

19a-36-D20. Definitions

Clinical Laboratories**19a-36-D20. Definitions**

As used in sections 19a-36-D20 through 19a-36-D39:

- (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. (Effective June 4, 1996.)

19a-36-D21. Licensure required

The owner shall apply to the department for licensure of the laboratory or renewal thereof on forms provided for that purpose. No clinical laboratory tests or examinations shall be performed therein until the licensee 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

19a-36-D22. Application for licensure

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.

(Effective June 4, 1996.)

19a-36-D22. Application for licensure

- (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.
- (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.

(Effective June 4, 1996.)

19a-36-D23. Inspection and investigation

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.

(Effective June 4, 1996.)

19a-36-D24. Terms of licensure

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;
- (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) 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.

(Effective June 4, 1996.)

19a-36-D25. Denial of licensure

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-

19a-36-D26. Suspension or revocation of licensure

D38 of the Regulations of Connecticut State Agencies, or of any applicable statute would not or could not be fulfilled, licensure shall be denied.

(Effective June 4, 1996.)

19a-36-D26. Suspension or revocation of licensure

- (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.
- (Effective June 4, 1996.)

19a-36-D27. Connecticut license number

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.

(Effective June 4, 1996.)

19a-36-D28. List of tests and fee schedules

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.

(Effective June 4, 1996.)

19a-36-D29. Acceptance and collection of specimens

- (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.
- (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.
- (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.
- (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

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19a-36-D30. Identification of specimens

- 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.
- (Effective June 4, 1996.)

19a-36-D30. Identification of specimens

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.

(Effective June 4, 1996.)

19a-36-D31. Examination of specimens

- (a) No specimen shall be examined if unsuitable for testing because of improper collection, improper preservation, apparent spoilage, excessive time lapse between collection and

19a-36-D32. Reports of findings

- examination when applicable, or other reasons sufficient to render the findings of doubtful validity.
- (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.
 - (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.
 - (d) There shall be available at all times, in the immediate bench area of personnel engaged in examining specimens and performing related procedures within a specialty (e.g., clinical chemistry, hematology, bacteriology) current laboratory manuals or other complete written descriptions and instructions relating to the analytical methods used by those personnel, properly designated and dated to reflect the most recent supervisory reviews. Such manuals shall also contain information concerning preparation and storage of reagents, control and calibration procedures, and pertinent literature references. Textbooks may be used as supplements to such written descriptions but may not be used in lieu thereof. Technical procedures employed in the laboratory for the processing and examination of specimens shall be performed according to directions detailed in the laboratory manual. Each laboratory shall verify or establish performance specifications for any new test method being utilized including accuracy, precision, reportable range or any other performance characteristic requirements for test performance. If the department deems it necessary, it shall review the laboratory's verification or performance specifications on new methodology to ensure its accuracy, precision, reportable range or other performance characteristic requirements for test performance.
(Effective June 4, 1996.)

19a-36-D32. Reports of findings

- (a) Laboratory findings on a specimen shall be reported directly to the licensed provider who ordered the testing pursuant to authority granted to such provider by chapter 370, 372, 373, 375, 377, 378, 379, 380 or 400j of the Connecticut General Statutes, and may be provided by laboratories other than the department's laboratory to lay persons upon the written request of the provider who ordered the testing. Laboratories other than the department's laboratory may also provide findings upon the written request of providers who did not order the testing, so long as the requesting provider is also statutorily authorized to order such testing pursuant to chapter 370, 372, 373, 375, 377, 378, 379, 380 or 400j of 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 town, city or state health officials as required by the Regulations of Connecticut State Agencies or the inspection or impounding of records of such reports by a representative of the department.
- (b) No 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

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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.

(Effective June 4, 1996; amended effective October 3, 2005.)

19a-36-D33. Qualifications of director

No person shall be the director of a clinical laboratory unless he meets the educational, training and/or experiential requirements identified in this section.

- (a) For laboratories performing tests categorized as high complexity, the director shall:
- (1) be a physician licensed to practice medicine in Connecticut who is certified in anatomic and/or clinical 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; or
 - (2) hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and:
 - (A) be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, the American Board of Medical Laboratory Immunology or other board deemed comparable by the Commissioner; or
 - (B) have at least two (2) years of laboratory training or experience, or both, and at least two (2) years of experience directing or supervising high complexity testing; or
 - (3) have a combination of education, training and experience in the clinical laboratory specialty, which, in the judgment of the commissioner, qualifies the individual to direct a laboratory whose services are limited to that specialty.
- (b) For laboratories performing tests categorized as moderate complexity, the director shall:
- (1) meet the qualification standards identified in subsection (a) of this section; or
 - (2) hold an earned doctoral degree in medicine or dentistry or in chemical, physical or biological sciences from an accredited institution and have at least one (1) year of experience directing or supervising non-waived laboratory testing; or
 - (3) have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution and have at least one (1) year of laboratory training or experience, or both, in non-waived testing and at least one (1) year of supervisory laboratory experience in non-waived testing; or
 - (4) have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution and have at least two (2) years of laboratory training or experience, or both, in non-waived testing and at least two (2) years of supervisory laboratory experience in non-waived testing.

(Effective June 4, 1996.)

19a-36-D34. Qualifications of other personnel

Clinical laboratory personnel other than the director shall meet the educational, training and/or experiential requirements identified in this section.

- (a) For laboratories performing tests categorized as moderate complexity, personnel shall meet the following requirements.
- (1) A technical consultant shall:
 - (A) be a physician licensed to practice medicine in Connecticut who is certified in anatomic and/or clinical pathology by the Board of Pathology

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- 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; or
 - (B) hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution and have at least one (1) year of laboratory training or experience, or both in non-waived testing, in the designated specialty areas of service for which the technical consultant is responsible; or
 - (C) have earned a bachelor's degree in chemical, physical or biological science or medical technology from an accredited institution and have at least two (2) years of laboratory training or experience, or both in the designated specialty or sub-specialty areas of services for which the technical consultant is responsible.
- (2) A clinical consultant shall be qualified to consult with and render opinions to the laboratory's clients concerning diagnosis, treatment and management of patient care and shall:
- (A) be qualified as a laboratory director in accordance with Section 19a-36-D33(a)(1) or (2)(A); or
 - (B) be a physician licensed to practice medicine, osteopathy or podiatry in Connecticut.
- (3) Testing personnel shall:
- (A) be a physician licensed to practice medicine or osteopathy in Connecticut or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; or
 - (B) have earned an associate degree in chemical, physical or biological science or medical laboratory technology from an accredited institution; or
 - (C) have earned a high school diploma or equivalent and have documentation of training appropriate for the testing performed prior to analyzing patient specimens.
- (b) For laboratories performing tests categorized as high complexity, personnel shall meet the requirements identified in subsection (a) of this section or the requirements identified in CLIA, Title 42, Part 493 of the code of federal regulations, whichever are more stringent.
(Effective June 4, 1996.)

19a-36-D35. Responsibilities of licensee and director

- (a) The licensee shall ensure that the laboratory is at all times under the direction of a director who meets the qualification standards identified in Section 19a-13-D33 of the regulations of Connecticut State Agencies. Whenever the designated director is to be on leave for more than thirty (30) calendar days, the licensee shall so notify the department in advance and shall designate an interim supervisor of the laboratory who meets the qualifications identified in subsection (c) of this section. The licensee shall notify the department at least thirty (30) days in advance of any proposed change of ownership or major expansion or alteration in quarters. 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 (6) weeks. In extenuating circumstances, permission to operate longer without a permanent director may be granted subject to conditions specified in writing by the department.
- (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 through 19a-36-D38 of the regulations of Connecticut State Agencies, and with other pertinent regulatory and statutory requirements. They shall advise the department within seven (7)

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- days of changes in operations or personnel. They shall submit to the department an annual report on forms provided for the purpose which shall relate to the numbers and types of laboratory examinations performed during the preceding year.
- (c) The director shall be responsible for the work of subordinates, the proper management of patient test specimens and records, the proper performance of all tests in the laboratory, and the continual application of quality control procedures to the work in accordance with recommendations and directives of the department. In the absence of the director for any cause, the interim supervisor shall assume the director's responsibilities. Such interim supervisor shall meet the qualification requirements identified in Section 19a-36-D34 of the regulations of Connecticut State Agencies.
- (d) Except for illness, vacation or other justifiable leave, the director shall be responsible for the overall operation of the laboratory. No person shall act as director of more than five (5) laboratories.
(Effective June 4, 1996.)

19a-36-D36. Unethical practices prohibited

- (a) Definitions. As used in this section:
- (1) "Bribe" means any valuable consideration given or promised by a laboratory providing service with a view to influence the behavior of a requester of laboratory services.
 - (2) "Fee-splitting inducement" means offering or implying a division of payment in any manner between a requester of 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 that submits specimens, refers specimens for laboratory services or requests or prescribes laboratory tests.
- (b) 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 may be allowed by the laboratory. If such discount is allowed, it must be available equally to all users of the laboratory's services. A statement of discount policy, if any, shall be clearly indicated on any and all price lists provided to any user of the laboratory's services. A copy of all price lists and fiscal, operating and other business records shall be submitted to the department upon request and at the time of the biennial renewal licensing application.
 - (2) Competitive bids for laboratory services are exempt from the provisions of subsection (b) (1) of this section. Any agreement resulting from such bidding must be in the best interest of the patient or consumer.
- (c) Prohibited practices: Bribes and fee-splitting inducements are prohibited
- (1) The following practices are prohibited as bribes: offering or providing to a requester of laboratory services office equipment or services of any kind, including, but not necessarily limited to receptionists, nurses or any other employees, except as provided in subdivision (2) of this subsection. Also prohibited are cars, trips, credit cards, or similar favors, free or discounted services to private patients of such requester of laboratory services to a greater extent than is provided by such requester.
 - (2) The following practices are excluded from the prohibitions identified in subdivision (1) of this subsection: the provision of phlebotomists to collect specimens to be sent to the laboratory for analysis, the provision of equipment or supplies that are used solely to collect, transport, process or store specimens or order or communicate the results of tests or procedures for the laboratory or the provision of specimen collection supplies needed by a physician to obtain and forward specimens for testing, or goods needed by phlebotomists to service

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institutions such as nursing facilities, or to make house calls or visits to other locations as directed by the requester of laboratory services.

- (3) The following are prohibited as fee splitting inducements:
- (A) payments of cash by a laboratory to a requester of laboratory services for referring patients or specimens;
 - (B) cash rebates for volume of business referred or for a period of time of referral except as permitted in subsections (b) (1) and (b) (2) of this section;
 - (C) payments by a laboratory to rent or lease a portion of the facilities of a requester of laboratory services not related to fair market value of the space or facilities utilized;
 - (D) payment of excessive fees to a requester of laboratory services for consultation, filing forms, providing standby emergency services to laboratory and blood collection facilities, or other services;
 - (E) payment of excessive interest by a laboratory on deposits collected for the loan of laboratory equipment;
 - (F) the sale of coupons, tickets or booklets, or other variations of prepayments by requesters of laboratory services that do not result in lower charges to the actual patient or recipient of laboratory services; and
 - (G) the purchase of corporation stock, or the purchase or rental of equipment or other tangible assets at more than fair market value by a laboratory.
- (4) The following are prohibited as fraudulent 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.

(Effective June 4, 1996.)

19a-36-D37. Referral of specimens to out-of-state laboratories

- (a) A Connecticut licensed 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) The Connecticut licensed clinical laboratory shall maintain documentation which verifies that the out-of-state clinical laboratory, to which specimens are referred from Connecticut, meets the specimen collection, identification, examination, and reporting requirements specified in Sections 19a-36-D29 through 19a-36-D32; 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 as correct on a yearly basis.
 - (c) The 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.
- (Effective June 4, 1996.)

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19a-36-D38. Minimum standards for the operation of private clinical laboratories

- (a) The laboratory shall be operated in compliance with all applicable state and federal laws and regulations, including but not necessarily limited to CLIA Title 42 Part 493 of the code of federal regulations and with all reasonable administrative directives pursuant thereto.
- (b) Quarters in which laboratory work is performed or specimens collected shall be kept free from filth, excessive dirt or litter or other objectionable condition, 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. Smoking and the 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.
- (c) Equipment shall be adequate and in good order at all times as considered necessary for the proper handling of work for which licensure may be granted.
- (d) The laboratory shall at all times be operated under the supervision of a director or other qualified person acceptable to the department.
- (e) No misrepresentation of the scope of laboratory services or of the qualifications or special abilities of persons associated with the laboratory shall be permitted.
(Effective June 4, 1996.)