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 Clinical Laboratory Technology [1200 - 1327] *(Chapter 3 repealed and added by Stats. 1951, Ch. 1727.)*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 3. Application of the Chapter [1240 - 1246.7] *(Article 3 added by Stats. 1951, Ch. 1727.)*

1240. This chapter does not authorize any person to practice medicine and surgery or to furnish the services of physicians for the practice of medicine and surgery. This chapter does not repeal or in any manner affect any provision of this code relating to the practice of medicine. This chapter does not prohibit the performance of tests not covered in Section 1206.

(Amended by Stats. 1970, Ch. 1377.)

1241. (a) This chapter applies to all clinical laboratories in California or receiving biological specimens originating in California for the purpose of performing a clinical laboratory test or examination, and to all persons performing clinical laboratory tests or examinations or engaging in clinical laboratory practice in California or on biological specimens originating in California, except as provided in subdivision (b).

(b) This chapter shall not apply to any of the following clinical laboratories, or to persons performing clinical laboratory tests or examinations in any of the following clinical laboratories:

(1) Those owned and operated by the United States of America, or any department, agency, or official thereof acting in his or her official capacity to the extent that the Secretary of the federal Department of Health and Human Services has modified the application of CLIA requirements to those laboratories.

(2) Public health laboratories, as defined in Section 1206.

(3) Those that perform clinical laboratory tests or examinations for forensic purposes only.

(4) Those that perform clinical laboratory tests or examinations for research and teaching purposes only and do not report or use patient-specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or for the assessment of the health of, an individual.

(5) Those that perform clinical laboratory tests or examinations certified by the National Institutes on Drug Abuse only for those certified tests or examinations. However, all other clinical laboratory tests or examinations conducted by the laboratory are subject to this chapter.

(6) Those that register with the State Department of Health Care Services pursuant to subdivision (c) to perform blood glucose testing for the purposes of monitoring a minor child diagnosed with diabetes if the person performing the test has been entrusted with the care and control of the child by the child's parent or legal guardian and provided that all of the following occur:

(A) The blood glucose monitoring test is performed with a blood glucose monitoring instrument that has been approved by the federal Food and Drug Administration for sale over the counter to the public without a prescription.

(B) The person has been provided written instructions by the child's health care provider or an agent of the child's health care provider in accordance with the manufacturer's instructions on the proper use of the monitoring instrument and the handling of any lancets, test strips, cotton balls, or other items used during the process of conducting a blood glucose test.

(C) The person, receiving written authorization from the minor's parent or legal guardian, complies with written instructions from the child's health care provider, or an agent of the child's health care provider, regarding the performance of the test and

the operation of the blood glucose monitoring instrument, including how to determine if the results are within the normal or therapeutic range for the child, and any restriction on activities or diet that may be necessary.

(D) The person complies with specific written instructions from the child's health care provider or an agent of the child's health care provider regarding the identification of symptoms of hypoglycemia or hyperglycemia, and actions to be taken when results are not within the normal or therapeutic range for the child. The instructions shall also contain the telephone number of the child's health care provider and the telephone number of the child's parent or legal guardian.

(E) The person records the results of the blood glucose tests and provides them to the child's parent or legal guardian on a daily basis.

(F) The person complies with universal precautions when performing the testing and posts a list of the universal precautions in a prominent place within the proximity where the test is conducted.

(7) Those individuals who perform clinical laboratory tests or examinations, 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, on their own bodies or on their minor children or legal wards.

(8) Those certified emergency medical technicians and licensed paramedics providing basic life support services or advanced life support services as defined in Section 1797.52 of the Health and Safety Code who perform only blood glucose tests that are classified as waived clinical laboratory tests under CLIA, if the provider of those services obtains a valid certificate of waiver and complies with all other requirements for the performance of waived clinical laboratory tests under applicable federal regulations.

(9) Those doctors of chiropractic listed on the most current federal Department of Transportation National Registry of Certified Medical Examiners that perform urine specific gravity, urine protein, urine blood, and urine sugar tests as those tests relate to the National Registry of Certified Medical Examiners, as adopted by the United States Department of Transportation, as published by the notice in the Federal Register, Volume 77, Number 77, Friday, April 20, 2012, on pages 24104 to 24135, inclusive, and pursuant to Section 391.42 of Title 49 of the Code of Federal Regulations, that are classified as waived clinical laboratory tests under CLIA for the sole purpose of completing the Department of Motor Vehicles Medical Examination Report, if the doctor of chiropractic obtains a valid certificate of waiver and complies with all other requirements for the performance of waived clinical laboratory tests under applicable federal regulations. If a doctor of chiropractic receives an abnormal finding, the doctor of chiropractic shall refer the applicant to the applicant's primary care physician.

(c) Any place where blood glucose testing is performed pursuant to paragraph (6) of subdivision (b) shall register by notifying the State Department of Health Care Services in writing no later than 30 days after testing has commenced. Registrants pursuant to this subdivision shall not be required to pay any registration or renewal fees nor shall they be subject to routine inspection by the State Department of Health Care Services.

(Amended by Stats. 2014, Ch. 269, Sec. 1. (AB 2143) Effective August 22, 2014.)

1241.1. (a) A primary care clinic, licensed pursuant to subdivision (a) of Section 1204 of the Health and Safety Code, that is operating within a network of primary care clinics, may be issued a license to operate a clinical laboratory pursuant to Section 1265, which authorizes the conduct of clinical laboratory tests and examinations from its network of primary care clinics, if all of the following conditions are met:

(1) The central laboratory's sole purpose is performing moderate or high complexity clinical laboratory tests and examinations, or both, for the patients of the clinics in the network.

(2) Prior to performing any tests or examinations, the central laboratory obtains a certificate under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) (CLIA) and a state laboratory license for the appropriate complexity level of clinical laboratory testing pursuant to Section 1265.

(b) For purposes of this section, "network of primary care clinics" means two or more primary care clinics operated by the same nonprofit corporation with the same board of directors and the same corporate officers, and operating under the same procedures and protocols.

(Added by Stats. 2006, Ch. 795, Sec. 1. Effective January 1, 2007.)

1242. Any person duly licensed under the provisions of this chapter to perform tests called for in a clinical laboratory may perform skin tests for specific diseases, arterial puncture, venipuncture, or skin puncture for purposes of withdrawing blood or for clinical laboratory test purposes as defined by regulations established by the department and upon specific authorization from any person in accordance with the authority granted under any provisions of law relating to the healing arts.

(Amended by Stats. 1999, Ch. 695, Sec. 1. Effective January 1, 2000.)

1242.5. Notwithstanding paragraphs (2) and (3) of subdivision (b) of Section 1241, the department may by regulation authorize laboratory personnel certified pursuant to Section 1246 to perform venipuncture, arterial puncture, or skin puncture for the purposes of withdrawing blood or for clinical laboratory test purposes, as defined by regulations established by the department.

(Amended by Stats. 1999, Ch. 695, Sec. 2. Effective January 1, 2000.)

1242.6. (a) Any registered nurse licensed under the provisions of Chapter 6 (commencing with Section 2700) of Division 2 may perform arterial puncture, venipuncture, or skin puncture for the purposes of withdrawing blood or for test purposes upon authorization from any licensed physician and surgeon or any licensed dentist.

(b) Any licensed vocational nurse licensed under the provisions of Chapter 6.5 (commencing with Section 2840) of Division 2 may perform arterial puncture, venipuncture, or skin puncture for the purposes of withdrawing blood or for test purposes upon authorization from any licensed physician and surgeon, or any licensed dentist if prior thereto the licensed vocational nurse has been instructed by a physician and surgeon and has demonstrated competence to the physician and surgeon in the proper procedure to be employed when withdrawing blood, or has satisfactorily completed a prescribed course of instruction approved by the Board of Vocational Nursing and Psychiatric Technicians or has demonstrated competence to the satisfaction of that board.

(c) Any respiratory care practitioner certified under the provisions of Chapter 8.3 (commencing with Section 3700) of Division 2 may perform arterial puncture, venipuncture, or skin puncture for the purposes of withdrawing blood or for test purposes upon authorization from any licensed physician and surgeon.

(Amended by Stats. 1997, Ch. 759, Sec. 10. Effective January 1, 1998.)

1243. A student regularly matriculated in any college or university accredited by an accrediting agency acceptable to the department, or in any legally chartered school approved by the department for training purposes may perform arterial puncture, venipuncture, or skin puncture as a part of the necessary training program when done under the direct and responsible supervision of a person licensed to perform tests under the provisions of this chapter or a licensed physician and surgeon.

(Amended by Stats. 1970, Ch. 1377.)

1244. (a) Nothing in this chapter shall restrict, limit, or prevent a program of nondiagnostic general health assessment provided that:

(1) The program meets the requirements of Section 1265 and complies with the requirements of CLIA for waived testing.

(2) The purpose of the program is to screen asymptomatic individuals for chronic health disorders and to refer individuals to licensed sources of care as indicated.

(3) The program does not test for human immunodeficiency virus or any reportable disease or condition identified in Section 120130 of the Health and Safety Code or the regulations adopted under that section.

(4) The program utilizes only those devices that comply with all of the following:

(A) Meet all applicable state and federal performance standards pursuant to Section 111245 of the Health and Safety Code.

(B) Are not adulterated as specified in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(C) Are not misbranded as specified in Article 3 (commencing with Section 111330) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(D) Are not new devices unless they meet the requirements of Section 111550 of the Health and Safety Code.

(E) Are approved as waived tests and are used according to the manufacturer’s instructions.

(5) Blood collection is performed by skin puncture only.

(6) Testing of a urine specimen is performed by the dipstick method only.

(7) Testing is performed on site and reported directly to the person requesting the test.

(8) The program maintains a supervisory committee consisting of, at a minimum, a licensed physician and surgeon and a clinical laboratory scientist licensed pursuant to this code.

(9) The supervisory committee for the program adopts written protocols that shall be followed in the program and that shall contain all of the following:

(A) Provision of written information to individuals to be assessed that shall include, but not be limited to, the following:

(i) The potential risks and benefits of assessment procedures to be performed in the program.

(ii) The limitations, including the nondiagnostic nature, of assessment examinations of biological specimens performed in the program.

(iii) Information regarding the risk factors or markers targeted by the program.

(iv) The need for followup with licensed sources of care for confirmation, diagnosis, and treatment as appropriate.

(B) Proper use of each device utilized in the program including the operation of analyzers, maintenance of equipment and supplies, and performance of quality control procedures including the determination of both accuracy and reproducibility of measurements in accordance with instructions provided by the manufacturer of the assessment device used.

(C) Proper procedures to be employed when collecting blood, if blood specimens are to be obtained.

(D) Proper procedures to be employed in handling and disposing of all biological specimens to be obtained and material contaminated by those biological specimens. These procedures shall comply with all county and city ordinances for medical waste management and blood-borne pathogen control that apply to the location where the program operates.

(E) Proper procedures to be employed in response to fainting, excessive bleeding, or other medical emergencies.

(F) Documentation that the testing personnel are following the instructions of the instrument's manufacturer, are trained in the performance of the test, and are competent to perform the testing without supervision.

(G) Reporting of assessment results to the individual being assessed.

(H) Referral and followup to licensed sources of care as indicated.

The written protocols adopted by the supervisory committee shall be maintained for at least one year following completion of the assessment program during which period they shall be subject to review by department personnel and the local health officer or his or her designee, including the public health laboratory director.

(b) If skin puncture to obtain a blood specimen is to be performed in a program of nondiagnostic general health assessment, the individual performing the skin puncture shall be authorized to perform skin puncture under this chapter.

(c) A program of nondiagnostic general health assessment that fails to meet the requirements set forth in subdivisions (a) and (b) shall not operate.

(d) For purposes of this section, "skin puncture" means the collection of a blood specimen by the finger prick method only and does not include venipuncture, arterial puncture, or any other procedure for obtaining a blood specimen.

(e) Nothing in this chapter shall be interpreted as prohibiting a licensed clinical laboratory from operating a program of nondiagnostic general health assessment provided that the clinical laboratory complies with the requirements of this section.

(f) A program for a health fair providing diagnostic or screening tests is not a nondiagnostic general health assessment program if all of the requirements of this chapter are met, and the laboratory performing the testing is licensed or registered under subdivision (a) of Section 1265. For a test that is not authorized for self-ordering pursuant to Section 1246.5 and that is not for a nondiagnostic general health assessment pursuant to this section, the licensed or registered clinical laboratory participating in the health fair shall assure that the test is ordered on-site only by a person licensed under this division who is authorized under his or her scope of practice to order the test or by a person authorized by that licensee. The results of a test performed at a health fair shall be provided to the test subject along with an explanation of the results.

(Amended by Stats. 2004, Ch. 450, Sec. 3. Effective January 1, 2005.)

1244.1. Thirty days prior to operating a program of nondiagnostic general health assessment, the entity or person operating that program shall file the following documentation with the local health officer in each county in which the program shall operate:

(a) The location of the program, the type and kind of nondiagnostic general health assessments being conducted, the dates and times of operation of programs, and evidence that the program shall be operated in compliance with Section 1244.

(b) The local health officer shall be notified in writing of any changes to occur in locations, dates, or times indicated in the documentation required in subdivision (a). The local health officer shall be notified of any changes at least 24 hours prior to the program operating at the different locations, dates, or times.

(Added by Stats. 1990, Ch. 195, Sec. 5. Effective July 9, 1990.)

1244.3. Responsibility for enforcement of Sections 1244 and 1244.1 shall be with the local health officer or his or her authorized designee, including public health laboratory directors. Nothing in this section shall prevent the department from using any necessary enforcement actions for the protection of the public health and safety.

(Added by Stats. 1990, Ch. 195, Sec. 6. Effective July 9, 1990.)

1244.4. Any fee for the filing of documentation and related enforcement activities pursuant to Section 1244, 1244.1, and 1244.3 shall be determined by the local enforcement agency and shall not exceed one hundred dollars ($100) except that those fees shall be adjusted annually by any annual increase in the California Consumer Price Index as determined pursuant to Section 2212 of the Revenue and Taxation Code. All moneys collected as fees pursuant to this section shall be deposited in the appropriate city, county, or city and county treasury and shall only be expended in carrying out Sections 1244, 1244.1, and 1244.3.

(Added by Stats. 1990, Ch. 195, Sec. 7. Effective July 9, 1990.)

1245. (a) Any individual may perform a blood gas analysis if all the following conditions exist:

(1) He or she has earned a high school diploma or equivalent, as determined by HCFA pursuant to CLIA.

(2) He or she performs the blood gas analysis in a clinic or a general acute care hospital, as defined respectively in Sections 1202 and 1250 of the Health and Safety Code.

(3) He or she has been instructed by a physician and surgeon licensed in this state, who is in charge of a department of pulmonary physiology or clinical pathology in licensed clinics or hospitals, as defined respectively in Sections 1202 and 1250 of the Health and Safety Code, in the proper procedure to be employed when performing a blood gas analysis.

(4) He or she performs the blood gas analysis under the direction and supervision of the physician and surgeon.

(5) He or she submits the analysis for interpretation to the physician and surgeon under whose direction and supervision he or she performed the analysis.

(b) After September 1, 1997, any person may perform a blood gas analysis classified as of high complexity under CLIA, if, in addition to the requirements of subdivision (a), he or she has earned an associate degree related to pulmonary function from an accredited institution as determined by HCFA pursuant to CLIA.

(c) Nothing contained in this section shall be construed as authorizing any individual, not otherwise authorized, to withdraw blood.

(d) Nothing contained in this section is applicable to a person licensed as a respiratory care practitioner under Chapter 8.3 (commencing with Section 3700). Those persons are authorized to perform those functions set forth in that chapter.

(Amended by Stats. 1995, Ch. 510, Sec. 23. Effective January 1, 1996.)

1246. (a) (1) On and after the effective date of the regulations specified in paragraph (2), any unlicensed person employed by a clinical laboratory performing the duties described in this section shall possess a valid and current certification as a certified phlebotomy technician issued by the department.

(2) The department shall adopt regulations for certification by January 1, 2001, as a certified phlebotomy technician that shall include all of the following:

(A) The applicant shall hold a valid, current certification as a phlebotomist issued by a national accreditation agency approved by the department, and shall submit proof of that certification when applying for certification pursuant to this section.

(B) An applicant with fewer than 1,040 hours of work experience shall complete education, training, and experience requirements as specified by regulations that shall include, but not be limited to, the following:

(i) At least 40 hours of didactic instruction.

(ii) At least 40 hours of practical instruction.

(iii) At least 50 successful venipunctures.

(C) An applicant who has at least 1,040 hours of work experience that includes at least 50 successful venipunctures shall complete at least 20 hours of didactic instruction, as specified in regulations adopted by the department.

(D) Each certified phlebotomy technician shall complete at least three hours per year or six hours every two years of continuing education or training. The department shall consider a variety of programs in determining the programs that meet the continuing education or training requirement.

(E) The applicant has been found to be competent in phlebotomy by a licensed physician and surgeon or person licensed pursuant to this chapter.

(F) The applicant works under the supervision of a licensed physician and surgeon, licensed registered nurse, or person licensed under this chapter, or the designee of a licensed physician and surgeon or the designee of a person licensed under this chapter.

(3) A certified phlebotomy technician may collect blood through a peripheral venous catheter if all of the following are met:

(A) The blood collection procedure is performed in a facility licensed under Division 2 (commencing with Section 1200) of the Health and Safety Code.

(B) The blood collection procedures or protocols are developed and approved by the facility's supervising physician and surgeon or licensed clinical laboratory director and approved by the licensed facility.

(C) The certified phlebotomy technician has received a minimum of three hours of training by the supervising physician and surgeon or their delegate in the proper procedures to be employed when collecting blood through a peripheral venous catheter.

(i) Training in the blood collection procedure through a peripheral venous catheter shall be conducted according to standardized training procedures developed and approved by the facility's supervising physician and surgeon or licensed clinical laboratory director. The facility shall make these standardized procedures available to the department upon request.

(ii) The instructor shall document the certified phlebotomy technician's successful completion of training. The facility shall maintain and make available to the department, upon request, documentation of training completed by a certified phlebotomy technician pursuant to this paragraph.

(D) The certified phlebotomy technician performs the blood collection procedure under the supervision of a physician and surgeon licensed under Chapter 5 (commencing with Section 2000). Notwithstanding subdivision (b), the physician and surgeon may only delegate the supervision duties in this subparagraph to a registered nurse. A physician and surgeon or a registered nurse may restrict or limit a certified phlebotomy technician's ability to collect blood from a patient's peripheral venous catheter.

(E) The certified phlebotomy technician performs the blood collection procedure using a device or devices approved by the licensed facility and the United States Food and Drug Administration.

(F) This paragraph does not authorize the certified phlebotomy technician to manage, stop, or restart a patient's active intravenous infusion or insert or remove a peripheral intravenous catheter.

(4) Paragraph (3) does not authorize a certified phlebotomy technician to withdraw blood through a peripherally inserted central catheter or central venous catheter.

(5) The department shall adopt regulations establishing standards for approving training programs designed to prepare applicants for certification pursuant to this section. The standards shall ensure that these programs meet the state's minimum education and training requirements for comparable programs.

(6) The department shall adopt regulations establishing standards for approving national accreditation agencies to administer certification examinations and tests pursuant to this section.

(7) The department shall charge fees for application for and renewal of the certificate authorized by this section of no more than one hundred dollars ($100) for a two-year period.

(b) (1) (A) A certified phlebotomy technician may perform venipuncture or skin puncture to obtain a specimen for nondiagnostic tests assessing the health of an individual, for insurance purposes, provided that the technician works under the general supervision of a physician and surgeon licensed under Chapter 5 (commencing with Section 2000). The physician and surgeon may delegate the general supervision duties to a registered nurse or a person licensed under this chapter, but shall remain responsible for ensuring that all those duties and responsibilities are properly performed. The physician and surgeon shall make available to the department, upon request, records maintained documenting when a certified phlebotomy technician has performed venipuncture or skin puncture pursuant to this paragraph.

(B) As used in this paragraph, general supervision requires the supervisor of the technician to determine that the technician is competent to perform venipuncture or skin puncture, or to collect blood, before the technician's first blood withdrawal, and on

an annual basis thereafter. The supervisor is also required to determine, on a monthly basis, that the technician complies with appropriate venipuncture, skin puncture, and blood collection policies and procedures approved by the medical director and required by state regulations. The supervisor, or another designated licensed physician and surgeon, registered nurse, or person licensed under this chapter, shall be available for consultation with the technician, either in person or through telephonic or electronic means, at the time of blood withdrawal.

(2) (A) Notwithstanding any other law, a person who has been issued a certified phlebotomy technician certificate pursuant to this section may draw blood following policies and procedures approved by a physician and surgeon licensed under Chapter 5 (commencing with Section 2000), appropriate to the location where the blood is being drawn and in accordance with state regulations. The blood collection shall be done at the request and in the presence of a peace officer for forensic purposes in a jail, law enforcement facility, or medical facility, with general supervision.

(B) As used in this paragraph, “general supervision” means that the supervisor of the technician is licensed under this code as a physician and surgeon, physician assistant, clinical laboratory bioanalyst, registered nurse, or clinical laboratory scientist, and reviews the competency of the technician before the technician may perform blood withdrawals without direct supervision, and on an annual basis thereafter. The supervisor is also required to review the work of the technician at least once a month to ensure compliance with venipuncture policies, procedures, and regulations. The supervisor, or another person licensed under this code as a physician and surgeon, physician assistant, clinical laboratory bioanalyst, registered nurse, or clinical laboratory scientist, shall be accessible to the location where the technician is working to provide onsite, telephone, or electronic consultation, within 30 minutes when needed.

(c) The department may adopt regulations providing for the issuance of a certificate to an unlicensed person employed by a clinical laboratory authorizing only the performance of skin punctures for test purposes.

(Amended by Stats. 2022, Ch. 685, Sec. 1. (AB 1120) Effective January 1, 2023.)

1246.5. Notwithstanding any other provision of law, any person may request, and any licensed clinical laboratory or public health laboratory may perform, the laboratory tests specified in this section. A registered clinical laboratory may perform the laboratory tests specified in this section if the test is subject to a certificate of waiver under CLIA and the laboratory has registered with the department under paragraph (2) of subdivision (a) of Section 1265. A program for nondiagnostic general health assessment that includes a laboratory test specified in this section shall comply with the provisions of Section 1244. The results from any test may be provided directly to the person requesting the test if the test is on or for his or her own body. These test results shall be provided in a manner that presents clear information and that identifies results indicating the need for referral to a physician and surgeon.

The tests that may be conducted pursuant to this section are: pregnancy, glucose level, cholesterol, occult blood, and any other test for which there is a test for a particular analyte 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. A test approved only as an over-the-counter collection device may not be conducted pursuant to this section.

(Amended by Stats. 2004, Ch. 450, Sec. 4. Effective January 1, 2005.)

1246.7. (a) Notwithstanding any other law, a person may perform a total protein test using a digital refractometer in a licensed plasma collection center in this state, if the department, as part of its routine, fee-supported inspection of the licensed plasma collection center, including its review of personnel reports for licensed and unlicensed personnel and job descriptions of all center positions for a licensed plasma collection center, determines that all of the following conditions are met:

(1) (A) The person has earned a high school diploma or equivalent, as determined by the federal Centers for Medicare and Medicaid Services (CMS) pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. Sec. 263a).

(B) The person has training sufficient to demonstrate that the individual has the skills and abilities described in paragraph (2) of subdivision (a) of Section 1269.

(2) (A) In addition to the education and training requirements specified in paragraph (1), the person has received five hours of training in the proper procedures to be employed when performing a total protein test using a digital refractometer, including evaluation of specimen acceptability and criteria for rejection of inadequate specimens, and the procedures for recording the test results pursuant to paragraph (9).

(B) Their training in the proper procedure to be employed when performing a total protein test using a digital refractometer has been certified by a moderate complexity laboratory technical consultant as specified in Section 1036.2 of Title 17 of the California Code of Regulations, by a physician and surgeon licensed in this state, or by a licensed clinical laboratory director who is in charge of the licensed plasma collection center.

(C) The instructor documents, and the plasma collection center maintains the documentation of, the individual's successful completion of training in the performance of the total protein test using a digital refractometer. This documentation shall be made available to the department upon request.

(3) The person performs the total protein test using a digital refractometer under the supervision of one of the following individuals:

(A) A moderate complexity laboratory technical consultant as specified in Section 1036.2 of Title 17 of the California Code of Regulations.

(B) A registered nurse licensed pursuant to Chapter 6 of Division 2.

(C) A physician or surgeon licensed pursuant to Chapter 5 of Division 2.

(D) A clinical laboratory director licensed pursuant to this chapter.

(E) A clinical laboratory scientist licensed pursuant to this chapter.

(4) The supervisor is physically onsite in the licensed plasma collection center and available for consultation during the entire time that the person is processing specimens and performing the test.

(5) The licensed plasma collection center's supervising physician and surgeon or licensed clinical laboratory director provides a written job description for each employee who performs a total protein test using a digital refractometer that specifies the responsibilities and supervision requirements as specified in this section.

(6) The person performs the total protein test using a digital refractometer in accordance with both of the following:

(A) Standardized operating procedures required by the licensed plasma collection center's license.

(B) Standardized procedures approved by the licensed plasma collection center's supervising physician and surgeon or licensed clinical laboratory director for administration of the total protein test by the persons authorized to perform the total protein test pursuant to this section. These standardized procedures shall be made available to the department upon request.

(7) The person does not draw the blood sample required for the test using a procedure that requires a registration, certification, or license under state law unless they are properly registered, certified, or licensed to perform the procedure.

(8) The person's competency in performing total protein tests using a digital refractometer is evaluated before testing on donors, and every six months thereafter, by the CLIA lab director or technical consultant by direct observation. A licensed plasma collection center shall maintain documentation of the competency evaluation, which shall be made available to the department upon request.

(9) The person accurately records the results of the predonation total protein test in a federal FDA 510k-approved blood establishment computer system (BECS).

(10) For each protein refractometer test system in use at the licensed plasma collection center, the center shall perform control procedures using the number and frequency specified by the manufacturer that meet the requirements of Section 493.1256 of Title 42 of the Code of Federal Regulations and this chapter.

(b) The digital refractometer used to perform a total protein test pursuant to this section shall meet all of the following criteria:

(1) Is used within 30 feet of the donor for whom the test is being conducted.

(2) Is used in accordance with the donor 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, if applicable to the licensed plasma collection center under federal law.

(3) Performs total protein tests classified as waived or of moderate complexity under CLIA.

(4) Performs total protein tests using a digital refractometer on biological specimens that require manual blood collection, centrifugation to separate the blood cells from the plasma, pipetting the plasma from the cells, and application of the plasma into the refractometer.

(5) Provides total protein test results without calculation or discretionary intervention by the testing personnel.

(6) Performs total protein tests without the necessity for testing personnel to perform calibration or maintenance, except basic cleaning, resetting, and daily standardization pursuant to the manufacturer's instructions.

(c) To assess the competency and performance of persons authorized to perform the total protein test pursuant to this section, a licensed plasma collection center utilizing this section shall make available to the department any information required by statute or

regulation to be collected or maintained by the licensed plasma collection center, and the results of any testing required by statute or regulation to be performed by the licensed plasma collection center, related to assessing the competency and performance of persons using a digital refractometer, as determined by the department. Information obtained pursuant to this subdivision shall be confidential and is not a public record. The department may contract for collection and review of the information required by this subdivision. The contract shall be exempt from Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code and shall be exempt from review or approval by any division of the Department of General Services.

(d) Records of digital refractometer test results collected pursuant to paragraph (9) of subdivision (a) shall be maintained for three years and made available to the department upon request.

(Amended by Stats. 2022, Ch. 429, Sec. 1. (AB 392) Effective January 1, 2023.)