

New York State Public Health Law
TITLE V

CLINICAL LABORATORY AND BLOOD BANKING SERVICES

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§ 570. Declaration of policy and statement of purpose.

The proper performance of clinical laboratory and blood banking services is a matter of vital concern, affecting the public health, safety and welfare. Clinical laboratories and blood banks provide essential public health services in aiding the health care provider by furnishing information invaluable to the diagnosis and treatment of disease. The improper performance of a laboratory procedure may induce an erroneous diagnosis or contribute to the selection of an inappropriate method of treatment, resulting in prolonged or unnecessary hospitalization, injury or even death. The protection of the people of this state requires affirmative action to insure that the performance of clinical laboratory and blood banking services meet high standards of public health care. It is the purpose of this title to promote the public health, safety and welfare by requiring the licensure of clinical laboratories and blood banks, by establishing minimum qualifications for directors, and by requiring that the performance of all procedures employed by clinical laboratories and blood banks meet minimum standards accepted and approved by the department.

§ 571. Definitions.

As used in this title:

1. "Clinical laboratory" means a facility for the microbiological, immunological, chemical, hematological, biophysical, cytological, pathological, genetic, or other examination of materials derived from the human body, for the purpose of obtaining information for the diagnosis, prevention, or treatment of disease or the assessment of a health condition or for identification purposes. Such examinations shall include procedures to determine, measure or otherwise describe the presence or absence of various substances, components or organisms in the human body. The term clinical laboratory shall not include any facility or activity specifically excluded by section five hundred seventy-nine of this title.
2. "Blood bank" means a facility for the collection, processing, storage and/or distribution of human blood, blood components or blood derivatives.

3. "Reference system" means a system of assessment of methods, procedures and materials of clinical laboratories and blood banks, including, but not limited to, ongoing validation which may include direct testing and experimentation by the department of such methods, procedures and materials, the distribution of standards and guidelines, inspection of facilities, periodic submission of test specimens for examination, and research conducted by the department that involves the study of new or existing methods, procedures and materials related to the quality of clinical laboratory medicine.
4. "Director" means the person who is responsible for administration of the technical and scientific operation of a clinical laboratory or blood bank, including supervision of procedures and reporting of findings of tests.
5. "Waived test" means a clinical laboratory test that has been designated as a waived test or is otherwise subject to certificate of waiver requirements pursuant to the federal clinical laboratory improvement act of nineteen hundred eighty-eight, as amended.
6. "Qualified health care professional" means a physician, dentist, podiatrist, physician assistant, specialist assistant, nurse practitioner, or midwife, who is licensed and registered with the state education department.
7. "Provider-performed microscopy procedure" means a procedure performed by a qualified health care professional acting within the scope of his or her licensed profession, which has been designated as a provider-performed microscopy procedure pursuant to the federal clinical laboratory improvement act of nineteen hundred eighty-eight, as amended.
8. "Laboratory test registrant" means a person, partnership, corporation, or other entity holding a valid certificate of registration to perform one or more waived tests or provider-performed microscopy procedures pursuant to section five hundred seventy-nine of this title.

§ 572. Certificates of qualification.

No person shall act as a director in a clinical laboratory located in or accepting specimens from New York state or in a blood bank located in or collecting, processing, storing or distributing blood products in New York state unless a valid certificate of qualification has been issued as provided in section five hundred seventy-three of this title. A certificate shall be issued authorizing the holder to perform or direct one or more procedures or one or more categories of such procedures.

§ 573. Issuance of certificates of qualification.

1. The public health council shall prescribe minimum qualifications for directors in areas of testing, including, but not limited to, microbiology, immunology, chemistry, hematology, biophysics, cytology, pathology, genetics and blood banking.
2. The department shall issue a certificate of qualification to any person who meets such minimum qualifications and who otherwise demonstrates to the department that such person possesses the character, competence, training and ability to administer properly the technical and scientific operation of a clinical laboratory or blood bank, including supervision of procedures and reporting of findings of tests.
3. Application for a certificate of qualification shall be made on forms provided by the department and shall contain the procedures or categories of procedures for which the certificate is sought and such other information as the department may require.
4. The certificate shall be valid for a period of two years from the date of issuance and may be renewed for successive two year periods thereafter. The original application and each renewal application shall be accompanied by a registration fee of forty dollars.
5. Notwithstanding the provisions of this section, the commissioner may issue a temporary certificate of qualification to any person pending the issuance of a certificate as provided in this

section. A temporary certificate shall be valid for a period of thirty days from the date of its issuance and may be renewed for a maximum of four successive periods of thirty days.

§ 574. Permits.

No person shall own or operate a clinical laboratory located in or accepting specimens from New York state or own or operate a blood bank which collects, processes, stores and/or distributes, human blood, blood derivatives or blood components, in New York state unless a valid permit has been issued as provided in section five hundred seventy-five of this title. A permit shall be issued authorizing the performance of one or more procedures or services within one or more categories. A separate permit shall be required for each facility at which clinical laboratory tests are to be performed or at which a blood bank is to be operated, provided, however that the department may adopt regulations not inconsistent with the federal clinical laboratory improvement act of nineteen hundred eighty-eight authorizing an owner to operate more than one facility under a single permit.

§ 575. Issuance of permits.

1. Application for a permit shall be made by the owner and the director of the clinical laboratory or blood bank in a manner and format prescribed by the department. The application shall contain the name of the owner, the name of the director, the procedures or categories of procedures or services for which the permit is sought, the location or locations and physical description of the facility or location or locations at which tests are to be performed or at which a blood bank is to be operated, and such other information as the department may require.
2. A permit or permit category shall not be issued unless a valid certificate of qualification in the category of procedures for which the permit is sought has been issued to the director pursuant to the provisions of section five hundred seventy-three of this title, unless all fees and outstanding penalties, if any, have been paid, and the department finds that the clinical laboratory or blood bank is competently staffed and properly equipped, and will be operated in the manner required by this title.
3. The permit shall be issued jointly to the owner and the director and they jointly and severally shall be responsible to the department for the maintenance and operation of the clinical laboratory or blood bank and for any violations of this title and the rules and regulations promulgated thereunder.
4. A permit shall be valid for the year for which it is issued. The initial application for a permit shall be accompanied by a registration fee of one hundred dollars.
5. The permit shall specify the names of the owners and the director, the procedures or categories of procedures or services authorized, and the locations at which such procedures or services may be performed. The permit and the certificate of qualification shall be displayed at all times in a prominent place in the laboratory.
6. A permit shall become void by a change in the director, owner, or location. A category on a permit shall become void by a change in the director for that category. The department may, pursuant to regulations adopted under this title, extend the date on which a permit or category on a permit shall become void for a period not to exceed sixty days from the date of a change of the director, owner or location. An application for a new permit must be made in the manner provided by this section.

§ 576. Duties and powers of the department.

1. The department may inquire into the operation of clinical laboratories and blood banks and may conduct periodic inspections and/or evaluations of facilities, methods, procedures, materials, staff and equipment to assess compliance with requirements set forth in this title, the

regulations promulgated hereunder and local laws, codes or regulations as specified in subdivision three of section five hundred eighty of this title.

2. The department may require clinical laboratories and blood banks to submit, in a form prescribed by the department, periodic reports of tests performed and such other information as the department may require to carry out the provisions of this title. The department may adopt regulations to require clinical laboratories and blood banks to report all serious adverse incidents which may be connected to the clinical laboratory or blood bank services provided. Such incident reports shall be deemed confidential in the same manner as such reports submitted pursuant to section twenty-eight hundred five-m of this chapter. The department may also require clinical laboratories and blood banks to submit lists of personnel who are employed to perform laboratory procedures and to notify the department promptly of any changes in such personnel.

3. The department shall operate a reference system and shall prescribe standards for the proper operation of clinical laboratories and blood banks and for the examination of specimens. As part of such reference system, the department may review and approve testing methods developed or modified by clinical laboratories and blood banks prior to the testing methods being offered in this state, and may require clinical laboratories and blood banks to analyze test samples submitted by the department and to report on the results of such analyses. The rules and regulations of the department shall prescribe the requirements for the proper operation of a clinical laboratory or blood bank, for the approval of methods and the manner in which proficiency testing or analyses of samples shall be performed and reports submitted. Failure to meet department standards for the proper operation of a clinical laboratory or blood bank, including the criteria for approval of methods, or failure to maintain satisfactory performance in proficiency testing shall result in termination of the permit in the category or categories of testing established by the department in regulation until remediation is achieved. Such standards shall be at least as stringent as federal standards promulgated under the federal clinical laboratory improvement amendments of nineteen hundred eighty-eight. Such failure and termination shall be subject to review in accordance with regulations adopted by the department.

4. (a) The department may adopt and amend rules and regulations to effectuate the provisions and purposes of this title. Such rules and regulations shall establish fees for clinical laboratories and blood banks in amounts not exceeding the cost of the reference system for clinical laboratories and blood banks and shall be subject to the approval of the director of the budget. For the purposes of this subdivision, standard federally established governmental cost allocation practices shall be used by the commissioner to determine the cost of the reference system. The department shall make available, on the department's website, information on the costs included in determining the permitted laboratories' fees. The department shall not deem as costs of the reference system, costs associated with federal grants and patents which are not related to the reference system. The fee paid by the department to maintain an exemption for clinical laboratories and blood banks from the requirements of the federal clinical laboratory improvement amendments of nineteen hundred eighty-eight shall be deemed a cost of the reference system.

(b) In determining the fee charges to be assessed, the department shall, on or before May first of each year, compute the costs for the preceding state fiscal year which were expended to operate and administer the duties of the department pursuant to this title. The department shall, at such time or times and pursuant to such procedure as it shall determine by regulation, bill and collect from each clinical laboratory and blood bank an amount computed by multiplying such total computed operating expenses of the department by a fraction the numerator of which is the gross annual receipts of such clinical

laboratory or blood bank during such twelve month period preceding the date of computation as the department shall designate by regulation, and the denominator of which is the total gross annual receipts of all clinical laboratories or blood banks operating in the state during such period.

(c) Each such clinical laboratory and blood bank shall submit to the department, in such form and at such times as the department may require, a report containing information regarding its gross annual receipts for all activities performed pursuant to a permit issued by the department in accordance with the provisions of section five hundred seventy-five of this title. The department may require additional information and audit and review such information to verify its accuracy.

(d) Partial payments equal to one-quarter of the total amount billed, may be made on or before June thirtieth, September thirtieth, December thirty-first and March tenth of the fiscal year to which the billing relates.

(e) On or before September fifteenth of each year, the department shall reconcile its costs and expenses for the reference system for the preceding state fiscal year and shall, on or before October fifteenth send to each clinical laboratory and blood bank, a statement setting forth the amount due and payable by, or the amount computed to the credit of, such clinical laboratory or blood bank, computed on the basis of the above stated formula, except that for the purposes of such computation the fraction shall be multiplied against the total recomputed expenses of the department for such fiscal year. Any amount due shall be payable not later than thirty days following the date of such statement. Any credit shall be applied against any succeeding payment due.

(f) The commissioner may waive all or any part of such fee charges for clinical laboratories or blood banks operated by local governments and for nonprofit clinical laboratories or blood banks performing examinations and analyses or providing services under contract with the state or its local governments.

(g) Subject to the approval of the director of the budget, the commissioner shall charge adequate and reasonable fees for the periodic inspection of out-of-state clinical laboratories and blood banks, not exceeding the estimated additional costs incurred for out-of-state inspections under this title.

5. The department, within the amounts appropriated, may employ inspectors, investigators, assistants and other employees or may contract with the city of New York to carry out the provisions of this title, set the compensation of such employees, within limits provided by law, and prescribe the duties of such employees.

6. The commissioner may appoint one or more advisory committees of persons expert in the major categories of clinical laboratory procedures to advise the commissioner in connection with the qualifications of technical personnel employed and the use of appropriate procedures. Each such advisory committee shall include at least one designee of the commissioner of the department of health of the city of New York.

7. The department may adopt rules or regulations applicable only to or in the city of New York which are designed to address special needs or circumstances existing in such city. The department shall consider the recommendations of the city of New York, or the department or board of health of such city, concerning the adoption or amendment of any such rules or regulations.

8. The department may enter into agreements with the secretary of health and human services as authorized by the federal clinical laboratory improvement act of nineteen hundred eighty-eight and title XVIII of the social security act to perform such acts as may be necessary to assure conformance with such laws by laboratories operating in the state.

§ 576-a. Clinical laboratories and cytotechnologists examining Pap smears.

1. Definitions.

As used in this section, unless the context clearly requires otherwise, the following terms shall have the following meanings:

- (a) "Cytotechnologist". A clinical laboratory professional specializing in the analysis of cytopathology samples, including Pap smears, for cervical cancer and related diseases who meets the qualifications specified by the department.
- (b) "Cytotechnologist work standard".
 - (i) A limitation on the number of Pap smears (also known as gynecologic slides) and non-gynecologic slides a cytotechnologist may examine during a particular time period, or other limitation on the quantity, speed or manner of examination of slides by a cytotechnologist, under regulations of the department.
 - (ii) Unless otherwise provided by the department, the cytotechnologist work standard shall be: No cytotechnologist may examine more than eighty one-slide gynecologic cases or fifty two-slide gynecologic cases per work day. If a cytotechnologist also examines non-gynecologic slides in a given work day the cytotechnologist's workload for gynecologic slides shall be correspondingly reduced, in accordance with written guidelines prepared by the clinical laboratory and filed with the department, so that a cytotechnologist examines no more than a total of one hundred gynecologic and non-gynecologic slides per work day.
- (c) "Employ". To employ or contract with a cytotechnologist to examine gynecologic slides.
- (d) "Clinical laboratory". A clinical laboratory issued a permit pursuant to this title.
- (e) "Work day". A twenty-four hour period during which a cytotechnologist examines gynecologic slides for a clinical laboratory.

2. Compliance with cytotechnologist work standard. No cytotechnologist shall exceed the applicable cytotechnologist work standard. No clinical laboratory shall require, authorize, encourage or permit any cytotechnologist to exceed the applicable cytotechnologist work standard. In determining whether a cytotechnologist exceeds the applicable cytotechnologist work standard, all work done by the cytotechnologist during a given work day shall be considered, without regard to which clinical laboratory or other person for which or whom it was performed.

3. Registration of cytotechnologist. All cytotechnologists who are employed by a clinical laboratory must register with the department. The department shall, by regulation, prescribe a form and procedure for the registration of cytotechnologists. The registration form shall include at least the name, address, and an individual identification number determined by the department. The department shall notify each registrant of his or her identification number.

4. Employment of registered cytotechnologists. No clinical laboratory shall employ a cytotechnologist unless the cytotechnologist is registered under this section.

5. Record-keeping.

- (a) Each clinical laboratory shall maintain records, in a form prescribed by the department, which set forth, for each cytotechnologist employed by the clinical laboratory:
 - (i) the name and identification number of the cytotechnologist;
 - (ii) the number of hours worked by the cytotechnologist in each work day;
 - (iii) the number of gynecologic slides and non-gynecologic slides examined by the cytotechnologist, and how many were one-slide and two-slide cases, during each work day; and
 - (iv) such other information as the department may require by regulation.
- (b) Each cytotechnologist shall maintain records, in a form prescribed by the department, which set forth:

- (i) the number of hours worked by the cytotechnologist in each work day;
- (ii) the number of gynecologic slides and non-gynecologic slides examined and how many were one-slide and two-slide cases, during each work day;
- (iii) the name and address of the clinical laboratory or other person for which or whom the slides were examined; and
- (iv) such other information as the department may require by regulation.

(c) Such records of clinical laboratories and cytotechnologists shall be made available for inspection and copying by the department upon request.

6. Multiple employers. Whenever a cytotechnologist is employed by more than one clinical laboratory or other person during a work day, the cytotechnologist shall advise each clinical laboratory of any previous employment during the work day and the amount of work performed, to insure that the applicable cytotechnologist work standard is not exceeded.

7. Standards for gynecologic slides.

(a) A gynecologic slide of a Pap smear shall not be tested or reported on if:

- (i) the apparent condition of the specimen indicates that it is unsatisfactory for testing or that it is inappropriate for the test requested;
- (ii) it has been collected, labeled, preserved or otherwise handled in such a manner that it has become unsatisfactory or unreliable as a test specimen;
- (iii) the slide is broken;
- (iv) it contains insufficient cells or the cells are obscured by inflammation, blood or lubricating ointment, so that an adequate diagnosis cannot be made; or
- (v) the slide is otherwise unsatisfactory, as defined by department regulations.

(b) If the slide is unsatisfactory as set forth in this subdivision, the clinical laboratory shall have an affirmative duty to advise the collecting physician or other practitioner that the slide is unsatisfactory and request the submission of a new slide.

8. Re-examination of slides. The department shall prescribe, by regulation, a system of targeted re-examination of gynecologic slides examined and found to be not abnormal or questionable. The factors to be considered in the targeted re-examination may include, but are not limited to, the prior cancer and other history of the patient, the results of previous slide examinations, and the experience and ability of the cytotechnologist. Each clinical laboratory shall follow the prescribed re-examination system.

9. Regulations. The department may, by regulation, establish cytotechnologist work standards. Those standards may include, but shall not be limited to, standards which take into account the experience and qualifications of the cytotechnologists and the performance of the clinical laboratory in proficiency testing programs conducted by the department. However, those standards shall not exceed by more than twenty percent the maximum numbers of slides which may be examined in a work day under clause (ii) of paragraph (b) of subdivision one of this section. Such standards shall be at least as stringent as federal standards promulgated under the federal clinical laboratory improvement amendments of nineteen hundred eighty-eight.

10. Notwithstanding any provisions of subdivisions one and nine of this section to the contrary, the department may, pursuant to regulation, increase the maximum number of slides which may be examined in a work day for clinical laboratories using slide examination or preparation technology approved by the federal food and drug administration, provided that such standards shall be at least as stringent as federal standards promulgated under the federal clinical laboratory improvement amendments of nineteen hundred eighty-eight or other applicable federal law.

11. Violations.

(a) Sections twelve, twelve-a, and twelve-b of this chapter shall apply to violations of this section, except that the civil penalty for a violation of this section by a cytotechnologist shall not exceed five hundred dollars.

(b) If a cytotechnologist violates this section, the department may suspend or revoke the cytotechnologist's registration under this section, pursuant to department regulations including appropriate due process protections for the cytotechnologist.

(c) If any clinical laboratory or other person violating this section is licensed, certified or registered by the department under other provisions of law, the violation of this section may be grounds for disciplining the person under such law.

§ 576-b. Performance of certain clinical laboratory services upon request.

1. A clinical laboratory may perform a clinical laboratory service (including accepting a specimen or assignment for examination and rendering a report), that it is otherwise allowed to perform, upon the request of the person on whom the service is to be performed and render a report directly to the person, where the service is for the same purpose as a test or collection device that has been approved or cleared by the Food and Drug Administration of the United States Department of Health and Human Services for sale or distribution to the public on a direct or over-the-counter basis without a prescription from a qualified health care practitioner.

2. All services conducted pursuant to this section shall comply with the standards for testing established by the department and with any other laws of this state, including requirements for confidentiality and pre-test and post-test counseling.

3. The results of any test conducted pursuant to this section shall be provided only to the person who requested the test. Such results shall be provided in a clear and concise manner that is understandable by lay persons and that identifies results indicating the need for referral to a physician or other qualified health care practitioner.

4. Nothing in this section shall authorize a clinical laboratory to engage in the practice of any health care profession under title eight of the education law. The report issued to a person for a test conducted pursuant to this section shall contain a clear statement, presented in a prominent manner, to the effect that the report should not be viewed as medical advice and is not meant to replace direct communication with a physician or other health care practitioner.

§ 576-c. Electronic reporting of disease and specimen submission.

1. Whenever a clinical laboratory or blood bank is otherwise required by this chapter to report evidence of a disease or health condition to the commissioner or a local health officer, the laboratory director shall report the test results and such data elements as are determined by the commissioner to be necessary as authorized by law. All reports shall be sent electronically to the department in a standards based electronic format, using a network, communications protocol, clinical syntax and vocabulary all as determined by the commissioner to be compatible with national health information standards promulgated by the federal centers for disease control and prevention and the department of health and human services. Reports shall be submitted on a schedule determined by the commissioner.

2. Clinical laboratories and blood banks may continue to submit reports in paper copy to the commissioner and/or local health officer as otherwise required by this chapter until the earlier of the date the laboratory director receives notice that the laboratory has been certified to report electronically or one year after the effective date of this section. Thereafter, all reports shall be sent electronically to the department.

3. In the event the system for electronic reporting is unavailable for any reason, including lack of certification for electronic reporting, clinical laboratories and blood banks shall make reports

to the local health officer of the county of the patient's residence and the commissioner using an alternate mechanism determined by the commissioner.

4. Whenever the commissioner or a local health officer determines that supplemental testing is necessary to confirm evidence of a disease or health condition otherwise required to be reported to the commissioner or a local health officer pursuant to this chapter, or to further identify the characteristics of a causative agent for reasons of public health protection, the laboratory shall submit all or part of the specimen or its derivatives with patient identifiers to the department or its designee, or the local health officer or his or her designee, in a manner and as directed by the commissioner.

5. The commissioner may adopt rules and regulations necessary to implement the provisions of this section.

§ 577. Enforcement.

1. A permit or certificate of qualification may be revoked, suspended, limited or annulled, or the holder thereof censured, reprimanded or otherwise disciplined by the department on proof that the certificate holder, owner or director, or one or more persons in his or her employ:

(a) has been guilty of misrepresentation in obtaining the permit or certificate or in the operation of the clinical laboratory or blood bank, including the submission to the department of proficiency test results obtained from another clinical laboratory;

(b) has knowingly accepted or permitted to be accepted a specimen or assignment for clinical laboratory examination from or rendered a report thereon to a person or persons not authorized by law to submit such assignment or specimen or receive such report;

(c) has engaged or attempted to engage or represented himself or herself as entitled to perform any procedure or category or procedures or services he or she is not authorized to perform;

(d) has rendered a report on work actually performed in another clinical laboratory or blood bank without designating the fact that the examination or procedure was performed in another clinical laboratory or blood bank;

(e) has demonstrated incompetence or shown consistent errors in performance of examinations or procedures;

(f) has failed to file any report required by the provisions of this title or the rules and regulations promulgated thereunder;

(g) has violated or aided and abetted in the violation of any provision of this chapter, including this title, title six of this article, or the rules and regulations promulgated pursuant to this chapter or a violation of title eleven of article five of the social services law or the rules and regulations promulgated thereunder related to laboratory services; or

(h) has violated or aided and abetted in the violation of local laws, codes or regulations as specified in subdivision three of section five hundred eighty of this title.

(i) has been found upon inspection by the department to be in noncompliance with a provision or provisions of this title or the rules and regulations promulgated hereunder, and has failed to address such findings as required by the department.

2. Proceedings under this section may be initiated by any person, corporation, association or public officer, or by the department, by filing written charges with the department.

3. No permit or certificate shall be revoked, suspended, limited or annulled without a hearing, except as provided in subdivision three of section five hundred seventy-six of this title.

However, a permit or certificate may be temporarily suspended without a hearing for a period not to exceed thirty days upon notice to the permit or certificate holder following a finding by the department that the public health, safety or welfare is in imminent danger.

4. The commissioner shall set a time and place for the hearing. A copy of the charges, together with the notice of the time and place of the hearing, shall be mailed to the permit or certificate holder, at the address specified on the permit at least fifteen days before the date set for the hearing. The permit or certificate holder shall file with the department, not less than five days prior to the hearing, a written answer to the charges.

5. Any person or entity which owns or operates a clinical laboratory and who does not hold a valid laboratory permit shall be liable to the people of the state for a civil penalty not to exceed two thousand dollars for each day for the unauthorized operation of the clinical laboratory.

§ 578. Penalties.

1. (a) A person who owns or operates a clinical laboratory or blood bank, and who does not hold a valid permit issued pursuant to the provisions of this title or who otherwise does not comply with this title or the New York city health code is guilty of a misdemeanor, punishable by imprisonment for not more than one year, or by a fine of not more than two thousand dollars, or by both such fine and imprisonment. For any subsequent offense, the penalty shall be both such fine and imprisonment.

(b) A person who owns or operates a clinical laboratory or blood bank and willfully misreports laboratory results or otherwise fails to comply with the provisions of this title is guilty of a class A misdemeanor, punishable by imprisonment for not more than one year, or by a fine of not more than one thousand dollars, or by both such fine and imprisonment.

2. A person who acts as a director after July first, nineteen hundred sixty-five, and who does not hold a valid certificate of qualification issued pursuant to the provisions of this title is guilty of a misdemeanor, punishable by imprisonment for not more than one year, or by a fine of not more than five hundred dollars or by both such fine and imprisonment.

§ 579. Scope and exceptions.

1. This title is applicable to all clinical laboratories and blood banks operating within the state, except clinical laboratories and blood banks operated by the federal government and clinical laboratories operated by a licensed physician, osteopath, dentist, midwife, nurse practitioner or podiatrist who performs laboratory tests or procedures, personally or through his or her employees, solely as an adjunct to the treatment of his or her own patients; to the extent authorized by federal and state law, including the education law, and consistent with any applicable written practice agreement.

2. This title shall not be applicable to and the department shall not have the power to regulate pursuant to this title:

(a) any examination performed by a state or local government of materials derived from the human body for use in criminal identification or as evidence in a criminal proceeding or for investigative purposes;

(b) any test conducted pursuant to paragraph (c) of subdivision four of section eleven hundred ninety-four of the vehicle and traffic law and paragraph (c) of subdivision eight of section 25.24 of the parks, recreation and historic preservation law;

(c) any examination performed by a state or local agency of materials derived from the body of an inmate, pretrial releasee, parolee, conditional releasee or probationer to (i) determine, measure or otherwise describe the presence or absence of any substance whose possession, ingestion or use is prohibited by law, the rules of the department of corrections and community supervision, the conditions of release established by the board of parole, the conditions of release established by a court or a local conditional release commission or the conditions of any program to which such individuals are referred and (ii) to determine whether there has been a violation thereof; or

- (d) any examination performed by a coroner or medical examiner for the medical-legal investigation of a death. Nothing herein shall prevent the department from consulting with the division of criminal justice services, the department of corrections and community supervision, the state police, or any other state agency or commission, at the request of the division of criminal justice services, the department of corrections and community supervision, the state police, or such other agency or commission, concerning examination of materials for purposes other than public health.
3. (a) This title shall not be applicable to any person, partnership, corporation or other entity performing any waived test or provider-performed microscopy procedure, provided such person, partnership, corporation or other legal entity:
- (i) holds a valid certificate of registration issued by the department authorizing the performance of one or more waived tests or provider-performed microscopy procedures; and
 - (ii) only performs tests authorized by the certificate of registration; and
 - (iii) otherwise complies with all applicable requirements of this subdivision.
- (b) The department may issue a certificate of registration authorizing the performance of one or more waived tests or provider-performed microscopy procedures for a period of up to two years if the applicant:
- (i) files a completed application with the department on such forms as the commissioner may prescribe;
 - (ii) provides documentation acceptable to the department demonstrating the ability to comply with the requirements of this subdivision; and
 - (iii) pays a two hundred dollar biennial registration fee for each location where services are rendered, except that the following may operate multiple locations under a single registration and pay a single registration fee:
 - (A) not-for-profit, state or local government laboratories or programs engaged in limited public health testing not exceeding fifteen types of tests per registration; or
 - (B) applicants that maintain a fixed location in the state and are approved by the department to move from testing site to testing site.
- (c) Laboratory test registrants shall:
- (i) provide only the tests and services listed on the registration issued by the department hereunder;
 - (ii) advise the department of any change in the registrant's name, ownership, location or qualified health care professional or laboratory director designated to supervise testing within thirty days of such change;
 - (iii) provide the department with immediate access to all facilities, equipment, records, and personnel as required by the department to determine compliance with this subdivision;
 - (iv) comply with all public health law and federal requirements for reporting reportable diseases and conditions to the same extent and in the same manner as a clinical laboratory;
 - (v) perform one or more tests as required by the department to determine the proficiency of the persons performing such tests; and
 - (vi) designate a qualified health care professional or qualified individual holding a certificate of qualification pursuant to section five hundred seventy-three of this title, who shall be jointly and severally responsible for:
 - (A) establishing, approving and continuously updating policies, procedures and personnel qualifications for each test employed;

- (B) establishing a comprehensive quality assurance system which includes, but is not limited to, test selection, test quality, laboratory proficiency and personnel competency;
 - (C) ensuring all tests are performed in accordance with the manufacturers' instructions and standards of practice in laboratory medicine;
 - (D) maintaining complete and accurate records of the tests performed, including but not limited to, the patient's name, results, person performing the test, and quality control data;
 - (E) ensuring that persons do not participate in diagnostic or treatment decisions using such test results unless such persons are authorized by law to do so;
 - (F) ensuring that provider-performed microscopy procedures are performed only by a qualified health care professional operating within the scope of practice for his or her profession and as part of the physical examination performed by such professional; and
 - (G) complying with other applicable laws, rules and regulations.
- (d) A certificate of registration shall become void by a change in the owner of the laboratory test registrant or location of testing.
- (e) Notwithstanding the foregoing, if the commissioner determines that the performance of a particular waived test or provider-performed microscopy procedure in a facility or location which does not possess a New York state clinical laboratory permit creates a risk of harm to the subjects of such test, the commissioner may issue an order prohibiting such test from being performed in any location other than a permitted clinical laboratory, physician's office or other location exempted by subdivision one or two of this section.
- (f) Registration under this subdivision may be denied, limited, suspended, revoked or annulled by the department upon a determination that a laboratory services registrant:
- (i) failed to comply with the requirements of this subdivision;
 - (ii) provided services that constitute an unwarranted risk to human health;
 - (iii) intentionally provided any false or misleading information to the department relating to registration or performing laboratory services; or
 - (iv) has demonstrated incompetence or shown consistent errors in the performance of examinations or procedures. A registration shall not be limited, suspended, revoked or annulled without a hearing conducted in accordance with subdivision four of section five hundred seventy-seven of this title. However, a registration may be temporarily limited, suspended, revoked or annulled without a hearing for a period not to exceed thirty days upon notice to the registrant following a finding by the department that the public health, safety or welfare is in imminent danger.
- (g) The commissioner may adopt such rules and regulations as may be necessary to effectuate the purposes of this subdivision.
- (h) Any person, partnership, corporation or other entity performing waived tests or provider-performed microscopy procedures without being authorized to do so pursuant to this title shall be subject to a civil penalty of up to five hundred dollars for each test performed, not to exceed two thousand dollars per day for each day tests are performed, in violation of this subdivision.
- (i) All fees and civil penalties collected pursuant to this subdivision shall be deposited in the special revenue account established for the receipt of inspection and reference fees collected pursuant to section five hundred seventy-six of this title and shall be subtracted from the operating expenses of the department prior to calculation of such inspection and reference fees.

§ 580. Construction.

1. Nothing in this title shall be construed as affecting the educational program of any college or university or any legally chartered school approved by the department of education which program is conducted for the training of its students.
2. Nothing in this title shall be construed as affecting facilities which perform laboratory tests solely for research purposes, nor as affecting laboratory testing by a public health officer as part of an epidemiological investigation in which no patient identified result is reported for diagnostic purposes to a health care provider or the subject of the test.
3. (a) Nothing in this title shall be construed to impair or affect the power or authority of the city of New York or a department or agency thereof, to enact or enforce additional laws, codes or regulations affecting clinical laboratories or blood banks, not inconsistent with the provisions of this title or any regulations promulgated hereunder, related to the control, prevention or reporting of diseases or medical conditions or to the control or abatement of public health nuisances. Noncompliance with such laws, codes or regulations as documented by the local public health officer may be a basis for the department's denial or non-renewal of a laboratory permit or a certificate of qualification.
(b) Such local laws, codes or regulations which are more restrictive than or additional to the requirements set forth in this title or the regulations promulgated hereunder shall be deemed not inconsistent.
4. The collection, processing, storage, distribution or use of blood, blood components or blood derivatives for the purpose of diagnosis, prevention or treatment of disease is hereby declared to be a public health service and shall not be construed to be, and is declared not to be, a sale of such blood, blood components or blood derivatives, for any purpose or purposes whatsoever.
5. Notwithstanding any inconsistent provision of the education law, individuals performing only waived tests or provider-performed microscopy procedures in accordance with the provisions of subdivision three of section five hundred seventy-nine of this title shall not be required to be licensed or certified as a clinical laboratory practitioner pursuant to the education law.

§ 581. Separability.

If any clause, sentence, paragraph, section or part of this title shall be adjudged by any court of competent jurisdiction to be invalid, the judgment shall not affect, impair, or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph, section, or part thereof directly involved in the controversy in which the judgment shall have been rendered.