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**RULES
OF
DEPARTMENT OF COMMUNITY HEALTH**

**CHAPTER 111-8
HEALTHCARE FACILITY REGULATION**

**111-8-10
LICENSURE OF CLINICAL LABORATORIES**

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111-8-10-.01 Legal Authority.

The legal authority for this chapter is found in Chapters 2, 7 and 22 of Title 31 of the Official Code of Georgia Annotated.

Authority: O.C.G.A. §§ 31-2-5 et seq., 31-7-1 et seq. and 31-22-1 et seq.

111-8-10-.02 Purpose.

The purpose of these rules is to implement the requirements of Chapter 22 of Title 31 of the Official Code of Georgia Annotated pertaining to the licensure of clinical laboratories and the qualifications and performances of laboratory personnel.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.03 Definitions. Amended.

Unless a different meaning is required by the context, the following terms as used in these rules and regulations shall have the meaning hereinafter respectively ascribed to them:

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(a) **Analyte** means a substance or constituent for which the laboratory conducts testing;

(b) **Board** means the Board of Community Health of the State of Georgia;

(c) **Clinical Laboratory** means a facility for the biological, microbiological, serological, immunological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from or produced by the human body for the diagnosis of, recommendation of, treatment of, or for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings, the term "Clinical Laboratory" shall include specimen collection stations and shall include blood banks which provide through their ownership or operation a system for the collection, processing, or storage of human blood and its components as well as tissue banks which procure, store, or process human or animal tissues designed to be used for medical purposes in human beings;

(d) **CLIA-exempt state** means a state where the Centers for Medicare & Medicaid Services (CMS) has determined that the state has enacted laws/rules relating to laboratory requirements that are equal to or more stringent than CLIA requirements. All laboratories subject to state licensure will be considered as "CLIA exempt" where the state has been determined to be CLIA exempt;

(e) **Commissioner** means the Commissioner of the Department of Community Health of the State of Georgia;

(f) **Department** means the Georgia Department of Community Health;

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(g) **Director** means a person who is responsible for the administration of the technical and scientific operation of a clinical laboratory, including supervision of procedures for testing and the reporting of results;

(h) **Evaluation Program** means a state-conducted or state-approved proficiency testing program;

(i) **Facility** means a building, structure, institution, place, or entity, which may be fixed or mobile;

(j) **Laboratory Advisory Council** means the Clinical Laboratory, Blood Bank and Tissue Bank Committee authorized and required by law and appointed by the Board;

(k) **Laboratory Test** means any examination and/or manipulation performed on a specimen produced by the human body, by procedures such as phlebotomy or blood diverted from a normal or life-sustaining circulatory path, or in vivo testing of body fluids for the purpose of diagnosis, treatment, monitoring or the assessment of the health of human beings;

(l) **Limited specialty laboratory or limited laboratory specialty** means a clinical laboratory, or part of a clinical laboratory, in which testing is restricted (limited) to a designated category or subcategory, including but not necessarily limited to the following examples: cytology, histology, tissue banking, special chemistries (radio bioassay, blood gases, toxicology, etc.), cytogenetics and histocompatibility;

(m) **Other Personnel** means non-technical personnel who may be employed in the laboratory such as aides, clerks, etc. These persons may assist laboratory technical staff, but do not themselves qualify as technical staff or perform tests;

(n) **Person** means any individual, firm, partnership, association, corporation, the State or any municipality or other

subdivision thereof, or any other entity whether organized for profit or not;

(o) **Pertinent Laboratory Experience** means full time or equivalent work in a clinical laboratory, directing, supervising or performing tests in all categories, or, when limited to laboratory specialty(ies), work is restricted to that category/subcategory;

(p) **Plan of Correction** means a written plan submitted by the laboratory director, owner, or other controlling authority, for approval by the Department. The plan shall identify the existing noncompliance of the laboratory and the proposed procedures, methods, means and reasonable period of time needed to correct the noncompliance;

(q) **Point of Care Technician** means a medical professional person subject to these rules, who has received special training in point of care testing as defined by these rules. Medical professional staff authorized to perform point of care testing are limited to registered professional nurses, certified nurse practitioners, licensed practical nurses, certified respiratory care professionals, physician assistants, certified paramedics, certified emergency medical technicians, perfusionists, laboratory technologists, laboratory technicians and certified cardiovascular technologists, radiologic technologists certified by a professional credentialing organization approved by the Department, and phlebotomists, certified by a professional credentialing organization approved by the Department;

(r) **Point of Care Testing** means testing performed in the immediate proximity of the patient. All point of care testing must be approved by and under the supervision of a Georgia-licensed laboratory, unless the test site meets the requirements for exemption. All such point of care testing shall be approved only in the specialties for which the laboratory holds a license. Testing shall be limited to procedures which meet all current Georgia rules

for quality control, quality assurance and Point of Care Testing personnel requirements. Point of Care Testing is exclusive of screening and monitoring tests;

(s) **Quality Assurance** means a comprehensive process used by the laboratory to prevent and control errors that may occur at any interval from the time a test is ordered until it is reported and charted;

(t) **Quality Control Program** means those quality control requirements established for clinical laboratories as provided in applicable federal law and regulations and in Georgia law and regulations;

(u) **Screening and Monitoring Tests.** Screening tests mean those simple laboratory tests, approved by the Board as screening tests, used to aid in the detection of previously undiagnosed conditions. Monitoring tests mean those simple laboratory tests, approved by the Board as monitoring tests, with performance characteristics (accuracy and precision) that allow the tests to be used for evaluation of the status of previously diagnosed conditions and/or for evaluation of response to medical management;

(v) **Specimen Collection Station** means a place or entity, without regard to location, that either collects specimens directly from patients or brings specimens together after collection for the purpose of forwarding them either intrastate or interstate to a licensed/certified clinical laboratory for examination;

(w) **Specimen Collector and/or Phlebotomist** means any person who has been trained in procedures requiring understanding and skills in the procurement of specimens for clinical laboratory analysis in Clinical Chemistry, Hematology, Immunohematology, Microbiology, and Immunology/Serology and

who works under the general supervision of the laboratory director, supervisor or technologist;

(x) **Supervisor** means an assistant to the director and a person with special scientific skills, who, under the general supervision of a clinical laboratory director, supervises technical personnel;

(y) **Technician** means any person other than the clinical laboratory director, supervisor, technologist, or trainee who functions under the supervision of a clinical laboratory director, supervisor, or technologist and performs only those clinical laboratory procedures which require limited skill and responsibility and a minimal exercise of independent judgment as described in 111-8-10-.06(5)(a). The degree of supervision by the clinical laboratory director, supervisor, or technologist of a technician shall be determined by the director, supervisor, or technologist based on:

1. The complexity of the procedure to be performed;
2. The training and capability of the technician; and
3. The demonstrated competence of the technician in the procedure being performed;

(z) **Technologist** means a person who performs clinical laboratory procedures which require the exercise of independent judgment and responsibility, with minimal supervision by the director or supervisor, in only those specialties or subspecialties in which they are qualified by education, training, experience, and certification.

(aa) **Trainee** means a person who is enrolled in an accredited training program or who, in a limited laboratory specialty(ies) for which there is no accredited training program available, trains

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under the supervision of a director, supervisor, or technologist qualified in the specialty(ies), but does not report actual patient test results without prior supervisory approval.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.04 License.

(1) Clinical Laboratory License.

(a) No clinical laboratory shall be operated without a license issued pursuant to these rules and regulations and without a licensed director. All laboratory activities, which are not specifically exempted by these regulations, must be performed in a license laboratory. Provided, however, a facility or part of a facility in which laboratory testing is done may qualify for exemption from personnel requirements when only specific tests or techniques, designated by the Department and used for screening and monitoring purposes only, are performed, and the facility or part of the facility is under the supervision of the laboratory as outlined in Rule 111-8-10-.16.

(b) A license shall be issued by the Department to a clinical laboratory after all requirements for licensure are met.

(c) A provisional license may be issued as an authorization to operate a clinical laboratory for a limited and specified period of time under the following conditions:

1. After a review of an application and on-site inspection of a new laboratory has indicated that the laboratory has the potential to meet required standards and appears to be in substantial compliance with the requirements of these rules and regulations;
or

2. An inspection or review of a licensed laboratory reveals only correctable deficiencies for which an acceptable plan of correction has been provided to Licensure of Clinical Laboratories Chapter 111-8-10 the Department and where the deficiencies do not constitute imminent hazards to patients or to laboratory personnel.

(d) A license shall authorize the performance of one or more categories, subcategories and/or test procedures and shall be valid for one year from the date of issue unless sooner canceled, suspended or revoked. Renewal of a license is subject to continued conformance with all rules and regulations.

(e) A license shall specify the names of the owner and director, categories and subcategories of tests, and the location of the laboratory. The laboratory license must be displayed at all times in view of the public.

(f) A license shall be valid only for the clinical laboratory (as defined at 111-8-10-.03(c)) at the stated location and shall not be subject of sale or transfer to any premises other than those for which it was issued. Should the laboratory change its location, or ownership, a new application shall be made.

(g) Laboratory licenses shall be maintained current and changes in categories/subcategories of tests or off site locations shall not be implemented without prior notification to and approval by the Department.

(h) Specimen collection stations which have a parent clinical laboratory which is licensed by the State of Georgia may be considered by the Department to be a part of that laboratory; but subject to all other applicable regulations.

(2) Director's License.

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(a) A director's license shall be issued by the Department to persons meeting the requirements stated in these rules and regulations. Applications for licensure or renewal as a director shall be made on a form provided by the Department accompanied by the non-refundable fee, and provide pertinent information as deemed necessary by the Department.

(b) The director's license shall be maintained current and changes in the required information shall be reported to the Department when they occur. Application shall be made and approved by the Department prior to assumption of duties as a laboratory director.

(c) Any licensed laboratory director who is convicted, pleads guilty or nolo contendere or receives first offender treatment under the laws of this state, the United States, or any other state of any criminal offense involving the manufacture, distribution, trafficking, sale, or possession of a controlled substance or marijuana shall notify the Department of the conviction within ten days following the conviction, plea or first offender treatment.

Authority: O.C.G.A. §§ 16-13-111 and 31-22-1 et seq.

111-8-10-.05 Fees.

(1) Each original application for licensure and each application for annual renewal for a clinical laboratory shall be accompanied by the non-refundable fee set by the Board. These fees as determined by the Board shall be applicable to all laboratories. Each screening and monitoring approval shall pay a non-refundable processing and inspection fee as set by the Board.

(2) A non-refundable fee set by the Board shall accompany each application and renewal for licensure as a clinical laboratory

director. Each license or renewal shall be valid for two years, unless suspended or revoked, or voluntarily terminated.

(3) Changes in fees and/or development of additional fee schedules may be established by the Board, without formal change in the rules and regulations.

Authority: O.C.G.A. § 31-22-1 et seq.

**111-8-10-.06 Laboratory Personnel Requirements,
Personnel Qualifications and Personnel Records.**

(1) Laboratory Personnel Requirements:

(a) **General.** The laboratory shall perform tests in only those categories, subcategories or procedures for which it is licensed and for which there is either a director, supervisor, or technologist having minimum qualifications as outlined for Clinical Laboratory Technologists in Rule 111-8-10-.06(4). (Special personnel requirements for donor screening and plasmapheresis and whole blood donor centers are outlined in Rule 111-8-10-.28). In addition, the following criteria shall be minimum personnel qualifications for the supervision of the categories and subcategories below:

1. Clinical Chemistry, Hematology, Immunohematology, Microbiology, Clinical Immunology and Serology: Supervisory requirements for these categories are those requirements for Clinical Laboratory Supervisor, outlined in Rule 111-8-10-.06(3).

2. Exfoliative Cytology. For the purpose of these rules, exfoliative cytology is defined as that part of laboratory science dealing with the examination of cells obtained from human body fluids, surfaces, tissues, and other sources. This service must be provided by either a licensed physician who is certified or eligible for certification in anatomic pathology or cytopathology by the

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American Board of Pathology or the American Osteopathic Board of Pathology or by applicants who have a doctoral degree and whose special field is cytology. Unless the physician/Ph.D. also serves as cytology general supervisor, the supervisor must meet the minimum qualifications outlined in Rule 111-8-10-.06(3)(b)5 or current federal regulations of § 353 of the Public Health Service Act and Title 42 U.S.C. 263a, whichever is more stringent.

3. Anatomic Pathology. For the purpose of these rules, anatomic pathology is defined as the examination and diagnosis of human tissues whether removed during life or after death. It deals with the morphologic study of normal or abnormal structure of tissues. For the purpose of these rules, this definition includes performance of all autopsies including medical-legal, and forensic autopsies. The laboratory director, if not so qualified, shall engage the services of a licensed physician who is certified or eligible for certification in an anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

4. Oral Pathology. For the purpose of these rules, oral pathology is defined as a branch of anatomic pathology (see (a)3. above). The laboratory director, if not qualified in oral pathology, shall engage the services of a licensed physician who is certified or eligible for certification in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or those of a dentist, licensed in the State of Georgia, who is certified or eligible for certification by the American Board of Oral Pathology.

5. Radiobioassay. For the purposes of these rules, radiobioassay is defined as the diagnostic in vivo study involving administration of radioactive materials to a human subject (with the exclusion of organ scanning). Laboratories performing tests in radiobioassay must have a director or supervisor who is a physician working in Georgia in the field of radiobioassay at the time of the adoption of these rules and regulations or is qualified

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and trained in nuclear medicine or radioisotopic pathology and/or is certified or eligible for certification by the American Board of Nuclear Medicine or the subspecialty of radioisotopic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology. If not so qualified, the laboratory must engage the services of one so qualified:

(i) In vitro studies of organs, tissues, or fluids, using radioactive materials are considered in the licensed category of Clinical Chemistry (special) and may be handled by those appropriately qualified in this area.

(ii) For both in vivo and in vitro studies, all users of radioactive material must comply with Georgia "Rules and Regulations for Radioactive Material", Chapter 290-5-23.

6. Qualifications for test areas not included in above general categories may be established as Department policy.

(b) **Directors.** Each licensed laboratory shall be under the direction of a licensed laboratory director whose responsibilities and qualifications are outlined in Rule 111-8-10-.06(2). The director may delegate Point of Care Testing oversight to qualified laboratory supervisors; however, such delegation must be in writing. In addition, delegation of authority does not relieve director of responsibilities as outlined in these regulations regarding Point of Care Testing.

(c) **Supervisors.** With the exception of a laboratory in which the director also qualifies and serves as supervisor, each laboratory shall have one or more supervisors who serve as assistants to the laboratory director and whose responsibilities are outlined in Rule 111-8-10-.06(3). Such personnel must spend an adequate amount of time in the laboratory to supervise the performance of the work in the laboratory and must be readily available at other times for on-site or telephone consultation.

(d) **Technologists and Technicians.** Each laboratory shall engage the services of a sufficient number of clinical laboratory technologists, and/or clinical laboratory technicians to meet the workload demands including prompt performance, reporting and record-keeping of test results, quality control and proficiency testing.

(e) **Point of Care Technicians.** Each point of care testing site subject to state licensure shall utilize medical professional staff, as defined in these rules to perform such testing.

(f) **Specimen Collectors and Phlebotomists.** A laboratory may employ specimen collectors and/or phlebotomists whose responsibilities are outlined in Rule 111-8-10-.06(7).

(g) **Other Personnel.** No person may perform laboratory tests within a licensed laboratory unless they qualify as a trainee, technician, technologist, supervisor, or director as defined in these rules. Other personnel may be employed in the laboratory such as aides, clerks, etc. These persons may assist the laboratory technical staff, but do not themselves qualify as technical staff, perform patient testing or operate clinical analyzers.

(h) **Personnel Records:**

1. Personnel records shall be kept current. They shall include a complete resume of each employee's training, experience, duties, competency evaluation and date or dates of employment. Personnel forms shall be submitted to the Department in a timely manner.

2. The laboratory is responsible for maintaining written documentation (in the personnel file of each employee performing testing) which demonstrates that the employee meets the personnel qualifications as set forth in these rules.

(2) **Licensed Laboratory Directors.**

(a) Responsibilities and general requirements:

1. Each licensed clinical laboratory shall be under the direction of a licensed laboratory director who is responsible for the operation of the laboratory at all times, who must spend an adequate amount of time in the laboratory to administer the technical and scientific operation of the laboratory, is responsible for the proper performance and reporting of laboratory findings, and is responsible for adequate staffing by qualified laboratory personnel, their in-service training and work assignment.

(i) There must be documentation completed by the laboratory director or supervisor, of competency to perform testing by an individual initially before patient testing is performed and not less than annually, thereafter, unless test methods or instruments change, in which case the director or supervisor is responsible for completing a new competency validation on the individual(s) before test results can be reported. Competency is to be measured against an established performance standard as defined by the laboratory director. Methods for validation of competency for each procedure must include:

(I) Direct observation of test performance through the testing of previously analyzed specimens and internal blind samples or external proficiency testing samples previously run and recorded. Testing samples may not be labeled as competency evaluation material, but must be treated as patient samples for routine processing;

(II) Review of test results from tests performed as a part of the competency assessment;

(III) Assessment of response to problems or situations related to the procedure;

(IV) Review of documentation of critical incidents related to the individual's performance of the procedure;

(V) Response to written or oral questions related to the procedures and, if applicable to the individual's responsibilities;

(VI) Assessment of the performance of calibration, and review of records pertaining to quality control and instrument maintenance.

(ii) The laboratory director may delegate the responsibility for competency assessment to other directors or supervisors in the laboratory meeting the qualifications described in 111-8-10-.06(2) and 111-8-10-.06(3).

(iii) The licensed laboratory director shall ensure that no individual performs any laboratory procedure independently without first having demonstrated competency for the procedure as described above in 111-8-10-.06(2)(a)1.(i).

(iv) When a director will be continuously absent for more than four weeks, arrangements must be made for a qualified substitute licensed director.

2. In addition to responsibilities outlined at 111-8-10-.06(8)(a) and (b) of these rules, the director is responsible for ensuring that all testing is instituted and conducted in a manner that complies with all applicable rules. The director, in consultation with appropriate medical staff, shall prepare an internal needs assessment for point of care testing which shall include evaluation of patient benefits and criteria for establishing the necessity of such testing. The assessment shall also include an evaluation of proposed methodologies for tests to be performed. The director is

responsible for terminating testing in cases where there is consistent non-compliance with applicable rules or substandard performance.

3. There must be a written plan of action for how patient testing and reporting is handled when either laboratory or point of care testing fails. The director must ensure that, when recommended by the manufacturer, all screening tests performed must have confirmatory tests performed in a timely manner. The director must also ensure that the laboratory is enrolled and successfully participates in an approved proficiency testing program and that each Point of Care Testing area either enroll and successfully participate in an approved proficiency testing program *or* successfully participate in an approved program subscribed to by the responsible laboratory. Point of Care Testing methods, analyzers, or test areas must be challenged the number of times a year as is consistent with the requirement for clinical laboratories under state and/or current federal regulations. The director may delegate his or her authority, to assure that all applicable state regulations are met, to a supervisor that is qualified as defined in these rules and regulations.

4. Each licensed clinical laboratory must be served by a licensed clinical laboratory director, (permitted to direct no more than three clinical laboratories at a given time), on a full time or regular part-time basis. However, no licensed clinical director (Restricted) shall be permitted to direct more than one clinical laboratory at a given time.

(b) Qualifications:

1. Each licensed clinical laboratory in Georgia shall be directed by a licensed clinical laboratory director who qualifies under either (i), (ii), (iii), (iv), or (v) below, and whose practice is to be restricted according to the subparagraph under which he/she qualifies.

(i) **Licensed Clinical Laboratory Director.** A licensed clinical laboratory director must hold a license to practice medicine and surgery pursuant to Chapter 34 of Title 43 of the Official Code of Georgia Annotated, or a Georgia license to practice dentistry, or hold an earned doctoral degree in biology, microbiology, chemistry or related fields, and must either be certified or eligible for certification by one of the following:

(I) The American Board of Pathology or the American Board of Osteopathic Pathology in Clinical and/or Anatomic Pathology;

(II) The American Board of Oral Pathology;

(III) The American Board of Medical Microbiology;

(IV) The American Board of Clinical Chemistry;

(V) The American Board of Bioanalysts [Clinical Laboratory Director (CLD) and/or Bioanalyst Clinical Laboratory Director (BCLD)]; or

(VI) The American Board of Medical Laboratory Immunology;
or

(VII) Qualified by other combinations of pertinent laboratory training and experience, in one or more of limited laboratory specialties, which are acceptable to the Department.

(ii) **Licensed Clinical Laboratory Director (Restricted).** In recognition that certain laboratories, due to varying circumstances, have difficulty providing a laboratory director qualified under the requirements above, the clinical laboratory director's license (restricted) is authorized for issuance to new applicants who are physicians or possess an earned doctoral degree and who are

qualified as laboratory supervisors under Rule 111-8-10-.06(3)(b)1. or (b)2. , and who meet the following requirements:

(I) The person will serve as director of only one laboratory at a given time;

(II) The served laboratory employs not more than ten full-time technical employees (supervisors, technologists, and technicians) or equivalent number of part-time technical employees; and

(III) The laboratory must also employ a qualified full-time or regular part-time clinical laboratory supervisor or pathologist.

(iii) **Licensed Clinical Laboratory Director (Plasmapheresis and/or Whole Blood Donor Centers).** The director of a plasmapheresis and/or whole blood donor center shall be a physician licensed in Georgia, who is qualified by training and/or experience in blood banking and/or plasmapheresis procedures and who shall be responsible for the medical, technical and clerical services, including special services such as phlebotomy for autologous transfusion, and special pheresis technique.

(iv) **Licensed Clinical Laboratory Director (Specimen Collection Station).** Each specimen collection station which is not a part of a parent clinical laboratory that is licensed by the State of Georgia must have a licensed clinical laboratory director. The director of a Specimen Collection Station shall be a person who is licensed to practice medicine in Georgia, or who holds an earned doctoral degree in biology, microbiology, chemistry or a related field and have pertinent clinical laboratory experience related to specimen collection.

(v) A person, who at the time of adoption of these regulations holds a current Georgia license as a clinical laboratory director, may renew the license and continue to function with same or

similar duties and responsibilities upon application and payment of license fee. Persons who qualify under this provision but who are inactive for two (2) consecutive years must meet current requirements. Provided, further, that individuals and laboratories so concerned must meet all other standards of performance required by law and accompanying rules and regulations.

2. In addition to the directorship of the clinical laboratory, the director may participate in actual laboratory work only in those areas in which qualified by training and experience. For those categories in which the director is not qualified, a supervisor must be employed who is qualified in accordance with Rule 111-8-10-.06(3) to perform and/or supervise those procedures independently.

3. The person serving as a hospital laboratory director must be a member of the hospital medical staff.

(3) Laboratory Supervisor.

(a) **Responsibilities and general requirements.** With the exception of a laboratory in which the director also serves as supervisor, each laboratory must have an adequate number of qualified personnel who are assistants to the director, and who, under his/her general direction may function as supervisors, depending upon the size of the laboratory and diversity of the laboratory testing. A supervisor must be available for two-way communication within 30 minutes during all hours of operation, for the purpose of supervising technical personnel. For Point of Care Testing areas, the responsible supervisor must be qualified at a minimum under subparagraph (3)(b)4 of this rule. In addition, the supervisor of the testing area must be available for two-way communication within 30 minutes during all hours of operation. The supervisor is responsible for developing a quality control and quality assurance program for each test area that is equal

to or more stringent than current federal and applicable state requirements. No Point of Care Testing area may be operated without a qualified supervisor.

(b) **Qualifications.** A supervisor shall meet one of the following minimum requirements:

1. Hold a license to practice medicine and surgery pursuant to Chapter 34 of Title 43 of the Official Code of Georgia Annotated and have at least two years of pertinent laboratory experience; or

2. Hold a doctoral degree from an accredited institution with a chemical, physical, or biological science as the major subject and have at least two years of pertinent laboratory experience; or

3. Hold a master's degree from an accredited institution with a major in one of the chemical, physical or biological sciences, allied health science or laboratory management, and have at least three years of pertinent laboratory experience as a technologist as outlined in Rule 111-8-10-.06(4)(b) of these rules and regulations; or

4. Qualify as a clinical laboratory technologist under Rules 111-8-10-.06(4)(b)1. , 2., 3. or 4. and have at least four years of pertinent laboratory experience as a technologist as outlined in Rule 111-8-10-.06(4)(b); or

5. In the limited specialty laboratory or limited laboratory specialty(ies), the supervisor must meet one of the above conditions or, if restricted to the category or subcategory, must meet one of the following:

(i) Hold a master's degree with a major in a chemical, physical, or biological science, allied health science, or laboratory management; be a graduate of an accredited program in the

specialty and have at least two years pertinent laboratory experience in the specialty as technologist; or

(ii) Hold a bachelor's degree in the specialty; or a degree with a major in chemical, physical, or biological sciences and be a graduate of a program in the specialty accredited by an agency accepted by the Department, or have one year of training in a clinical laboratory environment; and have at least three years of pertinent laboratory experience in the specialty as a technologist; or

(iii) Qualify as a technologist under Rule 111-8-10-.06(4)(b)6.(i) and have at least four years of pertinent laboratory experience in the specialty as a technologist.

(iv) A cytology supervisor must be a physician licensed to practice medicine in Georgia, and be certified in anatomic pathology by the American Board of Pathology, or the American Osteopathic Board of Pathology, and be licensed by the Department as a laboratory director.

(v) A cytotechnologist general supervisor must meet the requirements of Rule 111-8-10- 4(b)6.(iii) and have 3 years full time experience as a cytotechnologist in a clinical laboratory.

(vi) A histocompatibility supervisor must be a pathologist who is board certified in anatomical and clinical pathology, a licensed physician or doctor of osteopathy with four years experience in histocompatibility, or a Ph.D. with two years general immunology and two years histocompatibility experience.

(vii) The histopathology supervisor must be a licensed physician or doctor of osteopathy, and be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology, and licensed by the Department as a laboratory director.

(viii) The histotechnologist general supervisor must have formal training, be certified by an approved crediting agency and have two years of pertinent experience.

6. Persons who have been continuously engaged as laboratory supervisors in Georgia since July 1, 1970, are exempt from the personnel qualifications listed above. Persons who initially qualified under this provision and who become inactive for two (2) consecutive years for any reason must meet current requirements. Provided, further, individuals and laboratories so concerned must meet all other standards of performance required by this law and applicable rules and regulations.

(4) **Technologist.**

(a) **Responsibilities and general requirements.**

Technologists, under general supervision, exercise independent judgment to perform and report findings proficiently for clinical laboratory tests. In the case of technologists who are qualified only in limited laboratory specialties, work as a technologist shall be limited to those respective specialties in which qualified.

(b) **Qualifications.** Each technologist shall successfully complete a certification examination from the American Society for Clinical Pathology (ASCP), the American Medical Technologists (AMT), the National Credentialing Agency for Laboratory Personnel (NCA), the American Association of Bioanalysts (AAB), or another agency approved by the Department, and shall meet one of the following requirements, listed in 1. through 7. below:

1. Successful completion of a full course of study which meets all academic requirements for a bachelor's degree in medical technology from an accredited college or university; or

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2. Successful completion of three years of academic study (a minimum of 135 quarter hours or equivalent) in an accredited college or university and the successful completion of a course of training of at least 12 months in a school of medical technology accredited by an agency recognized by the Council for Higher Education Accreditation (CHEA) or the U.S. Department of Education; or

3. Successful completion in an accredited college or university of a course of study which meets all academic requirements for a bachelor's degree in one of the chemical, physical, or biological sciences, and have at least one year of pertinent laboratory experience or training accepted by the Department; or

4. Successful completion of 135 quarter hours in an accredited college or university, including 24 quarter hours of chemistry, 24 quarter hours of biology, and 5 quarter hours of mathematics, (thirty quarter hours of the total, with a minimum of fifteen in science, must be at the third or fourth year level), and have at least two years of pertinent laboratory experience; or

5. Successful completion of a full course of study which meets all academic requirements for an associate's degree in medical technology from an accredited college or university, or successful completion of two years of academic study (a minimum of 90 quarter hours or equivalent) in an accredited college or university which included at least 20 quarter hours of lecture and laboratory courses in chemical, physical, or biological sciences acceptable toward a major in science, with at least three years of pertinent laboratory experience; or graduation from high school and successful completion of a formal technician training course which is accredited by an accrediting agency accepted by the Department with at least four years of pertinent laboratory experience; or

6. In the limited specialty laboratory or limited laboratory specialty(ies) , a technologist is restricted to the category or subcategory of testing authorized to be performed in the limited laboratory, and must have satisfactorily completed either:

(i) Ninety (90) quarter hours in an accredited college or university with at least 20 quarter hours in science and one year of pertinent laboratory experience or training accepted by the Department; or

(ii) At least two years of pertinent laboratory experience as a technician under the supervision of a director qualified in the specialty, or a one-year formal training program accepted by the Department in the specialty; or

(iii) Cytotechnologists must be certified by specialty examination by the American Society for Clinical Pathology (ASCP), or another agency approved by the Department; or

(iv) Histotechnologists must have formal training and specialty certification by the American Society for Clinical Pathology (ASCP) or another agency acceptable to the Department.

7. Persons who possess the technologist qualifications under provisions (b)1. through 6. above and have recently moved into the state or have recently completed the academic and training/experience requirements may be temporarily classified once as technologists for eighteen (18) months to afford the persons an opportunity to successfully complete an approved qualifying examination.

8. Persons who have been continuously engaged as technologists in Georgia since July 1, 1970, are exempt from the personnel qualifications listed above. Persons who initially qualified under this provision but become inactive for two consecutive years must meet current requirements. Provided

further, that individuals and laboratories so concerned must meet all other standards of performance required by this law and applicable rules and regulations.

(c) **Technologist allowable testing.** Technologists shall be permitted to independently perform all laboratory procedures for which the technologist has been trained and demonstrated competency as described under 111-8-10-.06(2)(a)1.(i). Where the technologist chooses to delegate the performance of any test requiring more than limited skill and responsibility and exercise of independent judgment as described in 111-8-10-.06(5)(c):

1. The delegating technologist shall ensure that the individual to whom the testing has been delegated meets at a minimum the qualifications described in 111-8-10-.06(5)(b) and has documented competency for performance of the test as described in 111-8-10-.06(2)(a)1.(i);
2. The delegating technologist shall be responsible for the accuracy of the test results; and
3. The delegating technologist shall ensure that a qualified technologist is available onsite or by telephone for consultation regarding the testing or for review of results; and
4. In those cases where a qualified technologist is not available on site during the performance of the delegated test, but is only available on call, the performance of those tests shall only be delegated to an individual who has completed a technician-level certification test approved by the Department, has completed a full course of study which meets all academic requirements for an associate's degree in medical technology from an accredited college or university, and has completed a minimum of two years of pertinent full time laboratory experience, one year of which experience has been obtained in the laboratory where they will be performing the delegated test.

(5) **Technician.**

(a) **Responsibilities and general requirements.** The laboratory must employ a sufficient number of qualified technicians to meet the workload demands, and they must function under the direct supervision of a technologist, supervisor or director. The decision regarding the degree of supervision necessary shall be determined by consideration of the complexity of the procedure, the training and capability of the technician, and the demonstrated competency of the technician in the procedure to be performed. The determination of the degree of supervision under which the technician performs any type of laboratory testing must be documented in the technician's job description and personnel record. In the case of technicians who are qualified only in limited laboratory specialties, work as a technician shall be limited to those respective specialties in which qualified.

1. For any testing performed by a technician, there must be documentation in the technician's personnel record of training and competency testing of the technician to perform the test.
2. Documentation of the test and reporting of results must be retained, for the purpose of supervisory review, for all testing performed independently by a technician.

(b) **Qualifications.** Each technician shall successfully complete a certification examination from the American Society for Clinical Pathology (ASCP), the American Medical Technologists (AMT), the National Credentialing Agency for Laboratory Personnel (NCA), the American Association of Bioanalysts (ABB), or another agency approved by the Department and shall meet one of the following requirements listed in 1. through 4. below: 1. Has earned an associate's degree in medical laboratory technology; or successful completion of two years of academic study (a minimum of 90 quarter hours or equivalent) in

an accredited college or university which included at least 20 quarter hours of lecture and laboratory courses in chemical, physical, or biological sciences acceptable toward a major in science and have at least one year of pertinent laboratory experience or training accepted by the Department; or

2. Graduation from high school and successful completion of a formal technician training course which is accredited by an accrediting agency accepted by the Department; or

3. Graduation from high school and subsequent to graduation has obtained two years of pertinent laboratory experience in a clinical laboratory of a hospital, a health department, university, or in an independent clinical laboratory; or

4. For persons who possess the technician qualifications under provisions above and have recently moved into the state or completed the academic and/or training requirements, they may be temporarily classified once as technicians for eighteen (18) months to afford them an opportunity to successfully complete an approved qualifying examination.

5. Persons who have been continuously engaged as technicians in Georgia since July 1, 1970 are exempt from personnel qualifications listed above. Persons who initially qualified under this provision but become inactive for two consecutive years for any reason must meet current requirements. Provided, further, individuals and laboratories so concerned must meet all other standards of performance required by this law and applicable rules and regulations.

(c) **Technician allowable testing.** Technicians shall be permitted to perform tests requiring limited skill and responsibility and a minimal exercise of independent judgment, and for which the technician has demonstrated competency as described in 111-8-10-.06(2)(a)1.(i), to include:

1. CLIA waived tests;
2. Complete blood count (CBC) utilizing automated/semi-automated methods with internal support systems;
3. Routine chemistries utilizing automated/semi-automated methods with internal support systems; and
4. Coagulation studies utilizing automated methods.

(6) **Trainee.** A trainee is a person who is enrolled in an accredited training program, or who, in a limited laboratory specialty(ies) for which there is no accredited training program, works and trains under the direct supervision of a qualified director, supervisor, or technologist qualified in the specialty(ies), but does not report actual patient test results without prior supervisory review. A person may function as a trainee for the duration of the formal approved training program or for a maximum period of 24 months.

(7) **Specimen Collector and/or Phlebotomist.** The laboratory may employ specimen collectors, qualified by training and/or experience approved by the laboratory director, to perform, under general supervision, collection procedures requiring understanding and skills in the procurement of specimens for clinical laboratory analysis. Documentation of qualifying training and/or experience must be available in the laboratory's personnel files. The collector may also perform exempt screening and monitoring tests as outlined in Rule 111-8-10-.16 of these regulations. Phlebotomists certified by the American Society for Clinical Pathologists (ASCP), the American Medical Technologists (AMT), the National Healthcareer Association (NHA), the National Center for Competency Testing (NCCT), the American Association of Bioanalysts (ABB), or another professional credentialing

organization that has been approved by the Department , may perform Point of Care Testing in accordance with these rules.

(8) Point of Care Technician.

(a) **Responsibilities and general requirements.** Point of Care technicians must function under the supervision of a laboratory director and/or supervisor appointed by the director. These technicians must complete all training requirements as outlined in subparagraph (b) of this rule.

(b) Qualifications:

1. Professional background. Point of Care technicians must have one of the following medical professional backgrounds: licensed registered nurse, certified nurse practitioner, licensed practical nurse, certified respiratory care professional, physician assistant, perfusionist, certified paramedic or certified emergency medical technician, radiologic technologist, certified cardiovascular technologist certified by a professional credentialing organization approved by the Department, medical technologist and medical technician qualified by these rules, or a phlebotomist certified by a professional credentialing organization approved by the Department.

2. Training. The laboratory director is responsible for determining and maintaining documentation of an individual's credentials which qualify him or her to perform Point of Care Testing. The director may delegate this responsibility to a qualified supervisor. The documentation of qualifications to perform point of care testing must include the following: training, licensure, certification or other medical professional background information as well as competency certification documentation. In all cases, an individual must be trained and his or her competency verified prior to the director or supervisor allowing the individual to perform patient testing. Such training must include, at a minimum, proper

specimen collection and handling, proper use of test instruments, proper storage, handling and preparation of test kits/reagents, quality control, quality assurance, remedial action and record keeping. Training must also include troubleshooting to the extent that results will not be reported when instrument or quality control problems arise.

(9) **Other Personnel.** Other personnel may be employed in the laboratory, such as aides, clerks, etc. These persons may assist laboratory technical staff in the performance of non-clinical tasks, but do not qualify as technical staff, perform technical tests or operate testing devices.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.07 Application.

(1) Applications for licensure of clinical laboratories shall be made on forms provided by the Department and shall indicate from the following list, those categories, subcategories and/or procedures for which the facility requests licensure:

(a) Clinical Chemistry;

1. Routine;

2. Urinalysis;

3. Special (includes Radiobioassay, Blood Gases, Medical Toxicology, Therapeutic Drug Monitoring, Immunohistochemistry, etc.)

(b) Hematology;

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(c) Immunohematology (including Group/Type/Crossmatch, Antibody Screen/Identification, Storage, Transfusion Services, Pheresis/ Components, Donor Services (autologous, general), Histocompatibility.

(d) Microbiology;

1. Bacteriology (Level I – Direct microscopic examination of smears; Level II – Primary culture, report no growth and refer growth for identification; Level III – Culture and Identification and/or Sensitivity Testing);

2. Mycobacteriology (Level I – Direct microscopic examination of smears for acid fast organisms; Level II – Primary culture, report no growth and refer growth for identification; Level III – Culture, Identification and/or Sensitivity Testing);

3. Mycology (Level I – Direct microscopic examination for fungi; Level II – Primary culture, report no growth and refer growth for identification; Level III – Culture, Identification and/or Sensitivity Testing);

4. Parasitology; and

5. Virology.

(e) Clinical Immunology and Serology:

1. Syphilis;

2. Non-syphilis;

3. Viral Serology;

4. HIV (Screening/Confirmation).

- (f) Pathology;
 - 1. Exfoliative Cytology;
 - 2. Anatomic Pathology; and
 - 3. Oral Pathology.
- (g) Radiobioassay.
- (h) Tissue Banking.
- (i) Cytogenetics.
- (j) Inherited Metabolic Disorder Testing of Newborns.
- (k) Specimen Collection Station(s).
- (l) Point of Care Testing.
- (m) Other: (ART, andrology, molecular genetics).

(2) If a facility provides any laboratory testing services it must apply for and obtain one or more appropriate laboratory licenses (or screening and monitoring approvals) as needed to cover all laboratory services provided and must meet all requirements of these regulations. Where testing beyond the scope of authorized laboratory services is performed, these additional tests must be obtained from a duly licensed laboratory that meets all requirements of these regulations or from an out-of-state laboratory holding a current federal certificate for laboratory testing.

(3) The application for licensure in the category of specimen collection station shall be made on forms provided by the Department, and shall indicate the name and address of the

laboratory or laboratories to which specimens are submitted for testing.

(4) Application for screening and monitoring approvals shall be made on forms provided by the Department and shall provide pertinent information as deemed necessary by the Department.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.08 Sanitation and Safety.

(1) **General.** All laboratories shall be well lighted, maintained in a clean, neat, orderly and professional manner, and operated in a manner which will prevent undue physical, chemical, or biological hazards to its employees or other members of the community, and shall meet local and state sanitation and safety regulations:

(a) Adequate lighting shall be provided for the work area at bench top level.

(b) Syringes, needles, lancets, or other bloodletting devices capable of transmitting infection from one person to another shall be of a disposable type or shall be cleaned and sterilized before use, in accordance with accepted sterilization procedures.

(2) **Sanitary Facilities.** All laboratories shall have suitable sanitary facilities, including toilet and hand washing facilities, within the premises. New installations and major renovations completed after the effective date of these rules shall include hand washing and toilet facilities for visitors and patients, separate from those provided for employees.

(3) **Garbage and Rubbish Disposal.** All laboratories shall provide facilities for maintaining sanitary standards, including water

supply, sewage, garbage and refuse disposal, throughout the laboratory structure and premises. Such facilities shall meet local and state regulations, and shall be maintained in a clean and orderly manner. Cultures and specimens shall be discarded in an appropriate manner.

(4) **Safety.** Laboratory locations and facilities must conform to local and state building and safety and fire codes and ordinances where applicable. There shall be sufficient space, equipment and facilities to perform the services provided by the laboratory with reasonable accuracy and safety:

(a) Work involving the licensed subcategories of mycobacteriology (Levels II or III), mycology (Levels II or III), and appropriate virology shall be performed under a biological safety cabinet with a rating of Class IIA/B3. Safety cabinets shall exhaust filtered air directly to the outside when a recirculation air conditioning system is used. Laboratories utilizing a single pass ventilation system with their safety cabinet may exhaust air back into the laboratory. All laboratory procedures which involve liberation of large amounts of toxic, corrosive or explosive substances shall be performed under a fume hood that has a face velocity of 100 feet per minute and an independent exhaust system;

(b) Cylinders of compressed gas shall be properly secured by restraining chains, brackets or other materials that are sufficiently strong to support the weight of the cylinder;

(c) Flammable or combustible liquids shall be in containers not larger than one liter, in safety cans, in cabinets suitable for storage of flammable or combustible liquids or must otherwise comply with the requirements established by the state fire marshal; flammable liquids requiring refrigeration shall be stored in an Underwriters' Laboratory labeled explosion-proof refrigerator or

otherwise comply with the requirements established by the state fire marshal;

(d) Laboratories utilizing corrosive materials or solutions shall have an appropriately located safety spray hose or shower;

(e) Each plumbing fixture shall be provided with air gap or vacuum breaker where necessary to eliminate back-siphoning hazards.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.09 General Quality Control Requirements.

Each laboratory shall establish and follow written policies and procedures for a quality assurance program, comprehensive in scope and specific to that laboratory. The program shall monitor and evaluate the ongoing and overall quality of the total testing process from specimen collection to reporting of test results. The program shall identify and correct problems, assure the accurate, reliable and prompt reporting of test results and assure adequacy and competency of laboratory staff. Written procedures shall be revised when evaluation results indicate the need. There must be documentation of the ongoing quality assurance program as well as corrective action taken when necessary. The laboratory director is responsible for ensuring that the following quality controls are employed for all clinical testing authorized under the laboratory's license:

(a) Preventive maintenance, periodic inspection or testing for proper operation of equipment and instruments, based on but not limited to manufacturers' instructions. The laboratory must confirm the effectiveness of its preventive maintenance program;

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(b) Each quantitative method shall be validated prior to placing into routine use. Such validation shall include reportable range, sensitivity, specificity, accuracy and precision. Documentation of validation shall be maintained for the period the method is used, or for at least two years, whichever is longer;

(c) Evaluation of reagents and volumetric equipment;

(d) Maintenance of documentation verifying that test systems perform according to laboratory specification; such documentation must be available to the authorized persons ordering or receiving test results, and to the Department; the laboratory must establish its reference range for each method before reporting patient test results;

(e) Establishment and employment of policies/procedures for remedial action to be taken in response to quality control outside acceptable limits, equipment or methodology performance outside established operating limits, test results outside acceptable limits, tests not performed within laboratory established time frames, proficiency test results outside acceptable limits or errors detected in reported patient results;

(f) Adequacy of space, ventilation, facilities, equipment, instruments, and methods of performance of the procedures or categories of procedures for which a license application is filed or granted; proper lighting for accuracy and precision; convenient location of essential utilities; monitoring of temperature controlled spaces and equipment to assure proper performance of equipment and storage of specimens, tissues, reagents and supplies; the evaluation of analytical measuring devices, with respect to all critical operating characteristics, and the laboratory shall not report test results unless such operating characteristics are within defined acceptable ranges;

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(g) Labeling of all reagents and solutions to indicate identity, and when significant, titer, strength or concentration, recommended storage and preparation or expiration date, and other pertinent information. Material of substandard reactivity, expired, or deteriorated materials may not be used;

(h) Availability at all times, in the immediate bench area of personnel engaged in examining specimens and performing related procedures within a category, of laboratory manuals or other complete written descriptions and instructions (properly designated and dated to reflect an initial and periodic review by the current director) relating to the current analytical methods, specimen processing procedures, reagents, control and calibration procedures, microscopic examinations, remedial action procedures, limitations in methodologies, pertinent literature references and the date each procedure was placed into use. Textbooks may be used as supplements to such written descriptions but may not be used in lieu thereof;

(i) Written approval by the director of any and all changes in laboratory procedures; a copy of each procedure must be retained for two years after the procedure has been discontinued;

(j) Maintenance and availability to laboratory personnel, and to the Department, of records, reflecting dates, and where appropriate, the nature of inspection, validation, remedial action, monitoring, evaluation, and alternative test methods;

(k) Written materials designed to provide instruction for proper collection, labeling, preservation and transportation of specimens to assure accurate results suitable for clinical interpretation.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.10 Quality Control for Microbiology.

Chemical or biological solutions, reagents, and antiserum shall be tested and inspected as prescribed by the Department for reactivity and deterioration. Discs and systems used in antibiotic susceptibility testing are checked for deterioration and proper reactivity, using approved reference organisms.

(a) **Bacteriology, Mycobacteriology and Mycology.**

Staining material shall be tested for intended reactivity by weekly application to smears of microorganisms with predictable staining characteristics, with the exception of fluorochrome acid fast stains, which must be checked each day of use. Each batch of media shall be tested before or concurrently with use with selected organisms to confirm required growth characteristics selectivity, enrichment, and biochemical response. The laboratory may use commercial manufacturers' quality control checks of media if the laboratory has documentation to verify that the manufacturer meets the National Committee for Clinical Laboratory Standards (NCCLS) requirements for media quality control. Each day of use the laboratory must test direct antigen detection systems using positive and negative control organisms that evaluate both the extraction and reaction phases.

(b) **Parasitology.** A reference collection of slides, photographs, or gross specimens of identified parasites shall be available in the laboratory for the appropriate comparison with diagnostic specimens. A calibrated ocular micrometer shall be used for determining the size of ova and parasites, if size is a critical factor. Staining material shall be tested for intended reactivity, using a fecal sample control that will demonstrate staining characteristics, whenever a new lot number of reagent is opened or once a month, whichever comes first;

(c) **Virology.**

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1. Systems for the isolation of viruses and reagents for their identification shall be available to cover the entire range of viruses that are etiologically related to clinical diseases for which services are offered.
2. Records shall be maintained which reflect the systems used, and the reactions observed. In tests for the identification of viruses, controls shall be employed which will identify erroneous results.
3. Physical facilities and safety cabinets must be adequate and appropriate for the extent of testing offered.
4. There must be a written procedure in place and utilized by the laboratory for the proper disposal of infectious materials and biohazardous waste.
5. Host systems must be checked for sensitivity to viral agents and sterility.
6. Continuous cell lines must be checked for bacterial/fungal contamination as appropriate.
7. Storage requirements and expiration dates must be observed and recorded.
8. Diluents must be checked for sterility and pH.
9. Records must be kept of cell types, passage number, source, lot numbers and media used for growth and maintenance.
10. In tests for the identification of viruses, the laboratory must simultaneously culture uninoculated cells or cell substrate controls as a negative control to detect erroneous identification results.

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11. Inoculated cultures must be checked for cytopathic effect at appropriate intervals.

12. Records must be kept of all quality control and quality assurance for as long as required under current federal regulations or not less than two years, whichever is more stringent.

13. If serodiagnostic tests for viral diseases are performed, requirements for quality control as specified for serology and immunology shall apply as listed at 111-8-10-.09(4).

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.11 Quality Control for Serology/Immunology.

(1) Serologic and immunologic tests on unknown specimens shall be run concurrently with a positive control serum of known titer or controls of graded reactivity plus a negative control in order to detect variations in reactivity levels. Controls for all test components shall be employed to ensure reactivity and uniform dosage. Test results shall not be reported unless the redetermined pattern of the control is obtained.

(2) Each new lot of reagent shall be tested with one of known acceptable reactivity, or with known control sera before or concurrent with the new lot of reagent being placed into routine use.

(3) Equipment, glassware, reagents, controls and techniques for tests for syphilis shall conform to manufacturers' specifications, where applicable.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.12 Quality Control for Clinical Chemistry.

(1) The laboratory must verify (validate) that each method or testing system functions in the laboratory as specified by the manufacturer. Verification includes reportable range, accuracy, sensitivity and specificity. Verification studies must be done upon introduction of a new methodology; a laboratory may not report test results beyond or below its own established range.

(2) Calibration, or calibration verification must be performed:

(a) According to manufacturer specifications, or every six months, whichever is sooner;

(b) When a complete change of reagents (except where all reagents are packaged together) occurs;

(c) When major preventive maintenance or replacement of a critical part occurs;

(d) When controls begin to reflect an unusual trend or are consistently outside acceptable ranges; or

(e) At least every six months.

(3) Each quantitative assay procedure shall be rechecked at least once each day of testing (24-hour period) except for blood gases, which must be rechecked each shift (see (7) below); rechecks must be conducted using two levels of calibrators, controls, standards, or a combination of these materials.

(4) Limits for standards and reference samples shall be recorded and shall include the course of action to be instituted when the results are outside the acceptable limits for each lot

number of controls. Manufacturer's limits may be used only if they are verified by the laboratory.

(5) For urinalysis, the laboratory shall use a positive control each day of patient testing, which checks the reactivity of each constituent for which qualitative tests are reported.

(6) Counting equipment used for in vitro radioassay determination shall be checked for stability at least once each day of use with radioactive standards or reference sources. Records which document the routine precision of each method, automated or manual, and its recalibration scheduled, shall be maintained. At least one standard and one reference sample (control) shall be included with each run (as defined by guidelines) of unknown specimens.

(7) For blood gas analysis, a two point calibration must be performed and documented each shift; a third point verification must be run using a separate material from that used in the two point check; for blood gas analyzers which include other chemistries (electrolytes, glucose, bun, etc.) the quality control requirements are outlined under Rule 111-8-10-.09 and .09(5).

(8) For co-oximetry, preventive maintenance shall follow manufacturer's guide lines except where regulations are more stringent; a hemoglobin control shall be performed each day of testing. The calibration of the instrument shall be checked weekly unless required more frequently by the manufacturer.

(9) Drug screens for medical purposes must contain a standard which contains all drugs to be identified by the method used, or for which the laboratory reports, per each plate or run. The control must go through all phases of testing including extraction, unless technology that is more current has been approved by the Department. Positive qualitative tests must be

confirmed by a quantitative method, if required or recommended by the manufacturer.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.13 Quality Control for Immunochemistry.

Those clinical laboratories which provide for the collection, processing or storage of human blood and its components shall provide methods for the selection of blood and component donors as well as for the collection, storage, processing and transfusion of blood and its components, and shall ensure that the blood and component donation will not be detrimental to the donor and also protect, as far as possible, the recipient of the human blood or any of its components from infectious disease known to be transmissible by blood. The methods used shall conform to the following:

(a) **Selection of donor:**

1. On the day of donation, the donor shall be evaluated in order to protect the donor and the recipient of the donation. At a minimum, the following shall be used in the evaluation of the donor and records shall be retained.
2. The minimum age for donation is seventeen (17) years; the maximum age for a donor is left to the discretion of the director of the facility providing the donor is in good health.
3. Minimum weight for routine donation shall not be less than 110 lbs. (50 kg) with a maximum of 525 ml. of blood removed per donation; individuals weighing less than 110 lb. (50 kg) may donate relative to the volume collected; in this event, the volume of anticoagulant must be considered. Any recent unexplained weight

loss (e.g., more than 4.5 gk. or 10 lbs) should be evaluated by the donor's physician.

4. The volume of donation shall not exceed 545 ml in an eight week period; donation of whole blood must be deferred for at least 48 hours after apheresis.

5. The systolic blood pressure shall be no higher than 180mm of mercury, and the diastolic blood pressure must be no higher than 90 mm of mercury.

6. Pulse rate shall be between 50 and 100 beats per minute. Prospective donors with pathogenic cardiac irregularities must be deferred.

7. Donor hemoglobin or hematocrit must be determined prior to donation by a method acceptable to the Department; donors with a hemoglobin less than 12,5g/dL or a hematocrit less than 38% must not be considered for donation.

8. Prospective donors with chronic or acute illness must be evaluated by a physician prior to donation.

9. Routine donation must be deferred for six months after the conclusion of a pregnancy.

10. Prospective donors on therapeutic drugs must be evaluated by a physician prior to donation to protect the donor and the recipient.

11. The donor temperature (oral) shall not exceed 37.5 degrees C. (99.6 degrees F.).

(b) **Donor deferral:**

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1. Abnormal behavior: a prospective donor shall not appear to be under the influence of alcohol or any illegal substance.
2. The site of venipuncture shall be free of lesions; evidence of drug abuse shall indefinitely exclude the potential donor. At a minimum, both arms shall be inspected for parenteral drug use.
3. A history of syphilis or gonorrhea shall exclude the potential donor for a period of not less than six months after treatment of the disease.
4. Potential donors who have received blood, blood components, derivatives, or other human tissue known to be a possible source of blood borne pathogens shall be excluded as donors for a period of not less than 12 months.
5. Potential donors who have taken medication known to alter platelet function within the previous three days, shall be evaluated as to the impact on the patient who is to receive the platelets from this donor and that such donor is to be the sole source of the platelets.
6. Immunizations and vaccinations: Donors shall be evaluated for the impact of the immunizations and vaccinations on the donation in accordance with general accepted standards of practice. At a minimum the following actions shall be taken:
 - (i) Potential donors who have received toxoids and killed viral, bacterial, and rickettsial immunizations and/or vaccinations may be considered as a donor if symptom-free and afebrile.
 - (ii) Potential donors who received human diploid cell rabies shots may be considered if symptom-free and afebrile, unless the vaccine was given following an animal bite; the exclusion period for this event shall be no less than one year.

(iii) Potential donors shall be deferred after receiving the following vaccinations:

(I) Live attenuated viruses such as measles, rubella(a), mumps (oral), or yellow fever shall be deferred for a period of not less than two weeks.

(II) German measles (rubella) shall be deferred for a period of not less than four weeks.

(III) Hepatitis B Immune Globulin (HBIG) shall be deferred for a period of not less than twelve months.

7. Infectious diseases requiring indefinite deferral:

(i) Those potential donors with a history of hepatitis B after the age of eleven, or those who have been confirmed positive for hepatitis B surface antigen (HBsAg) or those who have had a repeatedly reactive test for antibodies to hepatitis B core (anti-HCc) on more than one occurrence.

(ii) Those potential donors with a present or past clinical history of infection with hepatitis C virus (HCV), human T-cell lymphatic virus (HTLV) or human immunodeficiency virus (HIV);

(iii) Those potential donors (male) who have had sex with another male since 1977;

(iv) Those potential donors who have had sex for money;

(v) Those potential donors who were born or emigrated from a country where heterosexual activity is thought to play a major role in the transmission of HIV-2 infection.

8. Deferral of potential donors having had contact with potential viral pathogens, application of a tattoo, mucus membrane

exposure to blood, exposure to blood or other body fluid through non-sterile skin penetration, non-casual contact with another person positive for hepatitis B surface antigen (HGsAg) or HIV, or being incarcerated in a correctional institution for more than 72 hours, shall be not less than twelve months.

9. Malaria:

(i) Potential donors diagnosed as having malaria must be excluded for a period of not less than 3 years after becoming asymptomatic;

(ii) A potential donor coming from a country considered endemic for malaria must be excluded for a period of not less than 3 years;

(iii) Potential donors who are permanent residents of a country in which malaria is not considered endemic, but who has traveled to a malaria endemic country must be excluded for a period of not less than 12 months, and they must be asymptomatic at the time of donation;

(iv) Malaria restrictions may not apply, if the donor is only donating plasma and the red cells are not used for transfusion purposes.

10. Other protozoan diseases: Potential donors with a history of Babesiosis or Chagas' disease shall be deferred indefinitely.

(c) **Donor Information.** Potential donors must be informed and sign a consent form. This information/form must contain, at least, information relative to the potential danger of donation, the significance of blood-borne pathogens, and post-phlebotomy care. The donor must be given the opportunity to confidentially request that his/ her donation not be used for transfusion. A physician associated with the collecting facility must establish a means to

notify donors of any significant abnormality detected during predonation evaluation or laboratory test results.

(d) **Autologous donor blood.** If a donation is only for autologous purposes, the donor requirements may be reduced, however, no donation shall be collected for an individual with a systemic infection. The unit must be labeled “autologous use only”. Autologous units must be stored under the same requirements as banked blood. However, the autologous units must be segregated from the regular banked blood and blood components. The facility must be licensed by the FDA for the collection and storage of autologous donations.

1. The facility must have policies and procedures for the selection of donors, the collection, processing (testing), storage and disposition of autologous donations.
2. The ABO group and Rh type on these units to be transfused must be determined.
3. Test for HBsAg, HIV-1, anti-HIV-1, anti-HIV-2, anti-HCV, anti-Hbc and a serological test for syphilis must be performed by the collecting facility prior to being transfused in another facility. The unit must be labeled positive for any positive test results.
4. The transfusing facility and the physician must be informed of any abnormal test results. Prior to autotransfusion, the ABO group and Rh type of the donor and recipient must be confirmed.
5. Autologous units must be labeled “autologous donor” and “for autologous use only”.

(e) **Therapeutic donations:**

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1. Therapeutic bleeding, to include hemapheresis, can only be performed with the written approval of the patient's physician and must be approved by the director of the laboratory.

2. There shall be written policies and procedures for performing the phlebotomy.

3. Records must be retained to document patient identification, diagnosis, and type of therapeutic procedure performed, extracorporeal blood volume, nature and volume of component removed, quality control of measuring device, any occurrence of adverse reactions to medication, disposition of the blood, and the unit shall be labeled "not for transfusion".

(f) **Reagent quality control.** All reagents must conform to FDA regulations and manufacturer's instructions must be followed.

1. ABO antisera must be quality controlled with a positive control each day of use.

2. Rh antisera and reagent cells must be quality controlled with a negative control each day of use; the negative control may be deleted if indicated by the manufacturer.

3. Other antisera must be quality controlled with a positive and negative control each day of use.

4. Anti human globulin sera must be quality controlled with a positive and negative control each day of use.

5. Antibody screening cells must be quality controlled with a positive control each day of use.

6. Each bottle of reagents used in testing must be evaluated in the quality control program on the day of use.

(g) **Transfusion services.** It is the responsibility of the laboratory director to assure that the needs of the physicians responsible for the diagnosis, management, and treatment of patients are met in reference to blood, blood components, blood products and blood bank testing services.

(h) **Preparation of blood components.** The process of component preparation must be sterile and a closed system is preferred.

1. If a closed system is not employed or the seal is broken, components stored between 1– 6° C shall have an expiration date of 24 hours.

2. All components must be traceable through identification numbers and lot numbers.

3. For red blood cells, the unit must contain the type of anticoagulant/ preservative used in the collection.

(i) Red blood cells and deglycerolized red cells designated for freezing, must be frozen within six days of collection.

(ii) Rejuvenated red blood cells: following rejuvenation, the cells may be washed and transfused within 24 hours or deglycerolized and frozen; the label on the unit of blood after rejuvenation must indicate the rejuvenating solutions.

(iii) Irradiated red blood cells: for red blood cells which have received at least 500 cGy irradiation, the dose shall be a minimum of 2,500 cGy targeted to the midpoint of the canister; if free-standing irradiation is used, or to the center midplane of an irradiation field if a respiratory instrument is used; the method used for irradiation must be monitored at least annually to verify the delivered cGy.

4. Plasma components. Fresh frozen plasma – removed from a single donor must be stored at -18°C ; if collected in CPD, CPD.2, OR CPDA-1, the plasma must be frozen within 8 hours of collection; if collected in ACD, the plasma must be frozen within 6 hours of collection. The freezing process must protect the plasma from chemical alteration.

(i) Cryoprecipitated antihemophilic factor (AHF) must be thawed at $1-6^{\circ}\text{C}$, separated from the plasma and stored frozen within one hour; there must be a method to monitor the amount of AHF and fibrinogen harvested. For platelets and platelet pheresis, a method to determine the concentration of platelets must be established and followed. When leukocyte reduction is a consideration, there shall be a method to determine the leukocyte contamination.

(ii) For granulocyte pheresis, a method shall be established and followed to monitor the concentration of the component.

(iii) When any blood components are mixed/pooled, any plasma alloantibodies must be compatible with red cell antigens.

(i) **Testing of donor blood.** Prior to transfusion, the testing laboratory must perform, at a minimum, the following tests on donor blood:

1. ABO group must be performed by testing the red cells with anti-A and anti-B, and by testing the serum or plasma for expected antibodies to A1 and B red blood cells.

2. Rh type must be determined with anti-D; if the anti-D is negative, a test for weak D must be performed; both tests must be negative in order for the unit to be labeled D negative; the donor's previous record must be checked relative to ABO and Rh, and any discrepancy must be resolved.

3. Testing for unexpected red cell antibodies: serum or plasma from donors with a history of transfusion or pregnancy must be tested for the presence of clinically significant antibodies; if any such antibody(s) is detected, it must be identified, if the blood is to be transfused, and the blood and its components labeled with the identity of the antibody(s).

4. Testing to prevent disease transmission: All blood for transfusion must be tested for HBsAg, anti-HBC, anti-HTLV, HIV-1-Ag, anti-HIV-1, anti-HIV-2, anti-HCV, and with a serological test for syphilis; blood should not be transfused prior to completion of testing; in the event of prior transfusion, follow up investigation must be documented and the recipient's physician must be notified if the unit was found to be positive for any or all of those markers.

(i) **Blood labeling.** The label on a unit of blood or blood component must identify the original unit and any component, or component modification; the label must be clear, eye-readable, and may be machine readable; handwritten labels must be legible and in permanent ink; prior to labeling, a review to reveal units not to be issued shall be completed; the labeling process must include a second check to determine if an error has occurred in the labeling; this check must verify ABO, expiration date, and other appropriate labels on the unit as well as components. An appropriate label must be affixed, should modification be made to the component.

1. Unit identification. A unique identifier must be assigned to each unit by the collection facility; such identification may not be removed or altered by subsequent facilities; other facilities may affix another unique identifier which must identify the facility; no more than two unit identifications may appear on the unit at a given time.

2. Labeling at collection or preparation. At the time of collection for whole blood, and at the time of preparation for

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components, the unit must be labeled as to whether it is whole blood, a component, or an intended component, unique identification, type of anticoagulant (not required for frozen, deglycerolized, rejuvenated, or washed blood cells); for platelets, low volume red blood cells, fresh frozen plasma, pooled components, or components prepared by apheresis, the approximate volume must appear on the container, sedimenting agent (if any), and the identification of any facility collecting or modifying the blood component.

3. Labeling prior to use. The final container label must indicate at least the following information:

(i) Temperature of storage, expiration date/time, if appropriate, identification of the facility preparing the final component, ABO group, Rh type and interpretation of unexpected antibody test, when positive, and instructions for the transfusionist, at a minimum; to properly identify intended recipient, the statement "This product may transmit infectious agents. Caution: Federal law prohibits dispensing without a prescription."

(ii) The type of donor: i.e., volunteer, paid or autologous.

(iii) Name of anticoagulant, except for components, prepared by hemapheresis, and type of cells, i.e., frozen, deglycerolized, rejuvenated or washed red cells.

4. Irradiated blood and components must be labeled as such, along with the name of the facility performing the irradiation.

5. CMV negative red blood cells or cellular components to be issued to a CMV negative recipient must be labeled CMV-negative.

6. Labeling for pooled components: In addition to the labeling requirements under "labeling at collection or preparation"

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and “prior to use”, the label for pooled components must contain the following: name of pooled component, final volume of pooled component, name of facility preparing the pooled component, and unique identification of pooled component. The following information must appear either on the label or on the attached tag:

(i) Number of units in the pool.

(ii) ABO group and Rh type in the pool (–Rh is not required for cryoprecipitate).

(iii) The record must contain the unique identification for each unit in the pool as well as the collecting facility.

7. Labeling of blood bags must meet FDA regulations (21 CFR 606 Subpart G).

(k) **Storage.** Refrigerators in which blood and blood components are stored must provide a uniform temperature. Blood and blood components must be stored within an acceptable temperature range.

1. Refrigerators, freezers, incubators, and other storage areas must have a continuously monitored record of the temperature; in those areas not continuously monitored, the temperature must be monitored and documented each four hours of storage.

2. Refrigerators and freezers used for the storage of blood and blood components must be equipped with an audible alarm, set to activate at a temperature to allow proper action to be taken before the blood and components reach unacceptable temperatures.

3. The alarm system used with liquid nitrogen storage must be set in such a manner as to alert personnel of an unsafe level of liquid nitrogen.

4. Blood and red blood cells must be transported in a manner to ensure a temperature of 1–10°C.

5. Components stored at 20–24°C.

6. Components stored in a frozen state must be transported to assure that they remain in the frozen state.

(l) **Expiration of blood and blood components.** Provided that FDA approved collection methods, solutions, labeling practices, storage, transportation and equipment are used, the expiration date that appears on the label must be followed under ordinary situations. In order to consider this the expiration date, the closed system under which the unit was collected must not have been compromised; dating periods must follow FDA regulations (21 CFR 610.5B).

(m) **Apheresis.** At a minimum, the following policies and procedures must be available and followed when blood or a blood component is to be returned to the donor in a timely manner to assure that only the donor's blood or blood component is re infused to the donor:

1. Only 0.9% USE injectable sodium chloride may be mixed with the blood as a diluent.

2. Donor must provide an informed consent.

3. A licensed physician must be responsible for the apheresis procedure and must assure donor care.

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4. Only sterile, pyrogen-free, non-toxic containers and additives which are compatible with the contents may be employed (those approved by the FDA).

5. For apheresis performed for the purpose of transfusion (i.e., platelet, AHF, granulocytes), there must be policies and procedures to evaluate the recovery with the recipient's needs considered; those products not meeting the established criteria must not be transfused without additional evaluation.

6. The procedures employed must assure the safe reinfusion of blood and avoid possible air embolism.

7. Any adverse reactions must be documented and medical advice must be rendered.

(n) **Plasmapheresis.** The donor criteria for an occasional (not to exceed one donation in a four-week period) donation shall be the same as those for a whole blood donor.

1. When plasmapheresis occurs more frequently than once every four weeks, FDA regulations 21 CFR 600-660 must be followed; for those donations not following this regulation, the donor must have a physical on the day of donation and a physician must request the donation and take responsibility for any undesirable outcome.

2. Cells shall be returned to the donor before collecting a second unit or within 2 hours of the initial phlebotomy; no more than 500 ml. of whole blood shall be removed at one time, or 1000 ml. for transfusion (or within 24 hours), unless, the donor's weight exceeds 176 lbs., in which case the amount shall be 600 ml. or 1200 ml. respectively.

3. If the pheresis is performed using an automated instrument, the amount of plasma collected shall not exceed the amount approved by the FDA for the instrument in use.

(o) **Compatibility Testing.** Requests for transfusion and samples from the recipient must contain sufficient information for positive identification of the recipient; the facility must establish policies to determine minimum criteria for recipient identification; these policies and procedures must contain provisions for emergency situations; the minimum acceptable information must be the patient's name (first and last) and an identification number, if not addressed in the emergency policy; any discrepancy must be resolved prior to testing. The facility must do the following as appropriate:

1. Recipient specimen labeling policies and procedures must be established by the facility. These policies and procedures must provide a method of positive recipient identification on the specimen, a unique identification between the recipient, the specimen(s), and the blood or components to be prepared for the patient, assure that the specimen is labeled at the time of collection in the presence of the recipient, and assure a method to identify and document the specific identity of the individual collecting the specimen. Should there be any discrepancy in the specific identification system, it must be resolved prior to testing.

2. The transfusion service must confirm the ABO group of all whole blood and red blood cells as well as the Rh type using a sample obtained from the attached segment. Any discrepancy in group and/or type must be reported to the collecting facility and the unit must be quarantined until notification from the collecting agency. This verification must be completed prior to release for transfusion. A label must be affixed to the unit indicating group and type confirmation.

3. Each blood specimen consisting of one or more tubes to be used in testing for the transfusion of whole blood and/or red

blood cells must be tested for ABO group and Rh type. A screen for unexpected antibodies to red blood cell antigens must be performed. If the transfusion is to take place more than three days in the future, the specimen must be recollected and re-screened for antibodies to red blood cell antigens if:

- (i) The patient has been transfused in the preceding three months with blood or components containing red blood cells;
- (ii) The patient has been pregnant in the preceding three months or;
- (iii) The patient history is not certain or unavailable.

4. ABO group must be determined using the red cells with anti-A and anti-B reagents. The serum or plasma must be tested using known A1 and B cells to determine the presence of expected antibodies to A1 and B cells. Any discrepancy must be resolved.

5. Rh typing must be determined using anti-D reagents. A control system must be employed, if indicated by the manufacturer of the anti-D reagent.

6. Screening for unexpected antibodies in the recipient's specimen must be conducted. This screen must be capable of detecting clinically significant antibodies and must include a 37° that are not pooled. With documentation of equivalent sensitivity, an alternative screening method may be employed. A control system using red blood cells sensitized with IgG must be applied to each test interpreted as negative. When a licensed test system is employed that does not allow the addition of IgG-sensitized cells, controls shall be used as recommended by the manufacturer.

7. Prior to release for transfusion of whole blood or red blood cells, the transfusion history or the patient must be reviewed in order to detect a possible error.

8. Except in cases of emergency, a sample of the recipient's serum or plasma must be crossmatched against a sample from the donor cells from a specimen attached to the unit of whole blood or red blood cells. The crossmatch must have the ability to demonstrate ABO incompatibility and clinically significant antibodies to red blood cell antigens and must include an antiglobulin test. If no clinically significant antibodies to red blood cell antigens are detected and the patient's history does not indicate a clinically significant antibody, then only serologic testing to detect ABO incompatibility is required.

9. A computer system that has been validated by the facility to prevent the release of ABO incompatible blood and blood components, may be used in place of a serologic crossmatch, provided that the system contains donor information to include the donor number, the component name, ABO group, and Rh type of the component and the interpretation of the ABO confirmatory test. The system must contain the recipient's ABO group and Rh type.

(i) There must be a method to verify correct entry of data prior to release of blood or components. The system must alert the user to discrepancies between the donor unit labeling and the blood group confirmatory test interpretation and to ABO incompatibilities between the recipient and the donor unit.

(ii) There must be documentation of initial training for those individuals using the system, and of annual training thereafter. After initial training, annual training may be limited to upgrades and/or changes in the computerized system. The facility must maintain a back-up program to implement in the event of failure or malfunction of the computerized system to assure uninterrupted service.

(q) Selection of blood and blood components for transfusion:

1. Recipients should receive ABO group specific whole blood of ABO group compatible red blood cells.
2. Whole blood and red blood cells must lack the red blood cell antigen when the recipient demonstrates the presence of a clinically significant, unexpected antibody(s) to a specific red blood cell antigen(s). In addition, the donor unit must lack the red blood cell antigen(s) when the recipient's history indicates the presence of a clinically significant antibody(s) directed toward a specific antigen.
3. Fresh frozen plasma should be ABO compatible, whenever possible.
4. The donor plasma in platelet preparations must be ABO compatible when the recipient is an infant. Red blood cells and granulocytes shall be ABO compatible with the recipient's plasma.
5. Each facility must have written and utilized policies and procedures for the release of blood and blood components for transfusion purposes.
6. When a recipient has received a volume of blood approximating his/her total blood volume in a 24-hour period, the compatibility testing procedure may be abbreviated. This is at the discretion of the director of the laboratory. There must be written policies and procedures for the laboratory personnel to follow.
7. Where recipients are under four months of age, the ABO group, using anti-A, anti-B, and the Rh type, using anti-D must be performed on the infant. For the antibody screen, serum or plasma from the infant or infant's mother may be used. If the initial red

blood cell antibody screen is negative, it is not required to crossmatch donor red blood cells for the initial or subsequent transfusions for the duration of that hospitalization. If the initial antibody screen is positive for clinically significant red blood cell antibodies, the infant must be transfused with red blood cells that are negative for the corresponding antigen or are compatible by antiglobulin crossmatch.

8. In the case of massive or exchange transfusion, only blood drawn to be hemoglobin S negative should be transfused.

(q) **Issuance and transfusion of blood and blood components.** At the time of release for transfusion, the donor unit must be labeled as specified in the facility's policy. The information must include, at a minimum, the recipient's name (first and last), identification number, donor unit number, and compatibility test interpretation, if performed. There must be a mechanism to identify the intended recipient and requested blood component at the time of issue. The transfusion record for each unit of blood, blood component or pooled component must contain the intended recipient's name, identification number, ABO group, and if required, the Rh type, the interpretation of the compatibility tests, if performed, and the date of transfusion. Following the transfusion, the record must be made part of the patient's medical record. A sealed specimen from the recipient and the donor must be maintained at 1– 6°C for a period of seven days post transfusion.

1. Blood must be inspected immediately before issuance. If it appears abnormal, the unit must not be transfused.

2. Blood that has been returned to the blood bank must not be reissued unless the container closure has not been disturbed, and blood has not been allowed to warm above place and followed to assure that temperature ranges are not exceeded. The record must indicate that the blood has been reissued, and that it has been inspected prior to being reissued.

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3. At least one sealed segment of integral donor tubing must remain attached to the container. Those segments removed may be reattached, if the identification number on them are identical to the segment(s) that remain attached.

4. When the requesting physician indicated with a signed statement, that a delay in transfusion could be detrimental to the patient, the blood may be released prior to the completion of the tests that are performed to reduce the transmission of infectious diseases as well as the compatibility testing. In that event, recipients whose ABO group can be determined (excluding the recipients' history) may receive ABO group specific or ABO group compatible red blood cells or whole blood. The unit must be labeled in a conspicuous manner to indicate that the compatibility testing was not performed at the time of release. Standard compatibility tests should be completed promptly on those units signed out as "uncrossmatched". All requirements relative to the labeling of specimens to assure positive identification must not be ignored during the collection, release, or the transfusion of blood during an emergency. After completion of required testing, the laboratory must notify the recipient's physician and the laboratory director, if a test result could effect the health and safety of the recipient.

(r) **Transfusion complications.** The facility must establish policies and procedures to assure that any transfusion complication is investigated. These policies and procedures must have a mechanism to detect errors in reporting, and evaluation of suspected complications of transfusion. All such investigations must be evaluated with a written interpretation by the laboratory director. The collection facility must be notified, if the complication appears to be attributed to the donor or the processing of the unit. Fatal transfusion reactions must be reported to the FDA, the collecting facility, and the Department.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.14 Quality Control for Hematology.

Instruments used in hematological examination of specimens shall be recalibrated, retested or reinspected, as appropriate, each day of use. Each procedure shall be recalibrated or rechecked each shift of use with standards or controls covering the entire range of expected values, unless required more frequently by the manufacturer or federal laboratory regulations. Tests such as the hematocrit and one-stage prothrombin time test shall be run in duplicate except as specified in published guidelines. Standard deviation, coefficient of variation, or other statistical estimates of precision shall be determined by the laboratory. All control materials used to satisfy the control requirement must have documented established limits.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.15 Quality Control for Exfoliative Cytology; Histopathology; and Oral Pathology.

(1) Exfoliative Cytology.

(a) The laboratory must establish and document an annual evaluation of the number of cytology cases examined, the number of specimens processed by type, the number of cases reported by diagnosis, including the number of cases reported as unsatisfactory for diagnosis, the number of gynecologic cases where cytology and available histology are discrepant, and the number of cases where histology results were unavailable for comparison. The evaluation must also include the number of gynecologic cases where the rescreen of a negative or normal test

results in a reclassification to a premalignant or malignant diagnosis.

(b) The laboratory must evaluate the case reviews of each person examining slides against the overall statistical values, document the reasons for deviations, and corrective actions taken, if needed.

(c) The laboratory must develop and implement procedures to detect inadequately prepared slides, assuring no diagnosis is reported on such cases. Such procedures must include a plan for promptly notifying referring physicians of inadequately prepared slides. The report must clearly distinguish specimens, or smears, or both, that are unsatisfactory for diagnosis interpretation. Documentation of unsatisfactory specimens and notifications must be retained by the laboratory for a minimum of five years.

(d) The laboratory director or supervisor qualified in cytology or cytotechnology shall rescreen for proper staining and correct interpretation at least a ten percent random sample of gynecological smears which have been interpreted to be in one of the benign categories by personnel not possessing director or supervisor qualifications. The review must include negative cases selected at random from the total caseload and from patients or groups of patients that are identified as having a high probability of developing cervical cancer, based on available patient information. Records of initial examination and rescreening must be available. Rescreening must be performed prior to reporting.

(e) No laboratory shall assign or permit an individual engaged in the evaluation of cytology preparations by non-automated microscopic technique to examine more than one hundred (one patient per slide, gynecologic or non-gynecologic, or both) slides in a twenty-four hour period. This limit represents an absolute maximum number of slides in any twenty-four hour period, unless slide preparations are made using automated,

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semiautomated, or other liquid-based slide preparatory techniques resulting in cell dispersion over one-half or less of the slide area, in which case the slide counts as one-half slide, if examined by nonautomated microscopic technique. The maximum number of one hundred slides shall be examined in not less than an eight-hour period. Recognizing individual differences in abilities, the laboratory must establish the maximum number of slides (not to exceed the 100 slide limit) each individual may screen in a twenty-four hour period, and records must be available to document that each individual's workload limit is reassessed at least every six months and adjusted, when necessary. For the purposes of establishing workload limits for individuals examining slides by nonautomated microscopic technique on other than an eight hour workday basis, a period of eight hours must be used to prorate the number of slides that may be examined by using the following formula:

$$\frac{\text{number of hours examining slides} \times 100}{8}$$

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(f) Records shall be maintained by the laboratory of the total number of slides examined by cytotechnologist during each twenty-four and eight hour period. It shall be the responsibility of each laboratory to maintain records of the number of slides read on and off the premises of the laboratory by cytotechnologists when such slides are assigned by that laboratory. All slides must be read on the premises of the licensed laboratory unless referred to another licensed laboratory.

(g) All gynecological smears interpreted to be in the "suspicious" or "positive" categories by cytotechnologists shall be confirmed by the laboratory director or supervisor, who is qualified in Exfoliative Cytology as specified in Rule 111-8-10-.06(1)(a)2. or (3)(b), and who shall personally sign all such suspicious or positive reports. All nongynecological cytological preparations, positive and negative, shall be reviewed by such a director or supervisor qualified in cytology. All slides for exfoliative cytology must be

retained as long as required by applicable federal law and regulations, but not less than five years from the date of examination.

(h) The laboratory must review, for each patient with premalignant or malignant gynecologic cytology results, all gynecologic cytology specimens received within the previous five years, if available. If significant discrepancies are found that would affect patient care, the laboratory must notify the patient's physician and issue an amended report.

(2) **Histopathology and Oral Pathology.** Special stains on tissue sections must be checked for intended reactivity by use of positive preparations, and results of reactions must be documented. Stained slides and tissue blocks shall be retained as long as required by applicable federal law and regulations, but not less than ten years for slides or two years for tissue blocks. Remnants of tissue specimens shall be retained in a fixative solution until those portions submitted for microscopy have been examined and a diagnosis made by a pathologist.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.16 Quality Control for Tissue Banks.

Tissue banks which procure, store, or process human or animal tissue designed to be used for medical purposes in human beings shall conform to the procurement, storage and processing requirements listed in this section. The tissue bank must maintain donor and patient recipient records and communications. These records must be retained for not less than seven years after the distribution of the tissue material. These records shall be evaluated and reviewed by the director to ensure the suitability of the donated tissue for its intended use. Records must include the following:

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(a) Each step in collection, preparation, testing, storage and distribution of the tissue must be documented concurrent with the performance of each step.

(b) Records must be legible and indelible and must include dates of testing, testing results, interpretations, assigned expiration date, if applicable, and the identity of the person performing the work.

(c) Donor identification and documentation of the pathological and microbiological evaluation of the donor shall be recorded.

(d) Each tissue and any component must be given a generic designation and a unique identification number which shall be used as the lot number throughout the collection, processing, distribution and utilization processes.

(e) All records concerning donor history, tissue processing and any other details deemed necessary (within the bounds of medical-legal and donor confidentiality) shall be available to authorized personnel upon request.

1. An adverse reaction file must be maintained.

2. An accurate inventory of all tissues (unprocessed, processed, and distributed) must be maintained.

3. There must be verification of step by step procedures under which tissue is procured, processed, tested and stored. Final disposition of the transplanted tissue must be recorded.

(f) Air drains, surfaces and water faucets shall include periodic sampling to ensure the tissue bank environment is maintained.

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(g) The tissue bank shall have a system to prevent unauthorized entry either by physical configuration and/or an adequate security system.

(h) Procedures for recruiting donors shall be established and approved by appropriate officials.

(i) Permission to obtain tissues from living or non-living donors shall be documented through informed consent. Tissue banks must comply with Georgia Rules and Regulations for Anatomical Gifts, Chapter 111-8-5, as may be applicable.

(j) Tissues shall be processed by procedures which are appropriate for the type of tissue and the manner in which it is retrieved. Processing shall not change the physical properties of the tissues.

(k) Tissue preservation and types of storage containers shall ensure that the biological and biochemical properties are retained.

(l) Tissues shall be sent only to licensed and approved facilities that have accepted responsibility for proper handling and use. There shall be an agreement for notifications of the tissue bank if tissues are received in defective packaging, have been removed from sterile containers but not used, or have been lost. The following criteria for distribution must be met:

1. Transportation methods shall maintain proper environmental conditions during transit.

2. Excess product remaining after use shall be discarded unless the tissue bank retains control of the product and the product remains sterile.

3. Upon receipt of tissue, a record shall be made of its description, date received, and the tissue supplier and, if applicable, expiration dates.

4. Tissue shall not be dispensed without a documented order from the physician or other authorized health professional, and records of the person to whom this tissue was dispensed, and the integrity of the container and label.

(m) Records must be retained indefinitely to permit tracing of any tissue from the donor to all recipients or other final dispositions. Records must include the following:

1. Receipt, storage, and transportation information;
2. Identity of the source facility;
3. Type of tissue and the numeric or alphanumeric identification;
4. Name(s) of the recipient(s);
5. Personnel who prepared the tissue for dispensing;
6. Personnel who dispensed the tissue;
7. Personnel who accepted the tissue for use;
8. Dates of dispensing and transportation;
9. Identification of the ordering physician or other authorized health professional;

(n) Storage temperature records must be retained for five years.

(o) Container labels must include:

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1. Name of product;
2. Name and address of tissue bank; and
3. Tissue identification number.

(p) Package labels must include:

1. Product name;
2. Name and address of the tissue bank;
3. Unique tissue identification number;
4. Expiration date of contents, if applicable;
5. Method of sterilization, if applicable;
6. Preservation and concentration or “no preservative” if preservative presents a safety factor;
7. Number of containers, if applicable;
8. Amount of product by weight;
9. Storage and handling instructions, including recommended storage temperature and special handling instructions relative to the product;
10. Sensitizing substances known to be present;
11. Antibiotics added during processing: type and calculated amount;
12. Product source, if a factor in safety of administration; and

13. A statement that the tissue donor was tested for HIV antibody and Hepatitis B surface antigen (HBsAg) using FDA approved tests and found to be nonreactive.

(q) Final container shall be packaged in a manner that ensures the integrity and sterility of the contents.

(r) A product insert must accompany all tissues.

(s) There shall be written procedures for tissue recall and notification of recipient centers of possible tissue contamination, errors detected in the processing, preparation or distribution process or other factors which may render the tissue unsuitable for its intended application.

(t) Standard nomenclature and units of measure shall be used to describe tissues and the processing they have undergone.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.17 Quality Control for Sperm Banks/Embryology and Assisted Reproductive Technology (ART).

(1) **Sperm Banks.** Facilities collecting semen specimens shall comply with the following:

(a) Sperm banks shall be staffed with personnel trained in the most current methods of cryobanking and who meet the personnel requirements of these rules.

(b) Records must contain a donor release and a complete history.

(c) Donor semen shall have specific identification codes for use during the freezing and storage processes. Codes shall in no way be linked to the donor or the recipient.

(d) Donor history shall include the following:

1. Interview;
2. Examination including personal, physical, sexual and genetic histories;
3. Examination of semen to ensure viability and motility, freedom from infection and/or foreign cells and freezing survival capabilities.

(e) Semen specimens shall be collected at the sperm bank and processing shall be initiated within one hour of collection. Test results and measurements shall be initiated within one hour of collection. Test results and measurements shall be documented concurrent with evaluation.

(f) An appropriate method of cryopreservation shall be chosen which ensures maximum viability and freedom from contamination. Documentation shall be available which validates the method chosen.

(g) Storage and handling instructions shall be made available to the requesting physician. Such instructions shall include handling and disposition of unused specimen. Donor semen shall not be refrozen or redistributed.

(2) **Assisted Reproductive Technology (ART).** Facilities providing ART shall comply with the following:

(a) The laboratory director must meet requirements at Rule 111-8-10-.06(2)(b) of these regulations; in addition, the director must have two years of documented experience in a laboratory performing ART procedures, have documented training of at least six months in an embryo laboratory which includes performing, at a

minimum, each ART laboratory procedure 60 times. Included in the responsibilities of the director of the laboratory performing these procedures shall be:

1. To establish and monitor a program to ensure that aseptic conditions are maintained in the laboratory;
2. To assure that procedure manuals meet requirements at Rule 111-8-10-.09(2)(h);
3. Establish and monitor a quality assurance program that meets requirements at Rule 111-8-10-.06(3)(a), as applicable.

(b) An ART supervisor shall meet the requirements at Rule 111-8-10-.06(3)(b)1., 2. , 3. , or .06(4)(b)1., or 3. , and have documented training which includes performing, at a minimum, each ART laboratory procedure sixty (60) times.

1. An ART supervisor must be accessible to laboratory personnel when ART procedures are performed, either on-site or via electronic means; and
2. An ART supervisor may perform director responsibilities as authorized, in writing, by the director.

(c) A reproductive biologist in an ART must meet the requirements for director, supervisor, or meet the following:

1. Requirements at Rule 111-8-10-.06(4)(b)1. , or 3.;
2. Have documented ART training for laboratory procedures; and
3. Training must include the performance of ART procedures at least 30 times under director and constant supervision.

(d) In addition to meeting all safety requirements at Rule 111-8-10-.08, an ART laboratory must also:

1. Be located in a secure place with access limited to authorized personnel;
2. Conduct laboratory activities under aseptic conditions;
and
3. Use no radioisotopes in the laboratory where ART procedures are performed.

(e) In addition to meeting all quality assurance requirements at Rule 111-8-10-.09, an ART laboratory must also:

1. Verify that materials which come in contact with sperm, oocytes, and embryos have been tested and found to be non-toxic to the sperm, oocytes and embryos;
2. Ensure patient confidentiality throughout the testing phase; and
3. Require that an authorized person's request for testing must be written or electronic; and that an oral request must be followed within 24 hours by a written or electronic request.

(f) In addition to meeting all quality control requirements, as applicable, at Rule 111-8-10-.09, an ART laboratory must also:

1. Have documented criteria for assessment of oocyte morphology, maturity, fertilization, and embryo quality;
2. Document the insemination schedule relative to oocyte maturity;

3. Document volume, numbers, and quality of sperm used for insemination of each oocyte;
4. Document disposition of oocytes with an abnormal number of pronuclei; disposition of excess oocytes; and
5. Document critical time periods for various procedures.

(g) In addition to meeting specimen, reporting and records requirements at Rules 111-8-10-.11, .12, and .13, an ART laboratory must also:

1. Keep records for the pre- and post-washing and concentration for insemination, the outcome of insemination and culture, and quality of all embryos at transfer, and the identity of testing personnel;
2. Use a reliable tracking method for cryopreserved specimens;
3. Use permanent labeling of containers; and
4. Assure that records are indelible and legible, retained for two years on-site and for ten years beyond the date of final disposition or disposal of all specimens obtained during each patient's ART cycle.

(h) If the ART laboratory ceases operation, it must make provisions for records to be maintained for the required time frames.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.18 Quality Control for Specimen Collection Stations.

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(1) A laboratory supervisor or designated supervisory qualified staff must make monthly on-site visits to specimen collection stations.

(2) Collection stations drawing specimens must have a written agreement with a designated person possessing medical emergency treatment skills to be available/on call during all hours of specimen collection.

(3) Procedure manuals for specimen collection stations must include procedures for:

(a) Proper collection of specimen;

(b) Types of specimens collected;

(c) Storage and handling of specimens;

(d) Proper identification and labeling of specimens;

(e) Instructing facilities forwarding specimens to the collection station, including criteria for unsatisfactory specimens; and

(f) Forwarding reports to the appropriate physician when reports are returned to the collection station.

(4) Accession records for specimen collection stations shall indicate the following:

(a) Patient name;

(b) Requesting physician;

(c) Test requested;

- (d) Date of specimen collection;
- (e) Date of referral to testing laboratory; and
- (f) Date results are received back from reference laboratory.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.19 Quality Control for Cytogenetics.

(1) Each laboratory performing cytogenetics procedures shall engage the services of a sufficient number of testing personnel who meet the requirements as noted in Rule 111-8-10-.06. In addition, the laboratory must document the competency of testing personnel in the areas of collection, handling, preparation and processing of various specimens, appropriate culture techniques for specimens submitted, proper techniques for setting up cell cultures and harvesting specimens, proper techniques of chromosome banding and staining, maintenance and use of microscopes, photographic and computer-generated imaging techniques and equipment, chromosome analysis including knowledge of normal and abnormal morphology, general laboratory skills, quality control, and understanding of general principles of genetics.

(2) Each cytogenetics laboratory must comply, at a minimum, with manufacturers' instructions except where applicable regulations are more stringent, when using reagents and equipment and must document all quality control activities.

(a) The laboratory must define and follow specific criteria for receiving specimens and for handling unacceptable specimens.

(b) The laboratory must establish and follow a maintenance schedule and must document routine maintenance and function

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checks on all instruments. Microscopes must have a sufficiently high resolution for examination of slides. The hoods used for processing and handling cultures must be designed to keep contaminants out, checked periodically to ensure that the filters are functioning properly and that the airflow meets specifications and protect employees.

(c) The laboratory must perform an acceptable quality control performance check on routine and fluorescent stains (the method must check the timing that is critical to the staining process). Corrective action must be documented, if staining time has to be adjusted. Reagents (purchased, made in-house or aliquoted) must be properly labeled, and include content and quantity, concentration or titer, storage requirements, date prepared or received, date placed in service and expiration date.

(d) For in-house culture media, an acceptable method of checking the pH, sterility, contamination and ability to support growth must be in place. The sterility of each lot or shipment of commercial media must be checked when received.

(e) The laboratory must establish procedures and follow the appropriate incubation period for cell cultures to achieve active cell division. Incubation time may vary for each diagnostic area. There must be a monitoring system in place to detect power failure which may affect the incubation phase.

(f) The laboratory must define and document chromosome analysis failure rates, maintain records of causes of failures and investigate cultures that failed.

(g) The laboratory must establish (based on standardized methods) the minimum number of cells examined for X and Y chromatin counts, fragile X, complete metaphases or other applicable analysis performed.

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(h) Critical limits must be established for appropriate tests and records must identify the appropriate person to be notified if results do not fall within established limits.

(3) The laboratory must maintain records that indicate the media used, reactions observed, number of chromosomes counted for each metaphase spread, quality of banding, and resolution to support the final results and number of karyotypes for each individual. Records must also be maintained of confirmatory testing on all atypical results, of at least two cells karyotyped for each use, and two cultures for each specimen type.

(4) The laboratory must establish guidelines, based on appropriate standards for setting time limits on signing out final reports. Preliminary reports must be submitted within a reasonable length of time as established by the laboratory. Laboratory reports must include type of banding used, number of cells counted and analyzed microscopically, number of cells from which photographic or computerized karyotypes were prepared, band resolution, preliminary report results, a narrative report of clinical pathology interpretation of the laboratory findings, diagnosis and identification of testing personnel. The current International System of Human Cytogenetic Nomenclature (ISCN) or other standard nomenclature recognized industrywide, must be used correctly in the final report. The results of tests performed must be reviewed and signed out by the director.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.20 Quality Control for Screening and Monitoring Tests.

(1) Facilities performing only screening and monitoring tests shall establish a training program with written guidelines and must

keep documentation of the training of those personnel designated for performance of specific tests.

(2) Quality control procedures for screening and monitoring tests shall be performed for each test, if available. Controls and control frequency shall be according to published guidelines. Only tests approved by the Department may be performed; a list of approved tests shall be available from the Department. Proficiency testing is required for all tests, where such is available and graded.

(3) Results of exempt screening and monitoring tests, including all quality control records, shall be maintained separate from the patient's medical record for two years. The records must include the test date, time, patient's first and last name or unique identifier, test site, control/calibration results, lot numbers of reagents/controls, and identification of testing personnel.

(4) Reports of test results provided to non-physicians shall contain a statement which recommends that the results of the test be reviewed by a physician or that medical advice be obtained.

(5) The results of the tests shall be clearly identified as being performed by a nonlicensed facility and shall be displayed in a manner which will clearly differentiate them from results of a licensed laboratory.

(6) Screening test results which indicate abnormal conditions shall be noted with a recommendation that the abnormal results be confirmed by a definitive laboratory test performed in a licensed laboratory.

(7) Safety instruction using CDC's universal precaution guide lines for handling blood and instructions for packaging, labeling and disposal of potentially infectious waste materials and sharps, must be available to and practiced by the facility personnel.

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(8) Each facility, performing whole blood cholesterol, HDL or other approved screening procedures, shall establish a training program with written guidelines and retain documentation of the training of those personnel designated for performing these procedures. The training shall include all areas of the testing process including the use of the instrument.

(a) Prior to performing cholesterol testing, the facility must evaluate the procedure for accuracy and precision. Maintenance and testing for proper operation of any analyzers shall be performed with the frequency specified by the manufacturer.

(b) Two levels of control must be performed at the beginning of each day of testing and one level of control must be performed if testing equipment is moved from site to site.

(c) Maintenance, quality control, current procedure manuals and test participant records shall be available at each test site or with each instrument in use.

(d) The screening facility shall recommend referrals for further cholesterol testing in accordance with the National Cholesterol Education Program (NCEP) published guidelines.

(e) Reports shall show the name, telephone number, street address, city and state of the screening facility/agency. The screening facility/agency shall provide privacy for blood sampling and confidential counseling about test results.

(f) Each screening entity shall have a medical review officer who is licensed to practice medicine in Georgia. This officer may authorize testing.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.21 Quality Control for Histocompatibility.

(1) Mechanical refrigerators and freezers with recording thermometers must have an audible alarm that is monitored 24 hours a day. If liquid nitrogen is used for storage of frozen cells, the level of liquid nitrogen in the cell freezers must be monitored periodically. Sera and reagents must be stored at an acceptable temperature range. Reagents, solutions, culture media, controls, calibrators or other materials must be labeled to indicate identity and when significant, titer, strength or concentration, recommended storage requirements, preparation and expiration date and other pertinent information. Reagents typing area (locally constructed trays) must indicate source, bleeding date, identification number and volume remaining.

(2) The laboratory must have available and follow written policies and procedures regarding specimen collection:

(a) Requisitions must include patient's first and last name or unique identifier, name and address of the authorized person who ordered the test, date and time of specimen collection and source of specimen.

(b) All specimens must be properly identified and easily retrievable. Blood samples must be labeled with the patient's first and last name or unique identifier, date of collection, and must be obtained in a manner which does not compromise aseptic techniques.

(3) The laboratory must maintain a system to ensure reliable specimen identification and document each step in the processing and testing of patient specimens. If "chain of custody" is a requirement, the laboratory must maintain records of the "chain of custody" of the sample, the phlebotomist who collected the sample, documentation to identify each specimen, and a signature to verify information submitted.

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(a) Computer assisted analysis and all reports must be reviewed and verified by the supervisor or director. Records may be saved in a computer file if back-up files are maintained to ensure against loss of data.

(b) The laboratory must, at least once a month, give each individual performing tests a characterized specimen as an unknown to verify his or her ability to reproduce results.

(4) Records of the results for each individual must be maintained for a minimum of two (2) years. In addition, the laboratory must participate in at least one national or regional cell exchange program, if available, or develop an exchange system with another licensed/ certified laboratory in order to validate interlaboratory reproducibility.

(a) The laboratory must maintain records of each result, including preliminary reports, for at least two (2) years. Worksheets must clearly identify the subject whose cells were tested, the typing sera used, date of test and the person performing the test. For each cellserum combination, the results must be recorded in a manner which indicates the approximate percent of cells killed.

(b) Membranes or autoradiography from nucleic acid analysis must be retained as a permanent record.

(c) For marrow transplantation, the donor must give his/her informed consent before blood is taken for typing and before the donor is placed on a list of donors available to be called. Donor records for marrow transplantation must be maintained so that donors can be rapidly retrieved according to HLA type. The report must contain the date of collection, name, street address, city and state of the testing facility, patient's name or unique identifier, date of testing, date of final report, test results, control values and normal ranges where appropriate, interpretation, and signature of the director or his/her designee.

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(5) Renal and Bone Marrow Transplantation. The laboratory must have established policies for selecting appropriate patient samples for crossmatching, preparing donor lymphocytes for crossmatching, and reporting crossmatch results; having available results of final crossmatches before an organ or tissue is transplanted, documenting efforts to obtain specimens for all potential transplant recipients at initial typing, for periodic screening, for pre-transplantation crossmatch and following sensitizing events such as transfusion and transplant loss. If transplantation is deferred, a new serum sample must be obtained from the patient at monthly intervals, screened for antibodies and stored in the frozen state for possible use in crossmatch tests. Serum used for crossmatching must be tested undiluted and with one or more dilutions. Crossmatching must use techniques documented to have increased sensitivity in comparison with the basic microlymphocytotoxicity test such as prolonged incubation, washing or augmentation with antiglobulin or flow cytometry. Final crossmatches performed prior to transplantation must utilize a serum sample collected within the past 48 hours before transplant if the recipient has class I lymphocytotoxic antibodies or has had a recent sensitizing event, otherwise, a serum collected within seven days may be used. Donors and recipients must be ABO and Rh typed according to blood bank standards.

(a) The laboratory must HLA type all potential transplant recipients and organ donors, and follow a policy that establishes when antigen redefinition and retyping are required.

(b) The laboratory must have and follow criteria for the preparation of lymphocytes for HLA-A, B and DR typing; select typing reagents which are made in-house or purchased commercially, assignment of HLA antigens and assure that reagents used for typing recipients and donors are adequate to define all major and International Workshops HLAA, B and DR specificities for which reagents are readily available.

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(6) Potential transplant sera must be screened for HLA-A, B and DR antibodies with a suitable lymphocyte panel on sera collected, at the time of the recipient's initial HLA typing and thereafter, following sensitizing events and upon request. A suitable cell panel, which contains all the major HLA specificities and common splits for screening patient sera, must be used.

(7) Transfusion and Non-Renal Transplantation. All requirements specified in (5)(a) must be met.

(a) The laboratory must check each typing tray using positive and negative control sera and must use positive controls for specific cell types (i.e., T cells, B cells and monocytes) when applicable. Controls must be used to monitor the test components and each phase of the test system to ensure an acceptable performance for each compatibility test, i.e., mixed lymphocyte cultures, homozygous typing cells for DNA analysis.

(b) Compatibility tests for cellularly-defined antigens must use techniques such as the mixed lymphocyte culture test, or homozygous typing cells for DNA analysis. If the laboratory uses immunologic reagents such as antibodies or complement to remove contaminating cells during the isolation of lymphocytes or lymphocyte subsets, the methods must be verified with appropriate controls.

(8) Non-Renal Solid Organ Transplantation. The results of final crossmatches must be available before transplantation when the recipient has demonstrated presensitization by prior screening, except for emergency situations. The laboratory must document the circumstances, if known, under which emergency transplants are performed, and records must reflect any information concerning the transplant provided by the patient's physician to the laboratory.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-22 Quality Control for Flow Cytometry.

(1) A standard, consisting of latex beads or other uniform particles, shall be run to insure proper focusing and alignment of all lenses in the path, and for both the existing light source and signal (light scatter, fluorescence, etc.) detectors. The results of optical focusing/ alignment must be recorded each day.

(2) A threshold value for acceptable optical standardization shall be established for all relevant signals for each instrument and the focusing procedure repeated until these values are achieved or surpassed. If a particular threshold value cannot be attained, a written protocol for instituting corrective action must be available and used.

(3) A fluorescent standard, for each fluorochrome to be used, shall be run to insure adequate amplification of the fluorescent signal(s) each day of use and after any maintenance or adjustment of the instrument. This standard may be incorporated in the beads or other particles used for optical standardization or may be a separate bead of fixed cell preparation. If acceptable fluorescence separation cannot be attained, a written protocol instituting corrective action must be available and used.

(4) When performing analyses using two or more fluorochromes simultaneously, an appropriate procedure must be used to compensate for "spill over" into the other fluorescence detectors.

(5) For laser based instruments, the current input (amps) and laser light output (milliwatts), at the normal operating wavelength measured after the laser is peaked and normal operating power set, must be recorded as part of a daily quality control record.

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(6) The use time of instruments with mercury fluorescent lamps must be recorded. Lamps must be replaced when the allowable use limit has been reached.

(7) The laboratory must run a positive and negative control each day of patient testing. The negative controls should include normal serum from a healthy individual. The positive control (using appropriate dilutions) should react with cells representing all HLA types (i.e., pulled high PRA sera).

(8) Each laboratory must establish and document its own threshold with multiple normal sera for discriminating positive crossmatches. For significant change in protocol, instrumentation, or software, the characterization of the positive threshold must be repeated.

(9) For internal labeling, the method used to allow fluorochrome labeled antibodies to penetrate the cell membrane must be documented as effective.

(10) Whether analyzed directly or fixed prior to analysis, labeled cells must be analyzed within a time period demonstrated by the laboratory to avoid significant loss of any cell sub-population or total cell numbers. Test samples must be analyzed within the same period, after staining, as the control samples.

(11) If analysis will be based on a population of cells selected by flow cytometry "gating" on size or density parameters, or selected depletion or enrichment techniques, control stains must be run for each test individual to detect the presence of contaminating cells in the selected population (i.e., monocyte contamination of lymphocytes gated by forward angle or forward angle vs. 90 degree light scatter must be detected with a monocyte specific marker antibody). For cell surface labeling, a method must be used to determine the proportion of viable cells in the

population of counted cells (i.e., thidium bromide staining, CD45 staining). If this value falls below an established laboratory threshold, an appropriate reanalysis of specific measurements must be done.

(12) Conclusions about abnormal proportions of abnormal cell surface marker shall only be drawn in comparison with local control data obtained with the same instrument, reagents and techniques. Conclusions about leukemia/lymphoma classification shall be based on local or published reference data. Determination of percent positives must take into consideration the results of the negative control reagent.

(13) The specificity of monoclonal antibodies shall be verified by the published and/or manufacturer's documentation and, whenever possible, verified locally through tests with appropriate control cells prepared and tested by the same analysis. The quantities of reagents used for each test sample must be determined by the manufacturers from published data and, whenever possible, should be verified locally by appropriate titration procedures.

(14) Terminology used must be defined and/or must conform to nomenclature recommended/approved by the most recent International Workshop of Differentiation Antigens of Human Leukocytes or other appropriate scientific organizations.

Authority: O.C.G.A. §§ 31-22-1, 31-22-4.

111-8-10-.23 Evaluation.

The Department shall conduct a clinical laboratory performance evaluation (proficiency testing) program with the following requirements:

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(a) All clinical laboratories shall enroll and successfully participate in a Department approved proficiency testing program. Point of Care testing areas shall be enrolled or participate in approved proficiency testing programs subscribed to by the responsible laboratory. No proficiency testing agency will be Department-approved unless it meets current requirements found in Title 42 U.S.C. Section 263a.

(b) In addition, the Department may require the clinical laboratory to analyze test samples submitted or authorized by the Department and to report on the results of such analysis.

(c) Laboratories shall enroll in one or more representative segments of approved proficiency testing programs, if available, based upon the categories, subcategories and/or procedures for which a license is issued, and shall have copies of the results sent to the Department. External proficiency testing is not required for blood, tissue, and/or plasmapheresis donor screening procedures.

(d) Proficiency testing must be conducted in the laboratory being evaluated, by regular employees of that laboratory and in the same manner as patient testing. If a laboratory is found to have intentionally sent proficiency testing samples to another laboratory for analysis prior to receiving results back from the testing agency, it shall have its license revoked for a minimum of one year or a period that is equal to or more stringent than current federal law and regulations and, shall be subject to other appropriate sanctions as provided for in Chapter 111-8-25 of the Georgia Rules and Regulations for General Licensing and Enforcement Requirements; all records of proficiency testing must be retained and available for inspection for a period of not less than two years.

(e) Proficiency testing performance standards must be consistent with current federal requirements unless the Department elects to require more stringent standards.

Authority: O.C.G.A. §§ 31-2-8 and 31-22-1 et seq.

111-8-10-.24 Specimens Examined.

(1) A licensed clinical laboratory shall examine human specimens only at the request of a licensed physician, dentist or other person authorized by law to use the findings of laboratory examinations.

(2) All specimens accepted by a licensed laboratory shall be tested on the premises, unless forwarded to another licensed clinical laboratory.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.25 Reporting.

The results of a test performed by a licensed clinical laboratory shall be reported only to (or as directed by) a licensed physician, dentist, or other authorized person requesting the test. Such reports shall include the name of the director and the name and street address of the clinical laboratory in which the test was performed. When a test is performed in a reference laboratory, the director, name and address of the laboratory performing the test must be clearly identified in the report.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.26 Records.

Records of all clinical laboratory services, including records of laboratory test requests and reports, shall be retained by the

laboratory for as long as required by federal law and regulations,
and:

- (a) For general laboratory records and quality control records, kept at least two (2) years,
- (b) For records of immunohematology and cytology, kept at least five (5) years, and
- (c) For records of surgical pathology, kept at least ten (10) years.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.27 Reports to the Department.

- (1) Clinical laboratories shall report to the Department evidence of selected infectious diseases on forms provided by the Department.
- (2) Clinical laboratories making such reports concerning infectious diseases shall not be held liable for having violated a trust or confidential relationship. The reports shall be deemed confidential and not subject to public inspection.
- (3) Reports of Serious Incidents/Events. The laboratory shall report to the Department the following incidents:
 - (a) Fatal transfusion reactions or transfusion complications affecting the patients;
 - (b) Laboratory testing errors which have resulted in the death or serious injury to a patient or employee;

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(c) Significant interruptions in service vital to the continued safe operation of the facility, such as the loss of electricity, gas or water services.

(4) The laboratory shall make the initial report of the serious incident/ event within twenty-four (24) hours or by the next regular business day from when the reportable event occurred, or from when the laboratory has reasonable cause to believe that the reportable event has occurred. The initial report shall be received by the Department in confidence and shall include at least the following:

(a) The name of the laboratory;

(b) The date of the event or the anticipated event and the duration of the incident, if known;

(c) Any immediate corrective actions that the laboratory has taken or expects to take.

(5) Within forty-five (45) days following the resolution of the event, the laboratory shall prepare a written report which includes a root cause analysis on systems and processes associated with the event to identify those improvements that are within the control of the laboratory that will be made to help prevent similar occurrences. The complete report shall be available to the Department for inspection at the facility. The laboratory is not required to complete a written report or a root cause analysis on interruptions in service for which the laboratory did nothing that contributed to the interruption in service.

(6) The Department will hold the initial self-report concerning the reportable serious incident/event in confidence and not release it to the public. However, where the Department determines that a rule violation related to the reported serious incident/event has occurred, the Department will initiate a separate complaint

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investigation of the incident. The separate complaint investigation report and survey results concerning the serious incident/event will not be kept confidential.

(7) Where a licensed laboratory is operated as an organized service of the licensed hospital, the laboratory may comply with the requirements for reporting serious incidents/events set forth in this rule by submitting its reports to the Department through the hospital- wide peer review committee, so long as the reports are made in a timely manner. Only one self-report of each serious incident/event is required to be made for the licensed laboratory that is operating within a licensed hospital.

Authority: O.C.G.A. §§ 31-7-15 and 31-22-1 et seq.

111-8-10-.28 Plasmapheresis and Whole Blood Donor Centers.

Clinical laboratories, including independent plasmapheresis and whole blood donor centers, which provide a system for the collection, processing or storage of human blood and/or its components shall provide methods for the selection of donors as well as methods for the collection, storage, processing, and transfusion, which shall ensure that the donation will not be detrimental to the donor and also protect (as far as possible) the recipient of human blood or any of its components from infectious disease known to be transmissible by blood.

(a) Special Personnel Requirements. In addition to the general personnel requirements outlined elsewhere in these Rules and Regulations, the following special personnel requirements are established:

1. Requirements for Directors and/or Physicians:

(i) In a whole blood, plasmapheresis or other blood component donor center, the director shall meet at least the requirements of Rule 111-8-10-.06(2)(b)1.

(ii) In a whole blood, plasmapheresis or other blood component donor center, the director and any other physician employed must be licensed in the State of Georgia and comply with all provisions of the Georgia Laboratory Licensure Law and associated regulations, and with all applicable federal regulations, specifically those provisions regarding physician requirements. The director shall be responsible, at all times, for all phases of operation.

2. Requirements for Other Personnel:

(i) Donor Selection (Screening) Area. The donor screening area shall be staffed with trained personnel with no lesser qualification than that of Licensed practical Nurse (LPN), Clinical Laboratory Technician or an equivalent level of training or experience. Every screener must be trained to recognize abnormalities, (i.e., blood pressure, pulse, etc.). Careful evaluation must be conducted by a skilled interviewer (based on the outline for donor selection published by the American Association of Blood Banks) to eliminate most donor reactions. A Clinical Laboratory Technologist or a licensed Registered Nurse (RN) must be assigned responsibility for supervision of the screening area, including such procedures as total protein, hemoglobin and hematocrit testing performed there.

(ii) Blood Collection (Phlebotomy) Area.

(I) The supervisors in the phlebotomy area must be persons who have a minimum of three months training and experience in a plasmapheresis or blood donor center and who are qualified as either a Registered Nurse or a Clinical Laboratory Technologist, Licensed Practical Nurse, or a Certified Physician's Assistant. One

person of such qualifications must be employed for one (1) to twelve (12) donors being processed at one time.

(II) The phlebotomists in the phlebotomy area must be persons who have a minimum of one month training in a plasmapheresis or blood donor center and who meet no lesser qualifications in phlebotomy and/or reinfusion than that of Licensed Practical Nurse (LPN), Clinical Laboratory Technician, or equivalent level of training and/or experience. A phlebotomist must be employed for one to six donors being processed on automated equipment, for manual processing there must be one phlebotomist for one to four donors being processed at a time, with a minimum of two phlebotomists in the phlebotomy area whenever any donors are processed. (The phlebotomy supervisors may also serve as phlebotomists).

(iii) Laboratory Testing Area. Personnel in the laboratory area of all whole blood, plasmapheresis or other blood component donor centers must meet qualifications required for any licensed clinical laboratory.

(iv) Other Personnel. Other personnel may be employed or used in the center, such as aides, clerks, volunteer workers, etc. These persons may assist technical staff, but shall not themselves perform technical laboratory duties.

(b) **Proficiency Testing Requirements.** Rule 111-8-10-.23 outlines proficiency testing requirements for hematology, immunohematology, syphilis serology, HIV testing and hepatitis testing. External proficiency testing is not required for blood, tissue and/or plasmapheresis donor screening procedures such as specific gravity, hematocrits, dipstick tests and serum proteins. This exemption from external proficiency testing does not, however, exempt such facilities from quality control requirements, inspection and licensure.

(c) **Documentation of Reactions.** The records system of the facility must maintain documentation of all reactions. Adequate reporting and recording forms must be available and used.

(d) **Blood Labeling and Associated Records.** In addition to labeling required as a part of good laboratory practices, it shall be the responsibility of the licensed laboratory director to comply with Chapter 24 of Title 31 of the Official Code of Georgia Annotated and Rules and Regulations for Blood Labeling, Chapter 111-8-9.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.29 Exemption of Specific Screening and Monitoring.

A facility or part of a facility in which laboratory testing is performed may apply and qualify for exemption from personnel requirements for specific screening and monitoring tests or techniques, as approved and published by the Board.

(a) The Department shall establish guidelines for the exempted screening and monitoring tests, which shall include adequate provisions for (1) personnel, (2) quality control, (3) reporting, (4) record keeping and (5) safety. The guidelines and list of tests or techniques will be periodically reviewed and published by the Department.

(b) Screening and monitoring approvals shall be issued by the Department and shall be valid for one year or a limited and specified time.

(c) Approvals, renewal of approvals or continuation of approvals are subject to continued conformance with the published guidelines, as determined by the Department. If

approval is not granted, the laboratory testing is subject to clinical laboratory licensure.

Authority: O.C.G.A. §§ 31-2-7 and 31-22-1 et seq.

111-8-10-.30 Inspections and Plans of Correction.

(1) Employees and agents of the Department shall have the right of entry into the premises of the laboratory during all hours of operation and full access to all records, reports and documents relevant to the licensure status of the laboratory as determined by the Department.

(2) Licensed laboratories shall submit to inspection by CMS or CMS agents as a condition of licensure, and failure to submit to such inspection shall constitute grounds for suspension or denial of the State license.

(3) A laboratory subject to CMS inspection is authorized and required by the Department to release to CMS or CMS agents all records and information required by CMS in the course of the inspection.

(4) The Department shall make periodic inspections of every clinical laboratory, at its discretion. The frequency of inspection shall take into consideration the compliance record of the laboratories, e.g., the laboratory personnel, proficiency testing performance, and the number or seriousness of deficiencies reported on or since the last on-site inspection.

(5) The director or the laboratory supervisor in charge of the laboratory in the director's absence shall be present during each inspection of the laboratory. In the case of hospital laboratories, the hospital administrator or the administrator's designee shall be available for interview at the opening and close of inspection.

(6) None of the inspections performed by the Department nor any reports generated by the Department shall relieve the licensee from its duty to maintain the safety of its equipment, the work place, or to ensure safe and accurate laboratory testing.

(7) **Plan of Correction.** If as a result of an inspection, violations of these licensing rules are identified; the laboratory will be given a written report of the inspection which identifies the rules violated. The laboratory shall submit to the Department a written plan of correction in response to the report of inspection, which states what the laboratory will do, and when, to correct each of the violations identified. The laboratory may offer an explanation or dispute the findings or violations in the written plan of correction, so long as an acceptable plan of correction is submitted within ten days of the facility's receipt of the written report of inspection. The laboratory shall comply with its plan of correction.

Authority: O.C.G.A. § 31-22-1 et seq.

111-8-10-.31 Exemptions.

These rules and regulations shall not apply to:

(a) Clinical laboratories operated by the Medical College of Georgia, the Emory University School of Medicine, Mercer University School of Medicine, Morehouse School of Medicine, or any other medical schools in Georgia, or the United States Government;

(b) Clinical laboratories operated and maintained exclusively for research and teaching purposes involving no patient or public health services;

(c) Clinical laboratories operated by duly licensed physicians exclusively in connection with the diagnosis and treatment of their own patients; or

(d) Pharmacists duly licensed in Georgia practicing in accordance with O.C.G.A. § 26-4-4 as it pertains to the performing or capillary blood tests and the interpretation of the results of those tests as a means to screen for or monitor disease risk factors and facilitate patient education. The capillary blood tests allowed under this exemption shall be limited to those capillary blood tests available to and for use by the public without licensure of the user of the test.

Authority: O.C.G.A. §§ 26-4-4 and 31-22-9.

111-8-10-.32 Variances and Waivers.

The Department, upon application or petition, may grant variances and waivers to these rules and regulations (after review and advice of Laboratory Advisory Council) when it is shown that the rule and regulation should not be applied as written, because strict application would cause undue hardship and that adequate standards affording protection of health, safety and care exist and will be met in lieu of the exact requirements, or that the purpose of the rule is met through equivalent standards affording equivalent protection of health, safety and care, or to allow experimentation or demonstration of new and innovative approaches to delivery of services, where the approach has the potential to improve service delivery and the intended protections afforded by the rule are being met.

Authority: O.C.G.A. § 31-2-7.

111-8-10-.33 Enforcement.

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(1) The administration and enforcement of these rules and regulations shall be in accordance with Chapters 2, 5 and 22 of Title 31 of the Official Code of Georgia Annotated and Chapter 13 of Title 50 of the Official Code of Georgia Annotated and the Rules and Regulations General Licensing and Enforcement Requirements, Chapter 111-8-25.

(2) A Clinical Laboratory and/or Clinical Laboratory Director License may be denied, revoked, suspended, limited or renewal denied for:

(a) Making false statements of material information on an application for a license or any other documents required by the Department;

(b) Permitting unauthorized persons to perform technical procedures or to issue or sign reports;

(c) Demonstrating incompetence in the performance or reporting of clinical laboratory examination and procedures;

(d) Performing a test for or rendering a report to a person not authorized by law to receive such services;

(e) Referring a specimen for examination to a clinical laboratory in this state which has not been licensed or exempted under Chapter 22 of Title 31 of the Official Code of Georgia Annotated or, if not in this state, certified under all applicable federal law and associated rules and regulations;

(f) Making a report on clinical laboratory work actually performed in another clinical laboratory without designating the director and the name and address of the clinical laboratory in which the test was performed.

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(g) Lending the use of the name of the licensed clinical laboratory or its personnel to an unlicensed clinical laboratory;

(h) Violating or aiding in the violation of any provision of Chapter 22 of Title 31 of the Official Code of Georgia Annotated, or these rules and regulations;

(i) Violating any other provisions of law applicable to the proper operation of a clinical laboratory.

(3) Upon being notified of a conviction, plea, or first offender treatment of a licensed laboratory director involving the manufacture, distribution, trafficking, sale, or possession of a controlled substance or marijuana, the Department shall suspend or revoke the license of such individual as follows:

(a) Upon the first conviction, the licensed individual shall have his or her license to direct a clinical laboratory suspended for a period of not less than three months, provided, however, that in the case of a first conviction, plea, or first offender treatment for a misdemeanor the Department shall be authorized to impose a lesser sanction or no sanction upon the licensed individual, and

(b) Upon the second or subsequent conviction, the licensed individual shall have his or her license to direct a clinical laboratory revoked. The failure of a licensed laboratory director to notify the Department of a conviction as required in subsection C of Rule 111-8-10-.04(2) shall be considered grounds for revocation of his or her license to direct a clinical laboratory.

(c) A licensed laboratory director sanctioned under the foregoing subsections (a) or (b) may be entitled to reinstatement of his or her license to direct a clinical laboratory upon successful completion of a drug abuse treatment and education program approved by the Department.

(4) The operation or maintenance of an unlicensed clinical laboratory in violation of Chapter 22 of Title 31 of the Official Code of Georgia Annotated and these rules may be declared a nuisance, inimical to the public health, welfare, and safety. The Commissioner may bring an action for an injunction to restrain such violation or to enjoin the future operation or maintenance of any such clinical laboratory until compliance with Chapter 22 of Title 31 of the Official Code of Georgia Annotated and these rules has been demonstrated to the satisfaction of the Department. (5) Any person who violates any provision of Chapter 22 of Title 31 of the Official Code of Georgia Annotated or any of the rules and regulations promulgated thereto shall be guilty of a misdemeanor.

Authority: O.C.G.A. §§ 16-13-110 et seq., 31-2-8 and 31-22-1 et seq.

111-8-10-.34 Severability.

In the event that any rule, sentence, clause or phrase of any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof and such remaining rules or portions thereof shall remain in full force and effect, as if such rule or portions thereof so determined, declared or adjudged invalid or unconstitutional were not originally a part thereof.

Authority O.C.G.A. § 31-22-1 et seq.