§ 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, optometrist performing a clinical laboratory test that does not use an invasive modality as defined in section seventy-one hundred one of the education law 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.

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 incarcerated individual, 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 a voluntary ambulance service as defined in article thirty of the public health law and operated under section two hundred nine-b of the general municipal law shall be exempt from the requirement to pay a fee to obtain this certificate of registration; and 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.