Connecticut Department of Public Health
Regulation Concerning
Clinical Laboratories

Section 1. Sections 19a-36-D20 to 19a-36-D31, inclusive, of the Regulations of Connecticut State Agencies are amended to read as follows:

Sec. 19a-36-D20. Definitions

As used in sections 19a-36-D20 [through] to [19a-36-D39] 19a-36-D31, inclusive, of the Regulations of Connecticut State Agencies:

[(1) "Advisory committee" means a group of consultants, appointed by the commissioner and serving in a voluntary capacity, to advise the department on matters relating to the regulation of clinical laboratories. The advisory committee shall consist of two hospital laboratory directors who are certified by the American Board of Pathology in both clinical and anatomic pathology; two private clinical laboratory directors; and four laboratory specialists specializing in the fields of cytopathology, clinical chemistry, hematology, and microbiology of which two shall represent laboratories in hospitals licensed in accordance with chapter 368v of the general statutes and two shall represent private clinical laboratories; and a physician who is not a pathologist and who has no financial interests in any laboratory licensed and/or registered with this department.
(2) "CLIA" means the Federal Clinical Laboratory Improvement Amendments of 1988, Title 42 Part 493 of the code of federal regulations.
(3) "Commissioner" means the commissioner of public health.
(4) "Department" means the department of public health.
(5) "Director" means the person designated by the licensee to be responsible for the daily technical and scientific operations of the laboratory, including choice and application of methods, supervision of personnel and reporting of findings.
(6) "Examination" means an investigation, all or any part of which is necessary to obtain an accurate result, which includes the process of instructing the patient, preparing the specimen collection site, choosing the appropriate collection technique, obtaining a valid specimen, assuring the patient's well being, the judicious handling, transporting and processing of the specimen, and reporting the results in a clear and concise manner to the practitioner whose order initiated the process.
(7) "High complexity tests" means laboratory tests categorized as high complexity in accordance with CLIA.
(8) "Laboratory" means any clinical laboratory as defined in Section 19a-30 of the Connecticut General Statutes or other area, except those specifically exempted by the Connecticut General Statutes, where any type of specimen or material derived from a human being or body is examined to obtain findings bearing upon the presence, absence, prognosis or treatment of disease or upon susceptibility thereto.
(9) "Licensee" means the person or persons in whose name licensure of a laboratory has been sought and granted; this shall be the owner if an individual, the owners if a partnership of two, or a responsible officer of any other group, firm or corporation owning the laboratory.
(10) "Moderate complexity tests" means laboratory tests categorized as moderate complexity in accordance with CLIA.
(11) "Non-waived laboratory tests" means moderate and high complexity tests which are not included in the waived tests as set forth in Title 42 Part 493 of the code of federal regulations.
(12) "Owner" means any individual, partnership, group, firm or corporation holding or claiming ownership of or title to a laboratory.

(13) “Specimen” refers only to materials derived from a human being or body.]

(1) “Advisory Committee” means a group of consultants, appointed by the commissioner and serving in a voluntary capacity, which may be established to advise the department on matters relating to the regulation of clinical laboratories. The advisory committee shall consist of any such members with relevant expertise as the commissioner may appoint.
(2) “Clinical Laboratory Improvement Amendments” or “CLIA” means the regulations adopted pursuant to the Clinical Laboratory Improvement Amendments of 1988 set forth in 42 CFR 493, as amended from time to time.
(3) “CLIA certified” means a clinical laboratory meets the CLIA requirements as regulated by the Centers for Medicare and Medicaid Services, and carries the appropriate CLIA certificate for operation.
(4) “Clinical laboratory” has the same meaning as section 19a-490(h) of the Connecticut General Statutes.
(5) “Commissioner’’ means the Commissioner of Public Health or the commissioner’s designee.
(6) ‘‘Department’’ means the Department of Public Health.
(7) “Direct-to-consumer” or “DTC” means consumer initiated testing of specimens without a practitioner’s order.
(8) ‘‘Director’’ means the person designated by the licensee to be responsible for the daily technical and scientific operations of the laboratory, including choice and application of methods, supervision of personnel and reporting of findings.
(9) ‘‘Examination’’ means an investigation or test, all or any part of which is necessary to obtain an accurate result, which includes the process of instructing the patient, preparing the specimen collection site, choosing the appropriate collection technique, obtaining a valid specimen, assuring the patient’s wellbeing, conducting the handling, transporting and processing of the specimen, and reporting the results in a clear and concise manner to the practitioner whose order initiated the process.
(10) “Licensee” means the person or business entity granted a license by the department to establish, conduct, operate or maintain a clinical laboratory.
(11) “Owner” means any person or business entity holding or claiming ownership of or title to a clinical laboratory.
(12) “Physician” means a physician licensed pursuant to chapter 370 of the Connecticut General Statutes.
(13) “Practitioner” means a health professional licensed in the state of Connecticut and authorized by state law to make diagnoses and issue orders for tests and examinations performed by a clinical laboratory.
(14) ‘‘Specimen’’ means samples of materials collected or derived from a human being or body.
(15) “Specimen collection facility” means any facility owned and operated by the licensee other than the clinical laboratory, that is used for the collection of specimens for subsequent delivery to a clinical laboratory for examination.

Sec. 19a-36-D21. [Licensure required] Licensure procedures

(a) No person or business entity shall establish, conduct, operate or maintain a clinical laboratory unless such laboratory, facility or center is licensed by the department in accordance with section 19a-36-E2 of the Regulations of Connecticut State Agencies. The owner or responsible officer shall apply to the department for licensure of the laboratory or renewal thereof on forms provided [for that purpose] by the department. No clinical laboratory tests or examinations shall be performed [therein] until the owner has been notified by the department that licensure is in effect. [No such tests or examinations shall be made after licensure has been suspended or revoked as provided in section 19a-36-D26 of the regulations of Connecticut State Agencies or after the licensee has voluntarily surrendered its license, until such licensure is renewed or reinstated].

(1) Application for initial or renewal licensure shall include the following:

(A) Name and location of the clinical laboratory;

(B) Statement of ownership and operation including name and address of the licensee;

(C) Name, address, and qualifications of the director;

(D) A roster of personnel including personnel qualifications;

(E) A list of laboratory tests and examinations, with itemized rate schedules, for which licensure is sought;

(F) Hours of operation;

(G) Copies of contracts with any practitioners to utilize the proposed laboratory services;

(H) A list of any reference laboratories outside of Connecticut the applicant proposes to utilize for referred tests;

(I) Certificates of malpractice and public liability insurance;

(J) Business identification number issued by the Secretary of State;

(K) The information required in section 19a-36-D23(d) of the Regulations of Connecticut State Agencies if the licensee seeks approval of any specimen collection facilities associated with the clinical laboratory;

(L) Licensing or renewal fees as provided in section 19a-565(f) of the Connecticut General Statutes; and

(M) Any such additional information as the department may require.

(2) Inspection and Investigation

(A) Upon the department's determination that the application materials are complete, the department shall notify the applicant of inspection. The applicant shall make the premises, facilities, equipment, policies and procedures required under section 19a-36-D22 of the Regulations of Connecticut State Agencies, and records available for department inspection upon request of the department. Laboratories with specimen collection facilities shall not operate such facilities unless approved by the department in accordance with section 19a-36-D23 of the Regulations of Connecticut State Agencies.

(B) The licensee shall cooperate with any representative of the department by furnishing information requested by the department in any inspection or investigation. Failure to allow the department to inspect upon application or in the course of any investigation constitutes cause for suspension or revocation of the laboratory's license.

(3) Issuance and renewal of license.

(A) The terms of initial licensure or licensure renewal may restrict the scope of laboratory operations or establish a time limit for the owner to meet conditions based upon inspection and investigation and set forth in a consent order under section 19a-565(e) of the Connecticut General Statutes. Initial licensure shall not be in effect until the department has sent notice of its effective date and term to the applicant.

(B) Application for renewal of licensure shall be made biennially. The duration of each license shall be set at the discretion of the department, for a period of not less than twenty-four nor more than twenty-seven months from its effective date. Applications for renewal shall be submitted to the department not later than five months prior to the expiration of the current license.

(4) The following laboratories are exempt from licensure as a clinical laboratory:

(A) Laboratories owned and operated by the United States or any agency of the federal government;

(B) Laboratories that perform tests or examinations for research purposes only;

(C) Laboratories that perform tests or examinations for forensic purposes only;

(D) Laboratories that only perform tests or examinations that are performed under a CLIA certificate of waiver in accordance with 42 CFR 493.15, as amended from time to time, or laboratories that only perform provider-performed microscopy procedures in accordance with 42 CFR 493.19, as amended from time to time; and

(E) Facilities licensed as source plasma donation centers in accordance with sections 19a-36-E1 to 19a-36-E6, inclusive, of the Regulations of Connecticut State Agencies and in accordance with section 19a-565 of the Connecticut General Statutes whose activities are limited to only those functions provided in section 19a-490(u) of the Connecticut General Statutes or facilities licensed as blood collection facilities in accordance with sections 19a-36-F1 to 19a-36-F6, inclusive, of the Regulations of Connecticut State Agencies.

[(b) At the discretion of the commissioner, the licensee may be directed by written notice to appear not less than five days thereafter at a hearing before the commissioner or the commissioner's designee to show cause why licensure should not be suspended or revoked. When, in the judgment of the commissioner, conditions so warrant, suspension of licensure may be invoked without prior hearing. Revocation of a suspended license shall become effective within thirty days after suspension unless otherwise ordered by the commissioner. Prior to revocation, the owner may request a hearing, stating upon what grounds such petition is based.]

(b) Change in facilities. Thirty days prior to any major expansion or facilities alteration of a clinical laboratory, which includes expanding the facilities through construction or relocating the laboratory testing area to another floor, the licensee shall notify the commissioner in a form and manner prescribed by the commissioner. A new application for licensure pursuant to the requirements of section 19a-36-D21 of the Regulations of Connecticut State Agencies shall be made prior to any relocation of the laboratory.

(c) Change of ownership. Any change in ownership shall be made in compliance with section 19a-493 of the Connecticut General Statutes.

(d) Change or absence of director. The licensee shall notify the department of a proposed change in director at least thirty days prior to such change. In the event of an unplanned change in director, or the absence of the director for greater than thirty days, the licensee shall notify the department within twenty-four hours of the unplanned change or absence of greater than thirty days, and the licensee may

designate an interim director who meets the qualifications set forth in section 19a-36-D28 of the Regulations of Connecticut State Agencies.

(e) Denial, suspension or revocation of licensure.

(1) The department may deny an initial or renewal application for licensure for any of the following reasons:

(A) The clinical laboratory has failed to comply with any applicable statute or regulation;

(B) The clinical laboratory has failed implement a plan of correction as required by the department;

(C) The clinical laboratory has failed to permit department inspection of the premises or access to the center's records upon request of the department;

(D) If licensure would pose a threat to the health, safety and well-being of the public pursuant to section 19a-565(e) of the Connecticut General Statutes; or

(E) A material misstatement of fact on the application.

(2) A license issued under this section may be revoked or suspended or subject to any other disciplinary action pursuant to section 19a-494 of the Connecticut General Statutes, in accordance with chapter 54 of the Connecticut General Statutes, for the following reasons:

[(1)] (A) [the] The laboratory has operated in violation of any applicable state, local or federal statute or regulation or has failed to implement a plan of correction submitted to the Department [department] under section 19a-496(b) of the Connecticut General Statutes;

[(2) the findings of the laboratory are found, after investigation, to be inaccurate or unreliable beyond the limits of error inherent in the method and such condition is not corrected forthwith;]

[(3)] (B) [findings] Laboratory results have been reported on specimens that were not tested or examined;

[(4)] (C) [the] The [owner] licensee has failed to comply with the requirements of a consent order issued pursuant to section 19a-565(e) or section 19a-491 of the Connecticut General Statutes;

[(5)] (D) The licensee's CLIA certification has been suspended or revoked; [or]

(E) Misrepresentation to the public of the scope of laboratory services or of the qualifications or special abilities of persons associated with the laboratory; or

[(6)] (F) [any] Any other condition of the laboratory that [is deemed prejudicial] presents a risk to the [public] health, safety or welfare of the public.

(f) Waiver.

(1) The commissioner may waive provisions of these regulations as provided in section 19a-495 of the Connecticut General Statutes if the commissioner determines that such waiver would not endanger the health, safety or welfare of any patient. The commissioner may impose conditions upon granting the waiver that assure the health, safety and welfare of patients, and may revoke the waiver upon a finding that the health, safety, or welfare of any patient has been jeopardized.

(2) The licensee requesting a waiver shall do so in a form and manner prescribed by the commissioner. Such request shall include:

(i) The specific regulations for which the waiver is requested;

(ii) Reasons for requesting a waiver, including a statement of the type and degree of hardship that would result to the clinical laboratory upon enforcement of the regulations;

(iii) The specific relief requested;

(iv) Any documentation that supports the request for waiver; and
(v) Proposed alternative policies and procedures.

(A) In determining whether to grant any request for waiver, the commissioner may consider:
(i) The impact of a waiver on services provided; and
(ii) Proposed alternative policies and procedures.

(B) The commissioner may request additional information in determining whether to grant the request for waiver.

Sec. 19a-36-D22. [Application for Licensure] Minimum standards for the operation of clinical laboratories

[(a) In applying for licensure, the applicant shall set forth the name and location of the laboratory, a complete statement of its ownership including the names and addresses of all owners and the agent for service of process and the agent's address, the name of the director, a list of laboratory tests and examinations for which licensure is sought and such other information as to ownership, quarters, facilities, personnel and proposed operations as the department may require. Application for renewal of licensure shall delineate changes made in the preceding licensure period. When applying for renewal of licensure under this section, the applicant shall simultaneously apply for renewal of any additional registration required by sections 19a-36-A25 through 19a-36-A33 of the regulations of Connecticut State Agencies, and such renewal, when granted, shall be considered to be in force for the issuance of such certificates of approval as are required by section 19a-36-A33 of the regulations of Connecticut State Agencies. The applicant shall, as part of each application, agree to abide by such standards of operation as are made a part thereof.]

(a) The laboratory shall operate in compliance with all applicable state, local, and federal laws and regulations, including but not limited to the CLIA, and with all administrative directives issued pursuant thereto.

[(b) The following clinical laboratories are exempt from licensure:
(1) laboratories owned and operated by the United States or any agency of the federal government;
(2) laboratories that perform tests or examinations for research purposes only;
(3) laboratories that perform tests or examinations for forensic purposes only; and
(4) laboratories that perform tests or examinations that are exempt for CLIA purposes.]

(b) Facilities and equipment.

(1) Facilities in which laboratory work is performed or specimens collected shall be kept free from filth, excessive dirt or litter or other objectionable condition, and shall utilize proper decontamination procedures for the testing area, shall be adequately lighted and ventilated, shall be equipped with utilities adequate for the work, shall be of adequate size and arrangement for the proper conduct of the work and shall be free from unnecessary safety hazards.

(2) Smoking and the storage and consumption of food or beverages shall be prohibited in those areas where the examination of specimens is being carried out. No food or beverage shall be stored in a refrigerator or freezer used for storing patient specimens or potentially infectious materials.

(3) Equipment shall be adequate and in good order at all times for the proper completion of laboratory work for which licensure may be granted. Equipment shall be validated for

installation, operation and performance, maintained and repaired according to manufacturer's written instructions, and monitored for compliance according to a documented schedule.

(c) The laboratory shall ensure that a qualified director supervises the overall operation and administration of the laboratory at all times unless such responsibility is delegated pursuant to 42 CFR 493, as amended from time to time, and in accordance with the director's qualifications and responsibilities set forth in sections 19a-36-28 and 19a-36-D29 of the Regulations of Connecticut State Agencies.

(d) The laboratory shall provide written policies and procedures setting forth the standards of operation of the laboratory in accord with 42 CFR 493, as amended from time to time, to the department for review upon request. Such policies and procedures shall be available to facility personnel for use in areas where procedures are performed. The licensee shall maintain written documentation that each person employed is fully trained in the policies and procedures setting forth minimum standards of operation as required pursuant to this section.

(e) The laboratory shall comply with data collection and reporting requirements in accordance with all applicable state and federal laws including the requirements of section 19a-215 of the Connecticut General Statutes.

(f) A Connecticut license number, which will be assigned to the laboratory by the department upon initial licensure, shall be inscribed on all test reports and posted on the laboratory's website if the laboratory maintains a website.

(g) The laboratory shall issue a list of all tests and fee schedules for all tests and shall maintain such list on file at the laboratory and be available to the department upon request.

Sec. 19a-36-D23. [Inspection and investigation] Specimen Collection Facilities

[The owner shall cause the quarters, facilities and records of the laboratory to be made immediately available for inspection upon request of a representative of the department and shall cooperate with such representative by furnishing information in any pertinent investigation. Failure to allow the Department to inspect constitutes cause for revocation of the laboratory's license.]

(a) A licensed laboratory shall not operate more than ten specimen collection facilities in Connecticut.

(b) Any specimen collection facility, other than one located in the clinical laboratory facility, that is used by the clinical laboratory for the collection of specimens by venipuncture shall be inspected by the department prior to use and shall not operate without a written certificate of approval issued by the department for inclusion under the clinical laboratory license. The licensee or director of a laboratory shall notify the department in writing thirty days prior to a planned termination of the operations of an approved specimen collection facility.

(c) An approved specimen collection facility shall meet the following minimum standards of operation:

(1) The facility shall possess at a minimum, a blood drawing chair or cot acceptable to the department, a telephone, adequate handwashing and lavatory facilities for employees and patients located on the same floor as the specimen collection facility, and proper equipment and supplies for the immediate labeling and storage of specimens.

(2) Equipment shall be adequate and in good order at all times as necessary for the proper handling of laboratory work. Equipment shall be validated for installation, operation and

performance, maintained and repaired according to the manufacturer's written instructions, and monitored for compliance according to a documented schedule;

(3) Blood collection supplies shall be maintained within their expiration date and stored according to the manufacturer's requirements;

(4) The facility shall be designed and constructed to ensure accessibility in accordance with state and federal law;

(5) The facility shall follow all applicable requirements for the storage and disposal of infectious or physically dangerous medical and biological waste;

(6) Any areas of the facility where procedures are performed or blood or specimens are collected shall be kept clean, adequately lighted and ventilated, and shall be of adequate size to ensure the health and safety of patients and staff;

(7) The facility shall maintain appropriate records in accordance with the requirements of section 19a-36-D27 of the Regulations of Connecticut State Agencies;

(8) The facility shall be identified by signs and advertising in a manner which shall not suggest that the facility is a laboratory. No laboratory examinations shall be performed in a specimen collection facility other than the separation of plasma and serum and the preparative procedures necessary for blood collection;

(9) The facility shall display the specimen collection facility certificate of approval conspicuously in the facility;

(10) The facility shall maintain written documentation of staff training and credentials; and

(11) The facility shall comply with all applicable federal, state and local laws and regulations.

(d) Each specimen collection facility shall develop and implement policies and procedures in compliance with all federal and state requirements setting forth minimum standards of operation. Such policies and procedures shall be provided to the department as part of the application for a certificate of approval under the clinical laboratory's license, and upon request at any time, and shall be available to facility personnel for use in areas where procedures are performed. Specimen collection facilities shall develop and implement such policies and procedures in writing that shall include, but not be limited to, the following:

(1) Specimen collection, labeling, storage, and transportation;

(2) Documentation and recordkeeping, including confidentiality and retention of records;

(3) Staffing including educational and training requirements;

(4) Staff and patient safety and emergency preparedness including a written protocol established by the director detailing the steps to be followed in the event of any emergency and including communication protocols with the facility director and with the department. Such protocol shall include, without limitation, the immediate availability of a physician or emergency medical service; and

(5) Quality assurance and infection control, including but not limited to:

(i) Handling and storage of specimens;

(ii) Handling and disposal of infectious or physically dangerous medical and biological waste;

(iii) Contamination policies and procedures to include aseptic methods of specimen collection in accord with the infection prevention and control guidelines of the Centers for Disease Control and Prevention;

(iv) Cleaning of equipment and facility; and

(v) Adequate personal protective equipment ("PPE") including the use of disposable lab coats or an onsite or offsite laundry service to ensure hygienically clean lab coats.

(e) The director of the laboratory which operates the approved specimen collection facility shall be responsible for all aspects of the specimen collection facility, including without limitation, physical plant, personnel and processing and transporting specimens. Such director shall be available to specimen collection facility personnel at all times during operation of the facility for in-person or telephone consultation. The director or the director's designee shall make on-site monthly inspections of the specimen collection facility to ensure suitable handling of patients and specimens.

(f) Any employee of a specimen collection facility who collects blood shall be proficient in venipuncture and emergency procedures required to aid a distressed patient.

(g) A certificate of approval issued under this section may be suspended or revoked in accord with chapter 54 of the General Statutes for the violation of any applicable state or federal statute or regulation or failing to implement a plan of correction submitted to the department under section 19a-496(b)(4) of the Connecticut General Statutes.

Sec. 19a-36-D24. [Terms of licensure] Acceptance and collection of specimens

[The duration of each license shall be set at the discretion of the department, for a period of not less than twenty-four (24) nor more than twenty-seven (27) months from its effective date. The terms of licensure or renewal thereof may restrict the scope of laboratory operations or establish a time limit for the owner to carry out recommendations based upon inspection and investigation. Initial licensure shall not be in force until notice of its effective date and term has been sent to the applicant. Application for renewal of licensure shall be made as follows:

(a) biennially within thirty calendar days prior to expiration of the license then current;]

(a) No specimen shall be accepted for analysis or collected by a licensee or an employee of the laboratory except when authorized in writing by a physician or other practitioner licensed in Connecticut and authorized by law to make diagnoses. No licensee may accept DTC testing of human specimens that are self-collected.

(b) No specimen requiring venipuncture shall be accepted for analysis unless taken by an employee of a laboratory licensed in accordance with sections 19a-36-D20 to 19a-36-D31, inclusive, of the Regulations of Connecticut State Agencies, except for specimens collected by a licensed physician or other licensed practitioner or an employee or contractor working under such practitioner's medical direction, or by an employee or contractor of a hospital or other health care facility licensed in accordance with chapter 368v of the Connecticut General Statutes.

[(b) thirty (30) days before any change in ownership that will result in an actual change of the licensee of the laboratory or a planned change of director is made; or]

(c) The licensee shall establish and follow written policies and procedures as required by 42 CFR 493, as amended from time to time, and make such written policies and procedures available to the department on request. Such policies and procedures shall govern the acceptance, collection, and handling of specimens including, but not limited to, the following as applicable:

(1) Patient preparation;

(2) Specimen collection date and time;

(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source;

(4) Specimen storage and preservation;

(5) Specimen processing;

(6) Specimen acceptability and rejection; and

(7) Specimen referral.

[(c) thirty (30) days prior to any major expansion or alteration in quarters, which includes expanding the quarters through construction or relocating the laboratory testing area to another floor, building or location.]

(d) No person shall be given any parenteral injection for the collection of a specimen except by a licensed physician or other practitioner authorized to do so by the Connecticut General Statutes.

(e) This section shall not prohibit the transmission of specimens collected as specified in subsections (a) and (b) to another licensed laboratory or to a qualified laboratory exempt from Connecticut licensure requirements, nor shall it prohibit the acceptance of specimens submitted by a representative of the department for evaluation of testing procedures.

Sec. 19a-36-D25. [Denial of Licensure] Identification of specimens

[Whenever inspection and investigation pursuant to an application for licensure yield evidence leading to a reasonable presumption that requirements of sections 19a-36-D20 through 19a-36-D38 of the Regulations of Connecticut State Agencies, or of any applicable statute would not or could not be fulfilled, licensure shall be denied.]

Each specimen received for testing shall be numbered or otherwise marked so that it may be identified definitively and related to the submitting licensed provider and the patient from whom it was derived. An appropriate, dated record of its receipt, disposition and examination and of the findings obtained shall be made and kept on file for a minimum of one year after receipt or in accordance with the CLIA, whichever is more stringent.

Sec. 19a-36-D26. [Suspension or revocation of licensure] Examination of specimens

[(a) Licensure may be suspended or revoked whenever in the judgment of the commissioner any one of the following conditions exists:

(1) the laboratory has operated in violation of any applicable statute or regulation or has failed to implement a plan of correction as submitted to the department;

(2) the findings of the laboratory are found, after investigation, to be inaccurate or unreliable beyond the limits of error inherent in the method and such condition is not corrected forthwith;

(3) findings have been reported on specimens that were not tested or examined;

(4) the owner has failed to comply with instructions from the commissioner for the correction of conditions adversely affecting the quality of work;

(5) CLIA certification has been suspended or revoked; or

(6) any other condition of the laboratory that is deemed prejudicial to the public health.

(b) At the discretion of the commissioner, the licensee may be directed by written notice to appear not less than five days thereafter at a hearing before the commissioner or the commissioner's designee to show cause why licensure should not be suspended or revoked. When, in the judgment of the commissioner, conditions so warrant, suspension of licensure may be invoked without prior hearing. Revocation of a suspended license shall become effective within thirty days after suspension unless otherwise ordered by the commissioner. Prior to revocation, the owner may request a hearing, stating upon what grounds such petition is based.]

No specimen shall be examined if unsuitable for testing because of improper collection, improper preservation, improper transport, apparent spoilage, excessive time lapse between collection and examination when applicable, other reasons sufficient to render the findings of doubtful validity, or if it does not meet the criteria for specimen acceptability outlined in the policies and procedures established pursuant to section 19a-36-D24 of the Regulations of Connecticut State Agencies.

Sec. 19a-36-D27. [Connecticut license number] Reports of findings

[A Connecticut license number, which will be assigned to the laboratory by the department upon initial licensure, shall be inscribed on all reports, lists of tests, fee schedules and advertisements of the laboratory.]

(a) Laboratory findings on a specimen shall be reported by the licensee directly to the licensed provider who ordered the testing pursuant to authority granted to such provider by the Connecticut General Statutes, and may be provided by laboratories other than the department's laboratory to persons authorized in accordance with 42 CFR 493.1291, as amended from time to time, or upon request by the patient or the patient's legally authorized representative. Laboratories may also provide findings upon the written request of providers who did not order the testing, if the requesting provider is statutorily authorized to order such testing pursuant to the Connecticut General Statutes and is providing care to the patient who is the subject of the testing. Nothing in this section shall prohibit the issuance of reports of laboratory findings to local or state health officials as required by the Connecticut General Statutes or Regulations of Connecticut State Agencies or the inspection or the issuance of an order to produce records of such reports by a representative of the department pursuant to section 19a-498 of the Connecticut General Statutes.

(b) No laboratory report shall be worded to convey or simulate a diagnosis or prognosis or to specify or suggest specific medication, surgical manipulation or other form of treatment unless signed by a physician licensed to practice in Connecticut or in the state in which the laboratory performing the examinations is located. This subsection shall not prohibit the laboratory from furnishing the normal ranges for the methods of analysis employed in such laboratory nor shall it prohibit the laboratory from identifying patient values that are outside the normal ranges for the methods of analysis employed. When the specimen has been referred for examination to an out-of-state laboratory, the report shall bear or be accompanied by a clear statement that such findings were obtained in such laboratory and shall specify its name and location.

(c) If a licensee discovers a medical error in the performance or reporting of any test, the licensee shall meet the reporting and notification requirements set forth in section 19a-565a of the Connecticut General Statutes.

Sec. 19a-36-D28. [List of tests and fee schedules] Qualifications of personnel

[A copy of each list of tests and each fee schedule issued by a laboratory shall be maintained on file at the laboratory and be available to the department upon its request.]

(a) The director of each clinical laboratory shall meet the educational, training, or experiential requirements, or a combination thereof, specified in the CLIA.

(b) Clinical laboratory personnel other than the director shall meet the educational, training, or experiential requirements specified in the CLIA.

Sec. 19a-36-D29. [Acceptance and collection of specimens] Responsibilities of licensee and director

[(a) No specimen shall be accepted for analysis or collected by an owner or an employee of the laboratory except when requested by a licensed physician or other licensed person authorized by law to make diagnoses.]

(a) The licensee shall ensure that the laboratory is at all times under the direction of a director who meets the qualification standards specified in CLIA regulations at 42 CFR 493, as amended from time to time, unless the director delegates such responsibility pursuant to 42 CFR 493, as amended from time to time. Whenever the director will be on a planned or unplanned leave for greater than thirty calendar days, the licensee shall notify the department in writing within twenty-four hours of the date the licensee receives notice of such unplanned change or absence greater than thirty days, and shall designate an interim supervisor of the laboratory who meets the qualifications set for in section 19a-36-D28 of the Regulations of Connecticut State Agencies. At such time that the director severs connection with the laboratory, the department may grant permission for the continued operation of the laboratory under an interim supervisor for not more than six weeks. In extenuating circumstances, permission to operate longer than six weeks without a permanent director may be granted subject to conditions specified in writing by the department.

[(b) No person shall be given any parenteral injection for the collection of a specimen except by a licensed physician or other person so authorized by the Connecticut General Statutes.]

(b) The licensee and director, if different persons, shall be jointly and severally responsible for the operation of the laboratory in compliance with sections 19a-36- D20 to 19a-36-D31, inclusive, of the Regulations of Connecticut State Agencies.

[(c) This section shall not prohibit the transmission of specimens collected as specified in subsection (a) to another licensed laboratory or to a qualified laboratory exempt from licensure requirements nor shall it prohibit the acceptance of specimens submitted by a representative of the department for evaluation of testing procedures.]

(c) Except for illness, vacation or other justifiable leave, the director shall be responsible for the overall operation of the laboratory in accordance with the director responsibilities in CLIA regulations at 42 CFR 493, as amended from time to time. No person shall act as director of more than five laboratories.

[(d) Except for specimens collected by a practitioner of the healing arts or an employee working under such practitioner's direction or by an employee of a hospital or other health care facility licensed in accordance with chapter 368v of the Connecticut General Statutes, no specimen requiring venipuncture shall be accepted for analysis unless taken by an employee of a laboratory licensed in accordance with sections 19a-36-D20 through 19a-36-D38 of the regulations of Connecticut State Agencies. Any blood collection facility other than the actual laboratory facility that is used for the collection of specimens by venipuncture shall be inspected prior to use and a written certificate of approval shall be issued by the department. The licensee or director of a laboratory shall notify the department in writing immediately

when the operations of an approved blood collection facility are about to terminate.

(e) An approved blood collection facility shall meet all the requirements set forth in subsection (b) of section 19a-36-D38 and shall possess as a minimum, a blood drawing chair or cot acceptable to the department, a telephone, adequate hand washing and toilet facilities for employees and patients located on the same floor as the blood drawing facility and a written procedure manual detailing the steps to be followed in the event of any emergency. Approved blood collection facilities shall be identified by signs and advertising in a manner which will not suggest that the facility is a laboratory. No laboratory examinations shall be performed in a blood collection facility other than the separation of plasma and serum and the preparative procedures necessary for the blood collection.

(f) The director of the laboratory of which the approved blood collection facility is a part shall be responsible for all aspects of the blood collection facility, including without limitation, physical plant, personnel and processing and transporting specimens. The director or supervisor of the laboratory of which the approved blood collection facility is a part shall be available to blood collection facility personnel at all times during operation of the facility for personal or telephone consultation and shall make on-site monthly inspections of the facility to ensure suitable handling of patients and specimens and to instruct the employees in such matters and in the most recent improvements. The director of the laboratory of which the approved blood collection facility is a part shall establish a protocol for action in cases of emergency which shall include, without limitation, the immediate availability of a physician or emergency medical service. Any technical employee of a blood collection facility shall be proficient in venipuncture, specimen processing as limited by sections 19a-36-D20 through 19a-36-D38 of the regulations of Connecticut State Agencies, and emergency procedures required to aid a distressed patient. Each licensed laboratory shall be limited to six (6) blood collection facilities.

(g) Out-of-state laboratories obtaining specimens in blood collection facilities located in Connecticut shall meet all applicable requirements in this section. In accordance with Sections 19a-36-A25 through 19a-36-A33 of the regulations of Connecticut State Agencies, blood collection facilities shall receive written approval from the department before any specimens are collected. Said approval may be revoked by the department at any time in accordance with Section 19a-36-D26 of the regulations of Connecticut State Agencies.]

Sec. 19a-36-D30. [Identification of specimens] Unethical practices prohibited

[Every specimen received for testing shall be numbered or otherwise marked so that it may be identified definitely and related to the submitting physician and the patient from whom it was derived. An appropriate, dated record of its receipt, disposition and examination and of the findings obtained shall be made and kept on file for a minimum of one (1) year after receipt or in accordance with the CLIA regulations, Title 42 part 493 of the code of federal regulations, whichever is more stringent.]

(a) **Definitions**. As used in this section:

(1) “Bribe” means any valuable consideration given or promised by a clinical laboratory providing service to influence the behavior of a requester of laboratory services unless allowed as a permitted practice pursuant to this section.

(2) “Fee-splitting inducement” means offering or implying a division of payment in any manner between a requester of clinical laboratory services and the laboratory providing the service.

(3) “Fraudulent practice” means one that involves deceit, trickery or cheating.

(4) "Requester of laboratory services" means any person, firm, corporation or other entity or an owner or agent thereof that submits specimens, refers specimens for laboratory services or requests or prescribes laboratory tests.

(b) Practices that violate any state or federal law related to fraud and abuse, false billing, or kickbacks are prohibited.

(c) The licensee shall provide price lists, fiscal records, operating records, and any other business records to the department on request.

(d) **Permitted practices.**

(1) Discounts that represent a reduction in rates due to an actual saving to the laboratory resulting from volume, cost or functional differences and that are available equally to all users of a clinical laboratory's services may be permitted. Any discounts shall be clearly stated in a statement of discount policy and such discount policy shall be included in all price lists provided to any user of the laboratory's services.

(2) Competitive bids for laboratory services are exempt from the provisions of subdivision (1) of this subsection. Any services provided pursuant to an agreement reached following such bids shall meet standards for the quality of care.

(e) **Prohibited practices and exemptions.**

(1) Bribes include but are not limited to the following practices:

(A) Offering or providing to a requester of laboratory services any office equipment or services, including but not limited to the services of laboratory employees, except as provided in the exemptions listed in subdivision (2) of this subsection;

(B) Favors or free or discounted services to private patients of a requester of laboratory services other than such services provided directly by the requester.

(2) The following practices are exempt from prohibition as bribes under subdivision 1 of this subsection:

(A) The provision of laboratory staff, equipment or supplies to collect specimens to submit to the laboratory;

(B) The provision of laboratory equipment or supplies solely to collect, transport, process or store specimens;

(C) The provision of laboratory equipment or supplies to order or communicate laboratory findings;

(D) The provision of supplies required by a licensed practitioner to obtain and forward specimens for testing; or

(E) The provision of supplies needed by laboratory staff to service institutions such as nursing facilities, or to make house calls or visits to other locations as directed by the requester of laboratory services.

(3) Fee-splitting inducements include but are not limited to the following practices::

(A) The practices prohibited as fee-splitting inducements in section 19a-565(h) of the Connecticut General Statutes;

(B) Payments from a laboratory to a requester of laboratory services for referring patients or specimens;

(C) Rebates for the volume of business referred or for a period of time for referral except as permitted in subdivisions (1) and (2) of this subsection;

(D) Payments by a laboratory to rent or lease a portion of the facilities of a requester of laboratory services at more than fair market value for the facilities utilized;
(E) Payment of excessive fees to a requester of laboratory services for consultation, filing forms, providing emergency services, or providing other services to the laboratory;
(F) Payment of excessive interest by a laboratory on deposits collected for a loan of laboratory equipment;
(G) Prepayments by requesters of laboratory services that do not result in lower charges to the actual patient or recipient of laboratory services; and
(H) The purchase of corporate stock or the purchase or rental of equipment or other tangible assets by a laboratory at more than fair market value.

(4) Fraudulent practices include but are not limited to the following practices:
(A) Any written or oral agreement between a clinical laboratory and a requester of laboratory services that results in utilization of laboratory services in excess of that needed to provide information for diagnosis, prevention, treatment, or assessment of health of the patient or recipient of such services or excessive charges for these services;
(B) Any system of billing or accepting payment for laboratory services that does not accurately identify the laboratory, the requester, the patient or recipient and the cost of such laboratory services; and
(C) Any system of billing for laboratory services or issuance of receipts for payment that does not accurately indicate the amount and the recipient of such payment.

Sec. 19a-36-D31. [Examination of specimens] Referral of specimens to out-of-state laboratories

[(a)No specimen shall be examined if unsuitable for testing because of improper collection, improper preservation, apparent spoilage, excessive time lapse between collection and examination when applicable, or other reasons sufficient to render the findings of doubtful validity.]

(a) A clinical laboratory may refer specimens for testing to an out-of-state clinical laboratory if the out-of-state laboratory is CLIA certified and is licensed, certified, registered, or approved in the state in which the laboratory is located, if applicable.

[(b) No specimen of excised tissue shall be subjected to pathological examination except by a physician who is licensed to practice medicine in the state in which the laboratory is located and is certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or meets all of the education, training or experience requirements to take the examination but has not actually taken and successfully completed the examination. Physicians qualified under these requirements may delegate the responsibility for examination and interpretation of histopathology specimens to an individual who is a resident in a training program leading to certification in anatomic pathology.]

(b) A clinical laboratory referring specimens to an out-of-state laboratory shall maintain documentation to verify that the out-of-state clinical laboratory meets the specimen collection, identification, examination, and reporting requirements specified in sections 19a-36-D29 to 19a-36-D31, inclusive, of the Regulations of Connecticut State Agencies; the referral requirements specified in subsection (a) of this section; the specimen collection, identification, urine drug testing, and reporting requirements specified in sections 31-51t through 31-51z of the Connecticut General Statutes; and the informed consent, HIV confirmation testing and confidentiality requirements specified in sections 19a-581 through

19a-590 of the Connecticut General Statutes if applicable. This documentation shall be verified by the licensee on a yearly basis.

[(c) No specimen of exfoliated tissue or cells shall be examined except under the supervision and review of a physician who is licensed to practice medicine in the state in which the laboratory is located and meets the personnel qualification standards specified in the CLIA regulations, Title 42 part 493 of the code of federal regulations, as applicable. The Commissioner or the Commissioner's designee may deem a Connecticut licensed physician who is not certified in anatomic pathology to be qualified if said physician possesses qualifications that are equivalent to those required for such certification.]

(c) The clinical laboratory shall maintain a list of out-of-state laboratories to which specimens are referred, stating the types of tests or examinations for which such specimens are submitted, which list shall be available to the department upon its request.

Sec. 2. Sections 19a-36-D32 to 19a-36-D38 are repealed.

Statutory Authority

The statutory authority for the proposed revisions to sections 19a-36-D20 to 19a-36-D31, inclusive, of the Regulations of Connecticut State Agencies, is section 19a-565(b) of the Connecticut General Statutes and section 19a-495(c) of the Connecticut General Statutes.

Statement of Purpose

1) The purpose of the regulation revisions is to align with statutory changes to section 19a-565 of the Connecticut General Statutes, whereby source plasma donations centers and blood collection facilities were established as separate categories of licensed facilities exempt from licensure as clinical laboratories. "Blood collection facilities" previously included the types of facilities now defined as "specimen collection facilities". The purpose of the revisions to the regulations concerning clinical laboratories is also to align with current federal regulatory standards, and to ensure best practices for the operation of clinical laboratories and associated specimen collection facilities.
2) Section 19a-36-D21 is revised to consolidate all existing sections related to licensure procedures including change in facilities, change in ownership, change or absence of laboratory director, disciplinary action, and waiver procedures. Section 19a-36-D22 is revised to set forth minimum standards for the operation of clinical laboratories in alignment with 42 CFR 493 of the federal CLIA regulations, and adds data collection and reporting requirements pursuant to section 19a-215 of the Connecticut General Statutes. Section 19a-36-D23 is revised to set forth minimum requirements for the facility and operational standards for specimen collection facilities approved by the department under a clinical laboratory license, and to expand the maximum number of specimen collection facilities per clinical laboratory license to ten. Section 19a-36-D24 is revised to align standards for the acceptance and collection of specimens with the federal regulations, as well as establish limitations on DTC testing and strengthen standards for

specimens collected by venipuncture by persons other than laboratory employees. Sections related to the identification and examination of specimens, and the reporting of findings are revised to align with federal requirements. Sections related to the qualifications of the laboratory director and other laboratory personnel are renumbered and revised to align with federal requirements, and standards for notifying the department in the event of the absence of the laboratory director are revised for consistency with the standards established for directors of blood collection facilities and source plasma donation centers. Section 19a-36-30 regarding prohibited unethical practices is revised for clarity and to include in exempt practices the sharing of laboratory staff other than phlebotomists for the collection of specimens. Sections 19a-36-32 to 19a-36-38, inclusive, to be repealed due to consolidation and restructuring.

3) The effect of the proposed revisions is to align the regulation of clinical laboratories with current state statute and with federal CLIA regulations.