before being authorized by the laboratory director to perform laboratory tests or examinations, testing personnel identified in subparagraph (A) shall participate in a preceptor program until they are able to perform the clinical laboratory tests or examinations authorized in this section with results that are deemed accurate and skills that are deemed competent by the preceptor. For the purposes of this section, a “preceptor program” means an organized system that meets regulatory requirements in which a preceptor provides and documents personal observation and critical evaluation, including review of accuracy, reliability, and validity, of laboratory testing performed.

(12) Any other person within a physician office laboratory if the test is performed under the supervision of the patient’s physician and surgeon or podiatrist who shall be accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed, and shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of the clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.

(13) A pharmacist, if ordering drug therapy-related laboratory tests in compliance with paragraph (2) of subdivision (a) of Section 4052.1 or paragraph (2) of subdivision (a) of Section 4052.2.

(c) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of high complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within their practice.

(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory if the test or examination is within a specialty or subspecialty authorized by the person’s licensure.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code if the test or examination is within a specialty or subspecialty authorized by the person's certification.

(5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.

(6) A perfusionist if authorized by and performed in compliance with Section 2590.

(7) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(8) A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107150) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.

(9) Any person if performing blood gas analysis in compliance with Section 1245.

(10) Any other person within a physician office laboratory if the test is performed under the onsite supervision of the patient's physician and surgeon or podiatrist who shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.

(d) Clinical laboratory examinations classified as provider-performed microscopy under CLIA may be personally performed using a brightfield or phase/contrast microscope by one of the following practitioners:

(1) A licensed physician and surgeon using the microscope during the patient's visit on a specimen obtained from their own patient or from a patient of a group medical practice of which the physician is a member or employee.

(2) A nurse practitioner practicing pursuant to Section 2837.103 or 2837.104 using the microscope during the patient's visit on a specimen obtained from their own patient or from a patient of a group nurse practitioner practice of which the nurse practitioner is a member or employee.

(3) A nurse midwife holding a certificate as specified by Section 2746.5, a licensed nurse practitioner as specified in Section 2835.5, or a licensed physician assistant acting under the supervision of a physician pursuant to Section 3502 using the microscope during the patient's visit on a specimen obtained from their own patient or from the patient of a clinic, group medical practice, or other health care provider of which the certified nurse midwife, licensed nurse practitioner, or licensed physician assistant is an employee.

(4) A licensed dentist using the microscope during the patient's visit on a specimen obtained from their own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

(Amended by Stats. 2022, Ch. 413, Sec. 1. (AB 2684) Effective January 1, 2023.)

1206.6. Subdivision (a) of Section 1206.5 shall not apply to a pharmacist at a community pharmacy who, upon customer request, performs only blood glucose, hemoglobin A1c, or cholesterol tests that are classified as waived under CLIA and are approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit, provided that all of the following requirements are satisfied:

(a) The pharmacy obtains a valid CLIA certificate of waiver and complies with all other requirements for the performance of waived clinical laboratory tests under applicable federal regulations. For purposes of CLIA, the person identified as responsible for directing and supervising testing oversight and decisionmaking shall be the pharmacist-in-charge, as defined in Section 4036.5.

(b) The pharmacy obtains a registration from the department pursuant to Section 1265 and complies with this chapter.

(c) The tests are performed only by a pharmacist, as defined in Section 4036, in the course of performing routine patient assessment procedures in compliance with Section 4052.4.

(Added by Stats. 2012, Ch. 874, Sec. 2. (SB 1481) Effective January 1, 2013.)

1206.7. (a) Notwithstanding Section 1206.5, a person may perform an analysis of samples to test for SARS-CoV-2, the virus that causes COVID-19, in a clinical laboratory if they meet the requirements under the Clinical Laboratory Improvement Amendments in Section 493.1489 of Title 42 of the Code of Federal Regulations for high complexity testing.

(b) This section shall remain in effect only until July 1, 2028, and as of that date is repealed.

(Amended by Stats. 2023, Ch. 276, Sec. 1. (AB 1341) Effective September 30, 2023. Repealed as of July 1, 2028, by its own provisions.)

1207. (a) As used in this chapter, "clinical chemist," "clinical microbiologist," "clinical toxicologist," "clinical genetic molecular biologist," "clinical cytogeneticist," "clinical laboratory geneticist," "clinical reproductive biologist," or "oral and maxillofacial

pathologist" means a person licensed by the department under Section 1264 to engage in, or supervise others engaged in, clinical laboratory practice limited to the person's area of specialization or to direct a clinical laboratory, or portion thereof, limited to their area of specialization. A licensed person who is qualified under CLIA may perform clinical laboratory tests or examinations classified as of high complexity under CLIA, and the duties and responsibilities of a laboratory director, technical consultant, clinical consultant, technical supervisor, and general supervisor, as specified under CLIA, limited to their area of specialty or subspecialty as described in subdivision (b), and shall only direct a clinical laboratory providing service within those specialties or subspecialties. A person licensed as a "clinical chemist," "clinical microbiologist," "clinical toxicologist," "clinical genetic molecular biologist," "clinical cytogeneticist," "clinical laboratory geneticist," "clinical reproductive biologist," or "oral and maxillofacial pathologist" may perform any clinical laboratory test or examination classified as waived or of moderate complexity under CLIA.

(b) The specialty or subspecialty for each of the limited license categories identified in subdivision (a), and the clinical laboratories that may be directed by persons licensed in each of those categories, are the following:

(1) For a person licensed under this chapter as a clinical chemist, the specialty of chemistry and the subspecialties of routine chemistry, endocrinology, clinical microscopy, toxicology, or other specialty or subspecialty specified by regulation adopted by the department.

(2) For a person licensed under this chapter as a clinical microbiologist, the specialty of microbiology and the subspecialties of bacteriology, mycobacteriology, mycology, parasitology, virology, molecular biology, and serology for diagnosis of infectious diseases, or other specialty or subspecialty specified by regulation adopted by the department.

(3) For a person licensed under this chapter as a clinical toxicologist, the subspecialty of toxicology within the specialty of chemistry or other specialty or subspecialty specified by regulation adopted by the department.

(4) For a person licensed under this chapter as a clinical genetic molecular biologist, the subspecialty of molecular biology related to diagnosis of human genetic abnormalities within the specialty of genetics or other specialty or subspecialty specified by regulation adopted by the department.

(5) For a person licensed under this chapter as a clinical cytogeneticist, the subspecialty of cytogenetics within the specialty of genetics or other specialty or subspecialty specified by regulation adopted by the department.

(6) For a person licensed under this chapter as a clinical laboratory geneticist, the subspecialties of molecular biology related to diagnosis of human genetic abnormalities, cytogenetics, biochemical genetics, or laboratory genetics within the specialty of genetics, or other specialty or subspecialty specified by regulation adopted by the department.

(7) For a person licensed under this chapter as a clinical reproductive biologist, the specialty of reproductive biology and the subspecialties of andrology and embryology related to diagnostic testing for management of primary and secondary infertility, fertility assessment, and fertility preservation, as well as the evaluation and assessment of gametes, embryos, and their associated fluids and tissues, or other specialty or subspecialty specified by regulation adopted by the department.

(8) For a person licensed under this chapter as an oral and maxillofacial pathologist, the subspecialty of oral pathology within the specialty of pathology or other specialty or subspecialty specified by regulation adopted by the department.

(Amended by Stats. 2022, Ch. 473, Sec. 5. (SB 1267) Effective January 1, 2023.)

1208. (a) For the purposes of this chapter whenever the department determines that a new category of license is necessary, either to direct a laboratory, or to perform clinical laboratory tests or examinations in specific specialties or subspecialties, or that the specialties or subspecialties authorized under an existing license category should be modified, it shall adopt regulations identifying the license category or modification, the education, training, and examination necessary to obtain the license, and the specialty or subspecialty, or both, included within the new license category, or within the existing category as modified.

(b) Any CLIA regulation adopted by HCFA as a final rule after January 1, 1994, shall be evaluated by the department in consultation with the multidisciplinary committee appointed pursuant to Section 1228. Any new federal regulation that is deemed by the department to be equivalent to or more stringent than California laws or regulations, shall become effective by operation of law as a regulation adopted under this chapter, 90 days after adoption by HCFA and the department publishes the notice required by subdivision (c), or on January 1, 1996, whichever is later. After publishing the notice required by subdivision (c), any new federal regulation deemed by the department to be less stringent than current California law or regulation shall be noticed by the department as a comparable state regulation for a rulemaking proceeding in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, which shall result in the adoption, amendment, or rejection of that noticed state regulation.

(c) The department shall publish a notice in the California Regulatory Notice Register indicating that a CLIA regulation has been adopted by HCFA as a final rule. The notice shall include the citation to the Federal Register or the Code of Federal Regulations for the CLIA regulation. The notice shall also include the department's determination regarding whether the regulation is more stringent, equivalent to, or less stringent than current California law or regulation.

(Amended by Stats. 1995, Ch. 510, Sec. 8. Effective January 1, 1996.)

1209. (a) As used in this chapter, “laboratory director” means any person who is any of the following:

(1) A duly licensed physician and surgeon.

(2) Only for purposes of a clinical laboratory test or examination classified as waived, except as provided in paragraph (G), is any of the following:

(A) A duly licensed clinical laboratory scientist.

(B) A duly licensed limited clinical laboratory scientist.

(C) A duly licensed naturopathic doctor.

(D) A duly licensed optometrist serving as the director of a laboratory that only performs clinical laboratory tests authorized in clause (ii) of subparagraph (E) of paragraph (5) of subdivision (a) of Section 3041.

(E) A duly licensed dentist serving as the director of a laboratory that performs only clinical laboratory tests authorized within the scope of practice of dentistry as delineated under Section 1625.

(F) A pharmacist-in-charge of a pharmacy serving as the director of a laboratory that only performs tests waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a), as authorized by the Pharmacy Law (Chapter 9 (commencing with Section 4000)).

(G) A certified nurse-midwife serving as the director of a laboratory that only performs clinical laboratory tests classified as waived or provider-performed microscopy authorized within the scope of the certificate to practice nurse-midwifery as specified in Section 2746.5.

(3) Licensed to direct a clinical laboratory under this chapter.

(b) (1) A person defined in paragraph (1) or (3) of subdivision (a) who is identified as the CLIA laboratory director of a laboratory that performs clinical laboratory tests classified as moderate or high complexity shall also meet the laboratory director qualifications under CLIA for the type and complexity of tests being offered by the laboratory.

(2) As used in this subdivision, “CLIA laboratory director” means the person identified as the laboratory director on the CLIA certificate issued to the laboratory by the federal Centers for Medicare and Medicaid Services (CMS).

(c) The laboratory director, if qualified under CLIA, may perform the duties of the technical consultant, technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to persons qualified under CLIA. If the laboratory director reapportions performance of those responsibilities or duties, they shall remain responsible for ensuring that all those duties and responsibilities are properly performed.

(d) (1) The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including administering the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to ensure compliance with this act and CLIA. They shall be responsible for the proper performance of all laboratory work of all subordinates and shall employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests, and report test results in accordance with the personnel qualifications, duties, and responsibilities described in CLIA and this chapter.

(2) Where a point-of-care laboratory testing device is utilized and provides results for more than one analyte, the testing personnel may perform and report the results of all tests ordered for each analyte for which they have been found by the laboratory director to be competent to perform and report.

(e) As part of the overall operation and administration, the laboratory director of a registered laboratory shall document the adequacy of the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for personnel, in addition to any CLIA requirements relative to the education or training of personnel.

(f) As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following:

(1) Ensure that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for, and the type of procedures that may be performed by, personnel in addition to any CLIA requirements relative to the education or training of personnel. Any regulations adopted pursuant to this section that specify the type of procedure that may be performed by testing personnel shall be based on the skills, knowledge, and tasks required to perform the type of procedure in question.

(2) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to ensure that they are competent and maintain their competency to process biological specimens, perform test procedures, and report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills.

(3) Specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of clinical laboratory tests or examinations, including which clinical laboratory tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, test performance, or results reporting, and whether consultant, supervisor, or director review is required prior to the individual reporting patient test results.

(g) The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory.

(1) The procedures for evaluating the competency of the staff shall include, but are not limited to, all of the following:

(A) Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen handling, processing, and testing.

(B) Monitoring the recording and reporting of test results.

(C) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

(D) Direct observation of performance of instrument maintenance and function checks.

(E) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.

(F) Assessment of problem solving skills.

(2) Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year an individual tests biological specimens. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual’s performance shall be reevaluated to include the use of the new test methodology or instrumentation.

(h) The laboratory director of each clinical laboratory of an acute care hospital shall be a physician and surgeon who is a qualified pathologist, except as follows:

(1) If a qualified pathologist is not available, a physician and surgeon or a clinical laboratory bioanalyst qualified as a laboratory director under subdivision (a) may direct the laboratory. However, a qualified pathologist shall be available for consultation at suitable intervals to ensure high-quality service.

(2) If there are two or more clinical laboratories of an acute care hospital, those additional clinical laboratories that are limited to the performance of blood gas analysis, blood electrolyte analysis, or both, may be directed by a physician and surgeon qualified as a laboratory director under subdivision (a), irrespective of whether a pathologist is available.

As used in this subdivision, a qualified pathologist is a physician and surgeon certified or eligible for certification in clinical or anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

(i) Subdivision (h) does not apply to any director of a clinical laboratory of an acute care hospital acting in that capacity on or before January 1, 1988.

(j) A laboratory director may serve as the director of up to the maximum number of laboratories stipulated by CLIA, as defined under Section 1202.5.

(Amended by Stats. 2023, Ch. 497, Sec. 1. (SB 667) Effective January 1, 2024.)

1209.1. (a) As used in this chapter, “histocompatibility laboratory director” means a physician and surgeon licensed to practice medicine pursuant to Chapter 5 (commencing with Section 2000) who is qualified pursuant to Section 1209, a bioanalyst licensed pursuant to Section 1260 who is qualified pursuant to Sections 1203 and 1209, or a person who has earned a doctoral degree in a biological science, who has completed, subsequent to graduation, four years of experience in immunology, two of which have been in histocompatibility testing.

(b) On and after January 1, 2007, in order to be eligible for licensure as a histocompatibility laboratory director, an applicant who is not a duly licensed physician and surgeon or a duly licensed bioanalyst shall provide evidence of satisfactory performance on a written examination in histocompatibility administered by the American Board of Histocompatibility and Immunogenetics, and have demonstrated satisfactory performance on an oral examination administered by the department regarding this chapter and Part 493 (commencing with Section 493.1) of Subchapter G of Chapter IV of Title 42 of the Code of Federal Regulations.

(c) A person licensed under Section 1260.1 as a histocompatibility laboratory director and qualified under CLIA may perform clinical laboratory tests or examinations classified as of high complexity under CLIA and the duties and responsibilities of a laboratory director, technical consultant, clinical consultant, technical supervisor, and general supervisor, as specified under CLIA, in the specialty of histocompatibility, immunology, or other specialty or subspecialty specified by regulation adopted by the department. A person licensed as a “histocompatibility laboratory director” may perform any clinical laboratory test or examination classified as waived or of moderate complexity under CLIA.

(Amended by Stats. 2006, Ch. 319, Sec. 1. Effective January 1, 2007.)

1209.5. (a) “Autoverification” means the use of a computer algorithm in conjunction with automated clinical laboratory instrumentation to review and verify the results of a clinical laboratory test or examination for accuracy and reliability.

(b) The laboratory director or authorized designee shall establish, validate, and document explicit criteria by which the clinical laboratory test or examination results are autoverified.

(c) The laboratory director or authorized designee shall annually revalidate the explicit criteria by which the clinical laboratory test or examination results are autoverified. The laboratory director shall approve and annually reapprove the computer algorithm.

(d) An authorized designee may be appointed by the laboratory director for the purposes of this section. The authorized designee shall be licensed to engage in clinical laboratory practice pursuant to this chapter and shall be qualified as a clinical consultant, technical supervisor, general supervisor, or technical consultant pursuant to regulations adopted by the department.

(e) A person licensed to perform the applicable type and complexity of testing pursuant to Section 1206.5 shall be physically present onsite in the clinical laboratory and shall have documented competency pursuant to Section 1209 in all tests being autoverified, and shall be responsible for the accuracy and reliability of the results of the clinical laboratory test or examination when the results are autoverified and reported.

(Amended by Stats. 2007, Ch. 61, Sec. 1. Effective July 12, 2007.)

1210. (a) As used in this chapter, “clinical chemist scientist,” “clinical microbiologist scientist,” “clinical toxicologist scientist,” “clinical immunohematologist scientist,” “clinical genetic molecular biologist scientist,” “clinical cytogeneticist scientist,” “clinical laboratory geneticist scientist,” “clinical reproductive biologist scientist,” and “clinical histocompatibility scientist” means a person, other than a person licensed to direct a clinical laboratory, or licensed as a clinical laboratory scientist or trainee, who is licensed under Sections 1261, 1261.5, and 1262 to engage in clinical laboratory practice. The licensed person who is qualified under CLIA may perform clinical laboratory tests classified as of high complexity under CLIA and the duties and responsibilities of a technical consultant, clinical consultant, technical supervisor, and general supervisor limited to the specialty or subspecialty as identified in subdivision (b) for which the person is licensed by the department. A person licensed as a “clinical chemist scientist,” “clinical microbiologist scientist,” “clinical toxicologist scientist,” “clinical immunohematologist scientist,” “clinical genetic molecular biologist scientist,” “clinical cytogeneticist scientist,” “clinical laboratory geneticist scientist,” “clinical reproductive biologist scientist,” or a “clinical histocompatibility scientist” may perform any clinical laboratory test or examination classified as waived or of moderate complexity under CLIA.

(b) The specialties and subspecialties included in each of the license categories identified in subdivision (a), are the following:

(1) For a person licensed under this chapter as a clinical chemist scientist, the specialty of chemistry and the subspecialties of routine chemistry, endocrinology, clinical microscopy, toxicology, or other specialty or subspecialty specified by regulation adopted by the department.

(2) For a person licensed under this chapter as a clinical microbiologist scientist, the specialty of microbiology and the subspecialties of bacteriology, mycobacteriology, mycology, parasitology, virology, or molecular biology and serology for diagnosis of infectious diseases, or other specialty or subspecialty specified by regulation adopted by the department.

(3) For a person licensed under this chapter as a clinical toxicologist scientist, the subspecialty of toxicology within the specialty of chemistry or other specialty or subspecialty specified by regulation adopted by the department.

(4) For a person licensed under this chapter as a clinical genetic molecular biologist scientist, the subspecialty of molecular biology related to the diagnosis of human genetic abnormalities within the specialty of genetics, or other specialty or subspecialty specified by regulation adopted by the department.

(5) For a person licensed under this chapter as a clinical cytogeneticist scientist, the subspecialty of cytogenetics within the specialty of genetics or other specialty or subspecialty specified by regulation adopted by the department.

(6) For a person licensed under this chapter as a clinical laboratory geneticist scientist, the subspecialties of molecular biology related to diagnosis of human genetic abnormalities, cytogenetics, biochemical genetics, or laboratory genetics within the specialty of genetics or other specialty or subspecialty specified by regulation adopted by the department.

(7) For a person licensed under this chapter as a clinical reproductive biologist scientist, the specialty of reproductive biology and the subspecialties of andrology and embryology related to diagnostic testing for management of primary and secondary infertility, fertility assessment, and fertility preservation, as well as the evaluation and assessment of gametes, embryos, and their associated fluids and tissues, or other specialty or subspecialty specified by regulation adopted by the department.

(8) For a person licensed under this chapter as a clinical immunohematologist scientist, the specialty of immunohematology or other specialty or subspecialty specified by regulation adopted by the department.

(9) For a person licensed under this chapter as a clinical histocompatibility scientist, the specialty of histocompatibility or other specialty or subspecialty specified by regulation adopted by the department.

(c) Clinical chemist scientists, clinical microbiologist scientists, clinical toxicologist scientists, clinical immunohematologist scientists, clinical genetic molecular biologist scientists, clinical cytogeneticist scientists, clinical laboratory geneticist scientists, clinical reproductive biologist scientists, and clinical histocompatibility scientists shall engage in clinical laboratory practice authorized by their licensure only under the overall operation and administration of a laboratory director.

(d) A person licensed under this chapter as a clinical genetic molecular biologist scientist may use molecular biology techniques to perform a clinical laboratory test or examination for the detection of any disease affecting humans.

(Amended by Stats. 2022, Ch. 956, Sec. 1.5. (AB 2107) Effective September 30, 2022. Operative January 1, 2023, pursuant to Sec. 2 of Stats. 2022, Ch. 956.)

1211. (a) As used in this chapter, “owner” means any person with an ownership or control interest in a clinical laboratory.

(b) “Person with an ownership or control interest” means a person, partnership, or corporation that meets any of the following descriptions:

(1) Has an ownership interest totaling 5 percent or more in a clinical laboratory.

(2) Has an indirect ownership interest equal to 5 percent or more in a clinical laboratory.

(3) Has a combination of direct and indirect ownership interests equal to 5 percent or more in a clinical laboratory.

(4) Owns an interest of 5 percent or more in any mortgage, deed of trust, note, or other obligation secured by the clinical laboratory if that interest equals at least 5 percent of the value of the property or assets of the clinical laboratory.

(5) Is an officer or director of a clinical laboratory that is organized as a corporation.

(6) Is a partner in a clinical laboratory that is organized as a partnership with no more than 25 partners, general or limited.

(7) Is a partner who exercises any operational or managerial control over a clinical laboratory organized as a partnership with more than 25 partners, general or limited.

(c) As used in this chapter “ownership interest” means the possession of equity in capital, stock, or profits.

(d) “Indirect ownership interest” means an ownership interest in an entity that has an ownership interest in a clinical laboratory, and includes an ownership interest in any entity that has an indirect ownership interest in a clinical laboratory.

(e) “Change in ownership” means any change in the persons who are owners.

(f) “Major change in ownership” means a change in ownership where 50 percent or more of the ownership interest is owned by persons other than the owners to whom the current clinical laboratory license or registration is issued.

(g) “Change in name” means any change in the name under which the laboratory operates or is doing business.

(h) “Change in location” means any change in the street and city address, or the site or place within the street and city address, for which a license or registration is issued.

(i) “Change in laboratory director” means any change in the laboratory director or directors to whom the current license or registration is issued.

(j) “Major change in laboratory directorship” means a change in laboratory director or directors resulting in the situation where less than 50 percent of the laboratory directors to whom the current laboratory license or registration is issued remain after the change.

(k) For purposes of this section, in the case of a pharmacy that applies for a registration pursuant to Section 1206.6, “laboratory director” means the pharmacist-in-charge identified pursuant to subdivision (a) of Section 1206.6.

(Amended by Stats. 2012, Ch. 874, Sec. 3. (SB 1481) Effective January 1, 2013.)

1211.5. For the purposes of this chapter, “cytological slides” shall refer to cellular materials submitted for preliminary cytologic examination.

(Added by Stats. 1989, Ch. 927, Sec. 1.5.)

1212. (a) As used in this chapter, “unlicensed laboratory personnel” means a laboratory aide, histocompatibility technician, cardiopulmonary technician, or other person performing the activities authorized by Section 1269.

(b) Any person who is authorized under California law or regulation to perform a clinical laboratory test or examination, or to engage in clinical laboratory practice, shall not come within the definition of “unlicensed laboratory personnel” when performing the clinical laboratory test or examination or engaging in the clinical laboratory practice authorized.

(Amended by Stats. 1995, Ch. 510, Sec. 13. Effective January 1, 1996.)

1213. As used in this chapter, “school” means any place, establishment, or institution organized and operated to offer training for one or more of the personnel classifications included in this chapter or the regulations pertaining thereto.

(Added by renumbering Section 1208 (as added by Stats. 1970, Ch. 1377) by Stats. 1971, Ch. 438.)

1214. As used in this chapter, “health fair” means a program of health assessment procedures offered to the general public that may include screening, self-ordered, or diagnostic clinical laboratory tests or examinations performed by a clinical laboratory licensed or registered under subdivision (a) of Section 1265 that meets all the requirements of this chapter.

(Added by Stats. 2004, Ch. 450, Sec. 2. Effective January 1, 2005.)