

Title 17. California Code of Regulations
Division 1. State Department of Health Services
Chapter 2. Laboratories
Subchapter 1. Service Laboratories
Group 2. Clinical Laboratory Regulations

ARTICLE 1. DEFINITIONS

(1) Amend section 1029 to read as follows:

Section 1029. General Definitions.

“Accreditation body” means an approved accreditation organization for laboratories, as defined in section 493.2 of title 42, Code of Federal Regulations.

“Accredited college or university” means an educational institution accredited by the Middle States Commission on Higher Education, the New England Association of Schools and Colleges Commission on Institutions of Higher Education, the North Central Association of Colleges and Schools Higher Learning Commission, the Northwest Commission on Colleges and Universities, the Southern Association of Colleges and Schools Commission on Colleges, the Western Association of Schools and Colleges Accrediting Commission for Community and Junior Colleges, or the Western Association of Schools and Colleges Senior Colleges and University Commission. A degree from a non-United States college or university that is not accredited by one of these accreditation associations shall be evaluated for comparability by a current member of the National Association of Credential Evaluation Services or endorsed member of the Association of International Credential Evaluators, Inc., or another organization approved by the Department.

“Accredited institution” has the same meaning as given in section 493.2 of title 42, Code of Federal Regulations.

“Accusation” means a written statement filed in order to initiate a hearing to determine whether a right, authority, license, or privilege should be revoked, suspended, limited, or conditioned, and which:

(a) Sets forth in ordinary and concise language the acts or omissions with which a person, entity, or laboratory and its owners or directors are charged with committing to the end that the person, entity, or laboratory and its owners or directors will be able to prepare a defense; and

(b) Specifies the statutes and regulations alleged to have been violated.

“Alternative sanction” means one or more of the following sanctions:

(a) Directed plan of correction;

(b) Civil money penalty; or

(c) Onsite monitoring.

“Antibody” means an immunoglobulin molecule that, due to its specific amino acid sequence, reacts to the antigen that induced its synthesis in the cells of the lymphoid series.

“Antigen” means any viral component including, but not limited to, proteins and nucleic acids.

“Approved public health laboratory” means a laboratory that has been issued a certificate of approval by the Department after its determination that the public health laboratory, as defined in Business and Professions Code section 1206(a)(11), is in conformity with chapter 7 (commencing with section 1000) of part 2 of division 1 of the Health and Safety Code and the regulations adopted thereunder.

“Arterial puncture” means the penetration of an artery with a needle to withdraw blood for clinical laboratory test or examination purposes.

“Certifying organization,” also called a national accreditation or accrediting board or agency, means an organization, agency, or body that creates competency

examinations that measure the skill, knowledge, and aptitude required of an individual a person in a profession, occupation, or discipline.

“Chapter 3” means chapter 3 (commencing with section 1200) of division 2 of the Business and Professions Code.

“Civil money penalties” means the civil money penalties imposed by the Department under the procedures identified in section 1067.5.

“CLIA” or “Clinical Laboratory Improvements Amendments” shall have the meaning as specified in section 1202.5 of the Business and Professions Code.

“CLIA certificate” means an unsuspended and unrevoked certificate of compliance, certificate for provider-performed microscopy procedures, certificate of accreditation, certificate of registration, or certificate of waiver, as defined in section 493.2 of title 42, Code of Federal Regulations.

“CLIA exempt status” means that the United States Department of Health and Human Services (HHS) has exempted clinical laboratories licensed, registered, or otherwise approved by the Department from the requirements of CLIA pursuant to subsection (p) of section 263a of title 42, United States Code and section 493.513 of title 42, Code of Federal Regulations.

“Clinical consultant” means a person who meets the requirements of section 493.1455 of title 42, Code of Federal Regulations, as published October 1, 1994, and who provides clinical consultation of a laboratory in accordance with section 1036 of this title and section 493.1457 of title 42, Code of Federal Regulations, as published October 1, 1994.

“Clinical cytogenetics” means the techniques used to isolate, replicate, and identify whole or parts of human chromosomes including culturing, manipulation, banding, staining, hybridizing, and analysis with respect to genotype and phenotype.

“Clinical laboratory practice” has the meaning set forth in section 1206(a)(7) of the Business and Professions Code. It shall include all activities that support clinical laboratory science, such as collecting and processing biological specimens, solving technical or instrument problems, providing general and technical supervision and consultation, reviewing quality control data, developing test methods, performing and reporting tests, and other activities defined in the work scope of the license category.

“Condition level deficiency” means noncompliance with one or more condition level requirements.

“Condition level requirement” means any of the requirements specified in section 1066.

“Department” means the California Department of Public Health.

“Deficiency” or “Violation” means noncompliance with one or more of the requirements in chapter 3, division 2 of the Business and Professions Code (commencing with section 1200) or any rule or regulation adopted thereunder.

“Direct and constant supervision,” as defined in section 1206 of the Business and Professions Code, 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.

“Direct and responsible supervision,” as defined in section 1206 of the Business and Professions Code, means both:

(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; and

(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.

“Direct patient care” means medical, psychiatric, nursing, or other health care which that is legally provided by a care giver or healthcare provider directly to a patient, and which that includes observation of the patient's physical or mental condition to enable the care giver or healthcare provider to report changes in the patient's condition.

“Direct supervision,” as defined in section 1269.3 of the Business and Professions Code, means that, for the purposes of section 1269.3, subdivision (b), a qualified pathologist shall be physically present onsite in the vicinity of the clinical laboratory where the specialty of pathology is performed and shall be available for consultation and direction during the time the personnel specified in subdivision (b) are engaged in the processing of specimens that involve dissection. For tissue processing that does not involve dissection, a qualified pathologist may be available by telephone or other electronic means.

“Directed plans of correction” means the directed plans of correction imposed by the Department under the procedures identified in section 1067.

“Electrolytes” means ionized calcium, sodium, potassium, and/or chloride.

“Evidence of satisfactory performance” means a copy of a document issued to an examinee by the Department for satisfactory performance on a Department-administered licensing examination, or by a certifying board or organization indicating satisfactory performance by the examinee on a written certifying examination approved by the Department for a license or certificate category.

“Field related to genetics” means a ~~major~~ in field of study such as biochemical genetics, biochemistry, biology, biomedical engineering, biotechnology, clinical cytogenetics and genomics, clinical genetics and genomics, clinical laboratory science, clinical molecular genetics and genomics, human genetics and genomics, medical genetics, molecular biology, molecular and cellular biology, molecular genetics and genomics, and reproductive biology; coursework may include such courses as biochemistry, bioinformatics, biology, cell biology, developmental biology, developmental genetics, evolutionary genetics, gene expression, gene mapping, genetic analysis, human genetics, inherited disease, inorganic chemistry, molecular genetics, organic chemistry, or population genetics.

“General supervisor” means a person who meets the requirements of section 493.1461 of title 42, Code of Federal Regulations, as published October 1, 1994, and who provides general supervision of a laboratory in accordance with section 1036.1 of this title and section 493.1463 of title 42, Code of Federal Regulations, as published October 1, 1994.

“HHS” means the federal Department of Health and Human Services, or its designee.

“High complexity tests or examinations” mean those clinical laboratory tests or examinations classified as high complexity under CLIA.

“Human Immunodeficiency Virus” or “HIV” means the etiologic virus of Acquired Immune Deficiency Syndrome, or AIDS.

“Immediate jeopardy” means a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more conditions has caused, or is likely to cause, serious injury or death to a person served by the laboratory or to the health or safety of the general public.

“Instrument” means a device, apparatus, implement, machine, or contrivance that is used for the performance of a clinical laboratory test or examination.

“Intermediate sanction” means either or both:

(a) Temporary suspension of a license, registration, or approval; or

(b) Temporary suspension of a provider of service under the Medi-Cal program.

“License,” for the purposes of this chapter, means license, certificate, registration, or other means to engage in a business or profession regulated by Chapter 3.

“Licensed general acute care hospital” means a facility as defined in section 1250(a) of the Health and Safety Code that has been licensed pursuant to chapter 2 (commencing with section 1250) of division 2 of the Health and Safety Code.

“Licensed surgical clinic” means a facility as defined in section 1204(b)(1) of the Health and Safety Code that has been licensed pursuant to chapter 1 (commencing with section 1200) of division 2 of the Health and Safety Code.

“Moderate complexity laboratory technical consultant” means a person who meets the qualifications of section 493.1411 of title 42, Code of Federal Regulations, as published October 1, 1994, and who provides technical oversight in accordance with

section 1036.2 of this title and section 493.1413 of title 42, Code of Federal Regulations, as published October 1, 1994.

“Moderate complexity tests or examinations” mean those clinical laboratory tests or examinations classified as moderate complexity under CLIA.

“Notice of Defense” means a document signed by or on behalf of the person, entity, or laboratory, that states the mailing address of the person, entity, or laboratory, and may:

(a) Request a hearing.

(b) Object to the accusation upon the ground that it does not state acts or omissions upon which the agency may proceed.

(c) Object to the form of the accusation on the ground that it is so indefinite or uncertain that the person, entity, or laboratory cannot identify the transaction or prepare a defense.

(d) Admit the accusation in whole or in part.

(e) Present new matter by way of defense.

(f) Object to the accusation upon the ground that, under the circumstances, compliance with the requirements of a regulation would result in material violation of another regulation enacted by another department affecting substantive rights.

“Official school transcript” means a copy of a student’s permanent academic record issued by a school, college, or university identifying the student and attesting to the student’s completion of specific courses with grades, credit hours, dates of attendance, academic major(s), degree or diploma granted, if any, including date of graduation, and any awards or honors. The hard copy official school transcript shall bear an official seal, unique identifier of the school, or signature of the registrar, dean, or other authorized official. An official transcript shall be received by the Department

(a) Directly from the school, college, or university registrar, dean, or other person responsible for issuing transcripts in a sealed envelope that bears a tamper-proof mark or seal attached by the school; or

(b) By secure electronic submission directly from the school, college, or university registrar, dean, or other person responsible for issuing transcripts.

“Onsite monitoring” means the onsite monitoring imposed by the Department under the procedures identified in section 1067.10.

“Oral and maxillofacial pathology laboratory director” means a dentist who possesses a valid, unexpired California license to direct an oral pathology laboratory in all areas of anatomic and clinical pathology related to the oral and maxillofacial region.

“Oral pathology” means the subspecialty of pathology that deals with the nature, identification, and management of diseases affecting the oral and maxillofacial regions, investigates the causes, processes, and effects of these diseases, and includes research and diagnosis of diseases using clinical, radiographic, microscopic, biochemical, or other examinations.

“Patient” means a person who is an inpatient or outpatient of a licensed health facility, licensed clinic, clinic that is exempt from licensure, or licensed home health agency, or a person who is under the care of a licensed physician and surgeon or osteopath, licensed dentist, or licensed podiatrist.

“Phlebotomist” means a person who collects blood for clinical laboratory tests or examination purposes.

“Phlebotomy” means the process of collecting blood by venipuncture, arterial puncture, or skin puncture for the purpose of obtaining blood for clinical laboratory test or examination purposes.

“Practical experience” means hands-on, direct work experience in clinical laboratory science and phlebotomy techniques on real patients in a clinical laboratory certified by CLIA, using equipment, instruments, kits, and materials routinely found in clinical laboratories performing moderate or high complexity tests or examinations, and does not include work done in academic, research, forensic, pharmaceutical, or veterinary laboratories.

“Preceptor” means:

(a) The laboratory director or the technical consultant of the laboratory, as that term is defined under CLIA; or

(b) A person who:

(1) Meets the qualifications of a technical consultant under CLIA and of Chapter 3 to perform clinical laboratory tests or examinations classified as moderate complexity; and

(2) Is assigned by the laboratory director or the technical consultant of the laboratory to act as a preceptor; or

(c) Any person listed in subdivision (b) of section 1206.5 of the Business and Professions Code, except for those persons listed in subsections (10), (11), or (12) of subdivision (b), and who:

(1) Has two years of experience performing moderate complexity tests upon the instrument(s) for which she or he will act as a preceptor; and

(2) Meets any CLIA requirements necessary to perform his or her duties and responsibilities in a preceptor program; and

(3) Is assigned by the laboratory director or the technical consultant of the laboratory to act as a preceptor.

“Principal sanction” means:

(a) Suspension or revocation of a registration or license issued under chapter 3 of division 2 of the Business and Professions Code; or

(b) Suspension or revocation of the approval to operate a public health laboratory granted under chapter 7 (commencing with section 1000) of the Health and Safety Code; or

(c) Suspension of a provider of service from further participation in, including reimbursement from, the Medi-Cal and Medicaid programs.

“Provider of service” has the same meaning as given in section 51051 of title 22 of the California Code of Regulations.

“Respiratory care practitioner” means a person licensed pursuant to chapter 8.3 (commencing with section 3700) of division 2 of the Business and Professions Code.

“Satisfactory performance” means achieving at least the minimum grade an examinee must obtain to receive a passing score on a written or oral examination.

“Skin puncture” means penetration of the skin for the purpose of collecting capillary blood for a clinical laboratory test or examination purposes.

“Specimen” has the same meaning as given for “biological specimen” in section 1206(a)(1) of the Business and Professions Code.

“State license” means the license identified in section 1265(a)(1) of the Business and Professions Code.

“State registration” or “registration” means the registration identified in section 1265(a)(2) of the Business and Professions Code.

“Statement of issues” means a written statement served on a person, entity, or laboratory that:

(a) Specifies the statutes and regulations with which the person, entity, or laboratory must show compliance by producing proof at the hearing, and

(b) Includes any particular matters that have come to the attention of the Department that could form the basis for a denial of the departmental action sought.

“Subspecialty of histocompatibility” means those clinical laboratory analyses of factors that determine the acceptance or rejection of grafted tissues or organs and that are performed in a histocompatibility laboratory as specified in section 493.1278 of title 42, Code of Federal Regulations, as published October 1, 1994.

“Technical supervisor” means a person who meets the qualifications of section 493.1449 of title 42, Code of Federal Regulations, as published October 1, 1994, and who provides technical supervision in accordance with section 1036.4 of this title and section 493.1451 of title 42, Code of Federal Regulations, as published October 1, 1994.

“Temporary suspension of a license, registration, or approval” means immediate suspension or limitation of a public health laboratory's approval to perform testing or a clinical laboratory's license or registration to perform tests or examinations in one or more, or all, specialties or subspecialties, prior to a hearing, based on a departmental finding of immediate jeopardy.

“Temporary suspension of a provider of service under the Medi-Cal program” means the immediate suspension imposed by the Department pursuant to section 51529(g) of title 22 of the California Code of Regulations under the procedures identified in section 1067.15.

“Test purposes,” as it relates to arterial puncture, venipuncture, and skin puncture, means withdrawal or injection of any test materials specifically required for a clinical laboratory test, provided that appropriate instructions relative to injection

technique have been given and that a licensed physician and surgeon is immediately available when test materials are injected. Unlicensed personnel may not inject test material for any purpose.

“Testing event” means the performance of the pre-analytical, analytical, and post-analytical activities related to performing a clinical laboratory test or examination on a biological specimen.

“Unprofessional conduct,” pursuant to the provisions of section 1320(m) of the Business and Professions Code, means:

(a) Acts of gross negligence in the performance of duties authorized by the license under chapter 3, division 2, Business and Professions Code;

(b) Acts of gross incompetence in the performance of duties authorized by the license under chapter 3, division 2, Business and Professions Code.

“Venipuncture” means the penetration of a vein with a needle to withdraw blood for clinical laboratory test or examination purposes.

“Waived laboratory technical supervisor,” also called “waived laboratory technical consultant,” means a person who meets the qualifications specified in section 1036.3(a) or (c) and provides technical oversight of a laboratory that performs only waived tests.

“Waived tests” mean those clinical laboratory tests or examinations classified as waived under CLIA.

Note: Authority cited: Sections 1208 and 1224, Business and Professions Code; Sections 100275 and 131200, Health and Safety Code; Stats. 1995, c. 510, Section 1; and Section 14105, Welfare and Institutions Code. Reference: Sections 23.7, 1202.5, 1203, 1204, 1205, 1206, 1206.5, 1207, 1208, 1209, 1209.1, 1210, 1212, 1213, 1220, 1222, 1222.5, 1223, 1224, 1225, 1227, 1241, 1242, 1242.5, 1242.6, 1243, 1244, 1246,

1246.5, 1260, 1260.1, 1260.3, 1261, 1261.5, 1262, 1263, 1264, 1265, 1267, 1269, 1269.3, 1269.5, 1270, 1275, 1280, 1281, 1282, 1285, 1286, 1288, 1288.5, 1289, 1300, 1301, 1301.1, 1310, 1320, 1322, 1323, 1324, 1325, and 1326, Business and Professions Code; 1002, 120580, 120775, 131050, 131051, and 131052, Health and Safety Code; 14123, Welfare and Institutions Code; 11503 and 11504, Government Code; Stats. 1995, c.510, Section 1; Stats. 1995, c. 510 (SB 113) Section 1(a)(6); 42 United States Code, Section 1395w-2 (Section 1846 of the federal Social Security Act); 42 United States Code, Section 1396a(a)(9) (Section 1902(a)(9)(C) of the federal Social Security Act).

(2) Renumber section 1029.5 to section 1029:

Section 1029.5. Accreditation Body. [Renumbered]

~~“Accreditation body” means an approved accreditation organization for laboratories, as defined in 42 Code of Federal Regulations, Section 493.2.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1223, 1265, 1281 and 1288.5, Business and Professions Code.

(3) Repeal section 1029.7 and renumber to section 1029:

Section 1029.7. Accredited College or University. [Renumbered]

~~“Accredited college or university” means an educational facility which has met the standards of the United States of America Accrediting Commission for Senior Colleges and Universities or the Accrediting Commission for Community and Junior Colleges; or, if a non-United States college or university, one that is evaluated and found equivalent by the American Association of Collegiate Registrars and Admissions Officers.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1260, 1261, 1261.5, 1263 and 1264, Business and Professions Code.

(4) Renumber section 1029.9 to section 1029:

Section 1029.9. Accredited Institution. [Renumbered]

~~“Accredited institution” has the same meaning as given in Title 42 of the Code of Federal Regulations, Section 493.2.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Section 120775, Health and Safety Code.

(5) Renumber section 1029.10 to section 1029:

Section 1029.10. Accusation. [Renumbered]

~~“Accusation” means a written statement filed in order to initiate a hearing to determine whether a right, authority, license, or privilege should be revoked, suspended, limited or conditioned, and which:~~

~~(a) Sets forth in ordinary and concise language the acts or omissions with which a person, entity, or laboratory and its owners or directors are charged with committing to the end that the person, entity or laboratory and its owners or directors will be able to prepare a defense; and~~

~~(b) Specifies the statutes and regulations alleged to have been violated.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1265, 1267, 1320, 1322 and 1326, Business and Professions Code; Section 11503, Government Code; and Section 14123, Welfare and Institutions Code.

(6) Renumber section 1029.15 to section 1029:

Section 1029.15. Alternative Sanction. [Renumbered]

~~“Alternative sanction” means one or more of the following sanctions:~~

~~(a) Directed plan of correction;~~

~~(b) Civil money penalty; or~~

~~(c) Onsite monitoring.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Stats. 1995, c.510, Section 1; and Section 1310, Business and Professions Code.

(7) Renumber section 1029.20 to section 1029:

Section 1029.20. Antibody. [Renumbered]

~~“Antibody” means an immunoglobulin molecule that, due to its specific amino acid sequence, reacts to the antigen that induced its synthesis in the cells of the lymphoid series.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Section 120775, Health and Safety Code.

(8) Renumber section 1029.25 to section 1029:

Section 1029.25. Antigen. [Renumbered]

~~“Antigen” means any viral component including, but not limited to, proteins and nucleic acids.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Section 120775, Health and Safety Code.

(9) Renumber section 1029.30 to section 1029:

Section 1029.30. Approved Public Health Laboratory. [Renumbered]

~~“Approved public health laboratory” means a laboratory that has been issued a certificate of approval by the department after its determination that the public health laboratory, as defined in Business and Professions Code section 1206(a)(11), is in conformity with chapter 7 (commencing with section 1000) of part 2 of division 1 of the Health and Safety Code and the regulations adopted thereunder.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1206, 1241 and 1288.5, Business and Professions Code.

(10) Renumber section 1029.31 to section 1029:

Section 1029.31. Arterial Puncture. [Renumbered]

~~“Arterial puncture” means the penetration of an artery with a needle to withdraw blood for clinical laboratory test or examination purposes.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1242, 1242.5, 1242.6, 1243, 1246 and 1269, Business and Professions Code; and Section 120580, Health and Safety Code.

(11) Renumber section 1029.34 to section 1029:

Section 1029.34. Certifying Organization. [Renumbered]

~~“Certifying organization”, also called a national accreditation or accrediting board or agency, means an organization, agency or body that creates competency examinations that measure the skill, knowledge and aptitude required of an individual in a profession, occupation or discipline.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1246, 1262, 1264 and 1270, Business and Professions Code; and Section 120580, Health and Safety Code.

(12) Renumber section 1029.35 to section 1029:

Section 1029.35. Chapter 3. [Renumbered]

~~“Chapter 3” means chapter 3 (commencing with section 1200) of division 2 of the Business and Professions Code.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Section 1224, Business and Professions Code.

(13) Renumber section 1029.40 to section 1029:

Section 1029.40. Civil Money Penalties. [Renumbered]

~~“Civil money penalties” means the civil money penalties imposed by the department under the procedures identified in section 1067.5.~~

Note: Authority cited: Section 1224, Business and Professions Code; Section 100275, Health and Safety Code; and Stats. 1995, c.510, Section 1. Reference: Section 1310, Business and Professions Code.

(14) Renumber section 1029.45 to section 1029:

Section 1029.45. CLIA Certificate. [Renumbered]

~~“CLIA certificate” means an unsuspended and unrevoked certificate of compliance, certificate for provider-performed microscopy procedures, certificate of accreditation, certificate of registration or a certificate of waiver, as defined in 42 Code of Federal Regulations section 493.2.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1224, 1265, 1281 and 1288.5, Business and Professions Code.

(15) Renumber section 1029.50 to section 1029:

Section 1029.50. CLIA Exempt Status. [Renumbered]

~~“CLIA exempt status” means that the United States Department of Health and Human Services (HHS) has exempted clinical laboratories licensed, registered or otherwise approved by the department from the requirements of CLIA pursuant to~~

~~subsection (p) of section 263a of title 42 of the United States Code and section 493.513 of title 42 of the Code of Federal Regulations.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Stats. 1995, c. 510 (SB 113) Section 1(a)(6).

(16) Renumber section 1029.51 to section 1029:

Section 1029.51. Clinical Consultant. [Renumbered]

~~“Clinical consultant” means a person who meets the requirements of Section 493.1455 of Title 42, Code of Federal Regulations, as published October 1, 1994, and who provides clinical consultation of a laboratory in accordance with Section 1036 of this title and Section 493.1457 of Title 42, Code of Federal Regulations, as published October 1, 1994.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1203, 1204, 1207, 1209, 1209.1 and 1210, Business and Professions Code.

(17) Renumber section 1029.52 to section 1029:

Section 1029.52. Clinical Cytogenetics. [Renumbered]

~~“Clinical cytogenetics” means the techniques used to isolate, replicate and identify whole or parts of human chromosomes including culturing, manipulation, banding, staining and hybridizing, and analysis with respect to genotype and phenotype.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1206, 1207, 1210, 1261.5 and 1264, Business and Professions Code.

(18) Renumber section 1029.55 to section 1029:

Section 1029.55. Condition Level Deficiency. [Renumbered]

~~“Condition level deficiency” means noncompliance with one or more condition level requirements.~~

Note: Authority cited: Section 1224, Business and Professions Code; Section 100275, Health and Safety Code; and Stats. 1995, c. 510, Section 1. Reference: Stats. 1995, c. 510, Section 1; and Section 1310, Business and Professions Code.

(19) Renumber section 1029.60 to section 1029:

Section 1029.60. Condition Level Requirement. [Renumbered]

~~“Condition level requirement” means any of the requirements specified in section 4066.~~

Note: Authority cited: Section 1224, Business and Professions Code; Section 100275, Health and Safety Code; and Stats. 1995, c. 510, Section 1. Reference: Stats. 1995, c. 510, Section 1; and Section 1310, Business and Professions Code.

(20) Renumber section 1029.65 to section 1029:

Section 1029.65. Deficiency. [Renumbered]

~~“Deficiency” or “Violation” means noncompliance with one or more of the requirements in chapter 3, division 2 of the Business and Professions Code (commencing with section 1200) or any rule or regulation adopted thereunder.~~

Note: Authority cited: Section 1224, Business and Professions Code; Section 100275, Health and Safety Code; and Stats. 1995, c. 510, Section 1. Reference: Stats. 1995, c. 510, Section 1; and Sections 1310, 1320, 1323 and 1326, Business and Professions Code.

(21) Renumber section 1029.70 to section 1029:

Section 1029.70. Direct Patient Care. [Renumbered]

~~“Direct patient care” means medical, psychiatric, nursing or other health care which is legally provided by a care giver or healthcare provider directly to a patient, and which includes observation of the patient's physical or mental condition to enable the care giver or healthcare provider to report changes in the patient's condition.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Section 1206.5, Business and Professions Code.

(22) Renumber section 1029.75 to section 1029:

Section 1029.75. Directed Plans of Correction. [Renumbered]

~~“Directed plans of correction” means the directed plans of correction imposed by the department under the procedures identified in section 1067.~~

Note: Authority cited: Section 1224, Business and Professions Code; Section 100275, Health and Safety Code; and Stats. 1995, c. 510, Section 1. Reference: Stats. 1995, c. 510, Section 1; and Section 1310, Business and Professions Code.

(23) Renumber section 1029.80 to section 1029:

Section 1029.80. Electrolytes. [Renumbered]

~~“Electrolytes” means ionized calcium, sodium, potassium and/or chloride.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Section 1206, Business and Professions Code.

(24) Renumber section 1029.81 to section 1029:

Section 1029.81. Evidence of Satisfactory Performance. [Renumbered]

~~“Evidence of satisfactory performance” means a copy of a document issued to an examinee by the department for satisfactory performance on a department-administered licensing written examination, or by a certifying board or organization indicating satisfactory performance by the examinee on a written certifying examination.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1208, 1260, 1261, 1261.5, 1262 and 1264, Business and Professions Code.

(25) Renumber section 1029.82 to section 1029

Section 1029.82. Field Related to Genetics.

~~“Field related to genetics” means a major in molecular biology, reproductive biology, biochemistry, clinical genetics, medical genetics, clinical cytogenetics, biochemical genetics, human genetics, clinical laboratory science, or clinical molecular genetics.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1206 and 1210, Business and Professions Code.

(26) Renumber section 1029.83 to section 1029:

Section 1029.83. General Supervisor. [Renumbered]

~~“General supervisor” means a person who meets the requirements of Section 493.1461 of Title 42, Code of Federal Regulations, as published October 1, 1994, and who provides general supervision of a laboratory in accordance with Section 1036.1 of this title and Section 493.1463 of Title 42, Code of Federal Regulations, as published October 1, 1994.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1203, 1204, 1207, 1209, 1209.1 and 1210, Business and Professions Code.

(27) Renumber section 1029.85 to section 1029:

Section 1029.85. HHS. [Renumbered]

~~“HHS” means the federal Department of Health and Human Services, or its designee.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1202.5 and 1224, Business and Professions Code.

(28) Renumber section 1029.86 to section 1029:

Section 1029.86. High Complexity Tests or Examinations. [Renumbered]

~~“High complexity tests or examinations” mean those clinical laboratory tests or examinations classified as high complexity under CLIA.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1202.5, 1203, 1204, 1206, 1206.5, 1207, 1209.1, 1210 and 1265, Business and Professions Code.

(29) Renumber section 1029.90 to section 1029:

Section 1029.90. Human Immunodeficiency Virus. [Renumbered]

~~“Human Immunodeficiency Virus” or “HIV” means the etiologic virus of Acquired Immune Deficiency Syndrome, or AIDS.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Section 120775, Health and Safety Code.

(30) Renumber section 1029.95 to section 1029:

Section 1029.95. Immediate Jeopardy. [Renumbered]

~~“Immediate jeopardy” means a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more conditions has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health.~~

Note: Authority cited: Section 1224, Business and Professions Code; Section 100275, Health and Safety Code; Stats. 1995, c. 510, Section 1; and Section 14105, Welfare and Institutions Code. Reference: Stats. 1995, c. 510, Section 1; and Sections 1310, 1320, 1323 and 1326, Business and Professions Code; and Section 14123, Welfare and Institutions Code.

(31) Renumber section 1029.100 to section 1029:

Section 1029.100. Instrument. [Renumbered]

~~“Instrument” means a device, apparatus, implement, machine, or contrivance that is used for the performance of a clinical laboratory test or examination,~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1206, 1206.5, 1209 and 1269, Business and Professions Code.

(32) Renumber section 1029.105 to section 1029:

Section 1029.105. Intermediate Sanction. [Renumbered]

~~“Intermediate sanction” means either or both:~~

~~(a) Temporary suspension of a license, registration or approval; or~~

~~(b) Temporary suspension of a provider of service under the Medi-Cal program.~~

Note: Authority cited: Section 1224, Business and Professions Code; Section 100275, Health and Safety Code; and Section 14105, Welfare and Institutions Code. Reference: Stats. 1995, c. 510, Section 1; and Section 1323, Business and Professions Code; Section 1002, Health and Safety Code; Section 14123, Welfare and Institutions Code; 42 United States Code, Section 1395w-2 (Section 1846 of the federal Social Security Act); and 42 United States Code, Section 1396a(a)(9) (Section 1902(a)(9)(C) of the federal Social Security Act).

(33) Renumber section 1029.108 to section 1029:

Section 1029.108. License. [Renumbered]

~~For the purposes of this chapter, "license" means license, certificate, registration or other means to engage in a business or profession regulated by Chapter 3.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 23.7, 1203, 1204, 1205, 1206.5, 1207, 1208, 1209, 1210, 1220, 1227, 1242, 1246, 1246.5, 1260, 1260.1, 1261, 1261.5, 1262, 1263, 1264, 1265, 1267, 1269.5, 1270, 1275, 1280, 1281, 1285, 1288.5, 1300, 1301, 1301.1, 1310, 1320, 1322, 1323, 1324 and 1325, Business and Professions Code; and Section 120580, Health and Safety Code.

(34) Renumber section 1029.110 to section 1029:

Section 1029.110. Licensed General Acute Care Hospital. [Renumbered]

~~"Licensed general acute care hospital" means a facility as defined in section 1250(a) of the Health and Safety Code that has been licensed pursuant to chapter 2 (commencing with section 1250) of division 2 of the Health and Safety Code.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1224 and 1265, Business and Professions Code.

(35) Renumber section 1029.115 to section 1029:

Section 1029.115. Licensed Surgical Clinic. [Renumbered]

~~“Licensed surgical clinic” means a facility as defined in section 1204(b)(1) of the Health and Safety Code that has been licensed pursuant to chapter 1 (commencing with section 1200) of division 2 of the Health and Safety Code.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1224 and 1265, Business and Professions Code.

(36) Renumber section 1029.118 to section 1029:

Section 1029.118. Moderate Complexity Laboratory Technical Consultant. [Renumbered]

~~“Moderate complexity laboratory technical consultant” means a person who meets the qualifications of Section 493.1411 of Title 42, Code of Federal Regulations, as published October 1, 1994, and who provides technical oversight in accordance with Section 1036.2 of this title and Section 493.1413 of Title 42, Code of Federal Regulations, as published October 1, 1994.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1203, 1204, 1207, 1209, 1209.1 and 1210, Business and Professions Code.

(37) Renumber section 1029.119 to section 1029:

Section 1029.119. Moderate Complexity Tests or Examinations. [Renumbered]

~~“Moderate complexity tests or examinations” mean those clinical laboratory tests or examinations classified as moderate complexity under CLIA.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1202.5, 1203, 1204, 1206, 1206.5, 1207, 1209.1, 1210 and 1265, Business and Professions Code.

(38) Renumber section 1029.120 to section 1029:

Section 1029.120. Notice of Defense. [Renumbered]

~~“Notice of Defense” means a writing signed by or on behalf of the person, entity or laboratory, stating the mailing address of the person, entity, or laboratory, and may:~~

~~(a) Request a hearing.~~

~~(b) Object to the accusation upon the ground that it does not state acts or omissions upon which the agency may proceed.~~

~~(c) Object to the form of the accusation on the ground that it is so indefinite or uncertain that the person, entity, or laboratory cannot identify the transaction or prepare a defense.~~

~~(d) Admit the accusation in whole or in part.~~

~~(e) Present new matter by way of defense.~~

~~(f) Object to the accusation upon the ground that, under the circumstances, compliance with the requirements of a regulation would result in material violation of another regulation enacted by another department affecting substantive rights.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1265, 1267, 1320, 1322 and 1326, Business and Professions Code; Sections 11503 and 11504, Government Code; and Section 14123, Welfare and Institutions Code.

(39) Renumber section 1029.125 to section 1029:

Section 1029.125. Onsite Monitoring. [Renumbered]

~~“Onsite monitoring” means the onsite monitoring imposed by the department under the procedures identified in section 1067.10.~~

Note: Authority cited: Section 1224, Business and Professions Code; Section 100275, Health and Safety Code; and Stats. 1995, c. 510, Section 1. Reference: Stats. 1995, c. 510, Section 1; and Section 1310, Business and Professions Code.

(40) Renumber section 1029.126 to section 1029:

Section 1029.126. Oral and Maxillofacial Pathology Laboratory Director.

[Renumbered]

~~“Oral and maxillofacial pathology laboratory director” means a dentist who possesses a valid, unexpired license to direct an oral pathology laboratory in all areas of anatomic and clinical pathology related to the oral and maxillofacial region.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1206, 1206.5, 1207, 1208 and 1209, Business and Professions Code.

(41) Renumber section 1029.127 to section 1029:

Section 1029.127. Oral Pathology. [Renumbered]

~~“Oral pathology” means the subspecialty of pathology that deals with the nature, identification and management of diseases affecting the oral and maxillofacial regions, which investigates the causes, processes and effects of these diseases, and includes research and diagnosis of diseases using clinical, radiographic, microscopic, biochemical or other examinations.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1206 and 1207, Business and Professions Code.

(42) Renumber section 1029.130 to section 1029:

Section 1029.130. Patient. [Renumbered]

~~“Patient” means a person who is an inpatient or outpatient of a licensed health facility, licensed clinic or a clinic that is exempt from licensure, licensed home health agency, or who is a patient of a licensed physician and surgeon or osteopath, licensed dentist, or licensed podiatrist.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1206, 1206.5, 1209, 1220, 1241 and 1269, Business and Professions Code.

(43) Renumber section 1029.132 to section 1029:

Section 1029.132. Phlebotomist. [Renumbered]

~~“Phlebotomist” means a person who collects blood for clinical laboratory test or examination purposes.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1206, 1208, 1212, 1242, 1242.5, 1246 and 1269, Business and Professions Code; and Section 120580, Health and Safety Code.

(44) Renumber section 1029.133 to section 1029:

Section 1029.133. Phlebotomy. [Renumbered]

~~“Phlebotomy” means the process of collecting blood by venipuncture, arterial puncture or skin puncture for the purpose of obtaining blood for clinical laboratory test or examination purposes.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1206, 1242, 1242.5, 1246 and 1269, Business and Professions Code; and Section 120580, Health and Safety Code.

(45) Renumber section 1029.134 to section 1029:

Section 1029.134. Practical Experience. [Renumbered]

~~“Practical experience” means hands-on, direct work experience in clinical laboratory science and phlebotomy techniques on real patients in a clinical laboratory certified by CLIA, using equipment, instruments, kits and materials routinely found in clinical laboratories performing moderate or high complexity tests or examinations, and does not include work done in academic, research, forensic, pharmaceutical or veterinary laboratories.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1206, 1208, 1222.5, 1242, 1242.5, 1243, 1246, 1260, 1260.3, 1261, 1261.5, 1264, 1269 and 1286, Business and Professions Code.

(46) Renumber section 1029.135 to section 1029:

Section 1029.135. Preceptor. [Renumbered]

~~“Preceptor” means:~~

~~(a) The laboratory director or the technical consultant of the laboratory, as that term is defined under CLIA; or,~~

~~(b) A person who:~~

~~(1) Meets the qualifications of a technical consultant under CLIA and of chapter 3 to perform clinical laboratory tests or examinations classified as of moderate complexity; and,~~

~~(2) Is assigned by the laboratory director or the technical consultant of the laboratory to act as a preceptor; or,~~

~~(c) Any person listed in subdivision (b) of section 1206.5 of the Business and Professions Code, except for those persons listed in subsections (10), (11), or (12) of subdivision (b), and who:~~

~~(1) Has two years of experience performing moderate complexity tests upon the instrument(s) for which she or he will act as a preceptor; and~~

~~(2) Meets any CLIA requirements necessary to perform his or her duties and responsibilities in a preceptor program; and~~

~~(3) Is assigned by the laboratory director or the technical consultant of the laboratory to act as a preceptor.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1206, 1206.5, 1209, 1220 and 1265, Business and Professions Code.

(47) Renumber section 1029.140 to section 1029:

Section 1029.140. Principal Sanction. [Renumbered]

~~“Principal sanction” means:~~

~~(a) Suspension or revocation of a registration or license issued under chapter 3 of division 2 of the Business and Professions Code; or~~

~~(b) Suspension or revocation of the approval to operate a public health laboratory granted under chapter 7 (commencing with section 1000) of the Health and Safety Code; or~~

~~(c) Suspension of a provider of service from further participation in, including reimbursement from, the Medi-Cal and Medicaid programs.~~

Note: Authority cited: Section 1224, Business and Professions Code; Section 100275, Health and Safety Code; Stats. 1995, c. 510, Section 1; and Section 14105, Welfare and Institutions Code. Reference: Stats. 1995, c. 510, Section 1; Sections 1320 and 1322, Business and Professions Code; Section 1002, Health and Safety Code; and Section 14123, Welfare and Institutions Code.

(48) Renumber section 1029.145 to section 1029:

Section 1029.145. Provider of Service. [Renumbered]

~~“Provider of service” has the same meaning as given in 22 CCR 51051.~~

Note: Authority cited: Section 1224, Business and Professions Code; Section 100275, Health and Safety Code; Stats. 1995, c. 510, Section 1; and Section 14105, Welfare and Institutions Code. Reference: Stats. 1995, c. 510, Section 1; and Section 14123, Welfare and Institutions Code.

(49) Renumber section 1029.150 to section 1029:

Section 1029.150. Respiratory Care Practitioner. [Renumbered]

~~“Respiratory care practitioner” means an individual licensed pursuant to chapter 8.3 (commencing with section 3700) of division 2 of the Business and Professions Code.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1206.5 and 1265, Business and Professions Code.

(50) Renumber section 1029.153 to section 1029:

Section 1029.153. Satisfactory Performance. [Renumbered]

~~“Satisfactory performance” means achieving at least the minimum grade that an examinee must obtain to get a passing score on a written or oral examination.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1208, 1260, 1261, 1261.5, 1262 and 1264, Business and Professions Code.

(51) Renumber section 1029.154 to section 1029:

Section 1029.154. Skin Puncture. [Renumbered]

~~“Skin puncture” means penetration of the skin for the purpose of collecting capillary blood for clinical laboratory test or examination purposes.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1206, 1242, 1242.5, 1246 and 1269, Business and Professions Code; and Section 120580, Health and Safety Code.

(52) Renumber section 1029.155 to section 1029:

Section 1029.155. Specimen. [Renumbered]

~~“Specimen” has the same meaning as given for “biological specimen” in section 1206(a)(1) of the Business and Professions Code.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1206, 1209, 1225, 1241, 1244, 1269, 1288, 1288.5 and 1320, Business and Professions Code.

(53) Renumber section 1029.160 to section 1029:

Section 1029.160. State License. [Renumbered]

~~“State license” or “license” means the license identified in section 1265(a)(1) of the Business and Professions Code.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1265, 1281 and 1288.5, Business and Professions Code.

(54) Renumber section 1029.165 to section 1029:

Section 1029.165. State Registration. [Renumbered]

~~“State registration” or “registration” means the registration identified in section 1265(a)(2) of the Business and Professions Code.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1265, 1281 and 1288.5, Business and Professions Code.

(55) Renumber section 1029.168 to section 1029:

Section 1029.168. Statement of Issues. [Renumbered]

~~“Statement of issues” means a written statement served on the person, entity or laboratory which:~~

~~(a) Specifies the statutes and regulations with which the person, entity or laboratory must show compliance by producing proof at the hearing, and~~

~~(b) Includes any particular matters which have come to the attention of the department that could form the basis for a denial of the departmental action sought.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1265, 1267, 1320, 1322 and 1326, Business and Professions Code; Sections 11503 and 11504, Government Code; and Section 14123, Welfare and Institutions Code.

(56) Renumber section 1029.169 to section 1029:

Section 1029.169. Subspecialty of Histocompatibility. [Renumbered]

~~“Subspecialty of histocompatibility” means those clinical laboratory analyses of factors that determine the acceptance or rejection of grafted tissues or organs and that are performed in a histocompatibility laboratory as specified in Section 493.1265 of Title 42, Code of Federal Regulations, as published October 1, 1994.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1206, 1209.1 and 1210, Business and Professions Code.

(57) Renumber section 1029.171 to section 1029:

Section 1029.171. Technical Supervisor. [Renumbered]

~~“Technical supervisor” means a person who meets the qualifications of Section 493.1449 of Title 42, Code of Federal Regulations, as published October 1, 1994, and who provides technical supervision in accordance with Section 1036.4 of this title and~~

~~Section 493.1451 of Title 42, Code of Federal Regulations, as published October 1, 1994.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1203, 1204, 1207, 1209, 1209.1 and 1210, Business and Professions Code.

(58) Renumber section 1029.173 to section 1029:

Section 1029.173. Temporary Suspension of a License, Registration or Approval. [Renumbered]

~~“Temporary suspension of a license, registration or approval” means immediate suspension or limitation of a public health laboratory's approval to perform testing or a clinical laboratory's license or registration to perform tests or examinations in one or more, or all, specialties or subspecialties, prior to a hearing, based on a departmental finding of immediate jeopardy.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Sections 1002 and 100275, Health and Safety Code. Reference: Stats. 1995, c. 510, Section 1; Section 1323, Business and Professions Code; and Section 1002, Health and Safety Code.

(59) Renumber section 1029.175 to section 1029:

Section 1029.175. Temporary Suspension of a Provider of Service Under the Medi-Cal Program. [Renumbered]

~~“Temporary suspension of a provider of service under the Medi-Cal program” means the immediate suspension imposed by the department pursuant to 22 CCR 51529(g) under the procedures identified in section 1067.15.~~

Note: Authority cited: Section 1224, Business and Professions Code; Section 100275, Health and Safety Code; and Section 14105, Welfare and Institutions Code. Reference:

Stats. 1995, c. 510, Section 1; Section 14123, Welfare and Institutions Code; 42 United States Code; Section 1395w-2 (Section 1846 of the federal Social Security Act); and 42 United States Code, Section 1396a(a)(9) (Section 1902(a)(9)(C) of the federal Social Security Act).

(60) Renumber section 1029.180 to section 1029:

Section 1029.180. Test Purposes. [Renumbered]

~~“Test purposes,” as it relates to arterial puncture, venipuncture, and skin puncture, means withdrawal, or injection of any test materials specifically required for a clinical laboratory test, provided that appropriate instructions relative to injection technique have been given and that a licensed physician and surgeon is immediately available when test materials are injected. Unlicensed personnel may not inject test material for any purpose.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1206, 1242, 1242.5, 1242.6 and 1246, Business and Professions Code.

(61) Renumber section 1029.185 to section 1029:

Section 1029.185. Testing Event. [Renumbered]

~~“Testing event” means the performance of the preanalytical, analytical, and postanalytical activities related to performing a clinical laboratory test or examination on a biological specimen.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1206, 1206.5, 1209, 1220, 1241, 1244, 1265, 1281, 1288.5, and 1300, Business and Professions Code.

(62) Renumber section 1029.190 to section 1029:

Section 1029.190. Unprofessional Conduct. [Renumbered]

~~“Unprofessional conduct,” pursuant to the provisions of Section 1320(m), Business and Professions Code, means:~~

~~(a) Acts of gross negligence in the performance of duties authorized by the license under chapter 3, division 2, Business and Professions Code.~~

~~(b) Acts of gross incompetence in the performance of duties authorized by the license under chapter 3, division 2, Business and Professions Code.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Section 1320, Business and Professions Code.

(63) Renumber section 1029.195 to section 1029:

Section 1029.195. Venipuncture. [Renumbered]

~~“Venipuncture” means the penetration of a vein with a needle to withdraw blood for clinical laboratory test or examination purposes.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1206, 1242, 1242.5, 1246, and 1269, Business and Professions Code; and Section 120580, Health and Safety Code.

(64) Renumber section 1029.196 to section 1029:

Section 1029.196. Waived Laboratory Supervisor. [Renumbered]

~~“Waived laboratory technical consultant” means a person who meets the qualifications specified in Section 1036.3(a) or (c) and provides technical oversight of a laboratory only performing waived tests.~~

Note: Authority cited: Sections 1208 and 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1203, 1204, 1207, 1208, 1209, 1209.1, and 1210, Business and Professions Code.

(65) Renumber section 1029.197 to section 1029:

Section 1029.197. Waived Tests. [Renumbered]

~~“Waived tests” mean those clinical laboratory tests or examinations classified as waived under CLIA.~~

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1202.5, 1203, 1204, 1206, 1206.5, 1207, 1209.1, 1210 and 1265, Business and Professions Code.

**ARTICLE 5.3. BLOOD ELECTROLYTE ANALYSIS BY RESPIRATORY CARE
PRACTITIONERS**

(66) Repeal Article 5.3 as follows:

**~~ARTICLE 5.3. BLOOD ELECTROLYTE ANALYSIS BY RESPIRATORY CARE
PRACTITIONERS.~~**

(67) Repeal section 1054.1 as follows:

Section 1054.1. Conditions for Performance.

~~(a) A Respiratory Care Practitioner may engage in clinical laboratory practice by performing a blood electrolyte analysis when all of the following conditions are met:~~

~~(1) The blood electrolyte analysis is performed on an instrument which is designed to perform both blood gas analysis and blood electrolyte analysis simultaneously or concurrently and from the same blood specimen;~~

~~(2) The blood electrolyte analysis is performed in a licensed laboratory that:~~

~~(A) is within a licensed surgical clinic or a licensed general acute care hospital;~~

~~(B) has a CLIA certificate to perform blood gas analysis and blood electrolyte analysis; and~~

~~(C) has established and maintains protocols for the performance and reporting of blood gas analysis and blood electrolyte analysis simultaneously or concurrently from the same blood specimen by Respiratory Care Practitioners;~~

~~(3) The blood electrolyte analysis is performed:~~

~~(A) under the overall operation and administration of the laboratory director, as required in Section 1029 of the Business and Professions Code; and~~

~~(B) in conformity with the protocols required in (2)(C), above; and~~

~~(C) in conformity with the manufacturer's instructions.~~

~~(4) The Respiratory Care Practitioner:~~

~~(A) has been trained in accordance with Section 1054.2; and,~~

~~(B) performs and reports simultaneous or concurrent blood gas analysis and blood electrolyte analysis in compliance with the requirements in (3), above; and~~

~~(C) meets CLIA testing personnel qualifications for the type and complexity of tests being performed.~~

Note: Authority cited: Section 1224, Business and Professions Code. Reference: Sections 1206, 1220, 1265, 1282, and 1285, Business and Professions Code.

(68) Repeal section 1054.2 as follows:

Section 1054.2. Training.

~~(a) Prior to performing a blood electrolyte analysis, a Respiratory Care Practitioner shall have completed the following training:~~

~~(1) instruction 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 the tests being performed, in:~~

~~(A) the operation of each instrument to be used for simultaneous or concurrent blood gas analysis and blood electrolyte analysis by the Respiratory Care Practitioner, including the following:~~

- ~~1. Equipment maintenance and calibration;~~
- ~~2. Method performance including the normal ranges and critical values for each test protocol;~~
- ~~3. Quality Control and Assurance requirements including remedial action and reagent and specimen handling and integrity; and,~~
- ~~4. Clinical significance of test results and clinical applications for simultaneous or concurrent blood gas analysis and blood electrolyte analysis.~~

Note: Authority cited: Section 1224, Business and Professions Code. Reference: Section 1209, 1220, and 1265, Business and Professions Code.