

DEPARTMENT OF COMMUNITY HEALTH

BUREAU OF LABORATORIES

CLINICAL LABORATORIES

(By authority conferred on the director of public health and the laboratory facilities council by section 3 of Act No. 235 of the Public Acts of 1968, as amended, being SS325.83 of the Michigan Compiled Laws)

PART 1. GENERAL PROVISIONS

R 325.2301 Definitions; A to C.

Rule 1. (1) For the purpose of these rules, the words and phrases have the same meaning as the words and phrases defined in the act.

(2) "Act" means Act No. 235 of the Public Acts of 1968, being SS325.81 to 325.92 of the Michigan Compiled Laws.

(3) "Assistant to the director" means an individual who under the general direction of a laboratory director or associate director supervises technical personnel, reports findings and performs tests requiring special skills.

(4) "Associate director" means a person who assists a laboratory director in the direction of a clinical laboratory and who possesses qualifications equivalent to those required for a laboratory director in those laboratory fields and procedures he directs. He need not possess a certificate of qualification as a laboratory director.

(5) "Cytology" means the examination and preparation of cells taken from surfaces or cavities of the body for the detection of the presence of disease.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2302 Definitions; D to P.

Rule 2. (1) "Dentist" means a person licensed as a dentist by the Michigan state board of dentistry.

(2) "Department" means the state department of public health.

(3) "Dermatopathology" means the histopathological examination of specimens of skin for the determination of the presence of disease.

(4) "History and pathology" means the histopathological examination of tissues from patients for the determination of the presence of disease.

(5) "Laboratory" means a clinical laboratory.

(6) "Oral pathology" means the histopathological examination of tissues or cells removed from the oral cavity for the determination of the presence of disease.

(7) "Physician" means a person licensed as a physician by the board of registration in medicine or the board of osteopathic registration and examination.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2311 Effect of rules on physicians' and dentists' licenses.

Rule 11. These rules shall not be interpreted to restrict the license of a physician or dentist except to the extent prescribed in the act.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2315 Reviews and revisions.

Rule 15. These rules shall be reviewed annually at a meeting of the laboratory facilities council. The director may call additional meetings of the laboratory facilities council and shall call additional meetings upon petition of at least 3 members of the council.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2319 Rescission.

Rule 19. The rules and regulations for the "Operation of Public Health Laboratories," being R 325.251 to R 325.256 of the Michigan Administrative Code and appearing on pages 2237 and 2238 of the 1954 volume of the Code, are rescinded.

History: 1954 ACS 68, Eff. June 10, 1971; 1979 AC.

PART 2. LICENSING OF LABORATORIES

R 325.2321 Applications and fees.

Rule 21. (1) An application for a license for a laboratory shall be made on forms authorized and provided by the director of public health and shall include the name of the proposed laboratory director, or, if he is not certified, an application for his certificate of qualification.

(2) The owner shall pay by check or money order the fee prescribed in the act and transmit it with the initial or renewal application.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2322 Scope of licenses.

Rule 22. A laboratory may be licensed for:

- (a) Microbiology.
- (b) Serology.
- (c) Biochemistry.
- (d) Hematology.
- (e) Immunohematology, but may be limited to diagnostic tests or transfusion services.
- (f) Pathology, but may be limited to histopathology, dermatopathology, oral pathology, or a combination of any 2 of these.
- (g) Cytology.
- (h) Biophysics.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2323 Locations and transfers.

Rule 23. (1) A license shall be effective only for a laboratory operated at a single location. To obtain a license for a laboratory at a different location, a separate application shall be filed regardless of ownership or laboratory director. However, a separate license will not be required for separate buildings on the same grounds.

(2) A license is valid only in the hands of the owner to whom it is issued and shall not be subject of sale, assignment or transfer.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2324 Terminations and renewals.

Rule 24. (1) A license is valid for 1 year and terminates on its anniversary date unless sooner suspended or revoked.

(2) A laboratory owner shall file with the director of public health an application or renew of a license at least 30 days before the expiration of a license. The application shall be made on forms furnished by the director of public health.

(3) When the license becomes void due to a change in the laboratory director, the director of public health shall be notified immediately. The laboratory owner shall designate an individual to be the laboratory director who is either certified or has a temporary certificate of qualification as a laboratory director. The laboratory upon application may be relicensed with the same anniversary date as the original license with no additional fee.

(4) a laboratory shall apply to the director of public health for a change in the scope of its license. The director of public health shall act on the application within 30 days. A laboratory shall notify the director of public health of the addition to the list of tests furnished with the application for license within 90 days after the addition.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2325 Denial.

Rule 24. The grounds for denial of a laboratory license are:

(a) Falsification of a statement on an application for a laboratory license or on any other document required by the director of public health.

(b) Failure to pay a proper license fee.

(c) Failure to execute the required agreement form.

(d) Refusal to permit entry by an authorized representative of the director of public health at any reasonable time to inspect laboratory operations, equipment, conditions or records.

(e) Refusal to participate in the state conducted or approved proficiency testing program.

(f) Failure to correct laboratory deficiencies in accordance with standards of the director of public health.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2326 Revocations, suspensions, and limitations.

Rule 26. A laboratory license maybe revoked, suspended or limited if the director of public health, after notice and an opportunity for hearing finds that the owner of the laboratory, laboratory director or an employee acting with knowledge of the owner or laboratory director has violated any part of section 9 of the act or conditions have changed which led to a provisional certification of the laboratory director.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2327 Inspections.

Rule 27. (1) A representative of the director of public health shall inspect each laboratory at least biennially.

(2) Pertinent information relating to personnel, facilities, and equipment shall be obtained at the time of inspection, and reports and records shall be reviewed by the department.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

PART 3. CERTIFICATES OF QUALIFICATIONS OF LABORATORY DIRECTORS

R 325.2331 Applications and fees.

Rule 31. (1) A laboratory director shall submit a fully completed application for a certificate of qualification on a form prescribed by the director of public health. The application shall be accompanied by documents or give information as to training and experience for each discipline for which the certificate is sought.

(2) The laboratory director shall paid by check or money order the fee prescribed in the act and transmit it with his initial or renewal application.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2332 Certification; extent; physicians and dentists.

Rule 32. (1) An applicant shall be certified in all fields for which he applies and qualifies.

(2) A position certified in anatomical pathology by the American board of pathology for the American osteopathic board of pathology or who possesses formal training equivalent to that required for certification by these boards at the time of completion of training shall be certified as a laboratory director in his histology, pathology, and cytology

(3) A position certified in clinical pathology by the American board of pathology or the American osteopathic board of pathology or who possesses formal training equivalent to that required by these boards at the time of completion of training shall be certified as a laboratory director in microbiology, erology, biochemistry, hematology, immunohematology, or biophysics.

(4) A position or dentist who is certified by the American board of oral pathology or who has a certificate of completion of residency or a master of science degree in oral pathology shall be certified in oral pathology.

(5) A physician who is certified by the American board of dermatology, and has taken full-time formal training in dermatology for least one year shall be certified in dermatology.

(6) A physician who was qualified under subrule (2) or has one year of full-time formal Cytology training in an institution approved for training in cytology shall be certified and cytology. The practice of cytology shall be limited to tests on anatomic sites for which the physician is qualified.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2333 Certification in microbiology.

Rule 33. A person shall be certified as a laboratory director in microbiology who meets either of the following requirements:

(a) He holds an earned a doctoral degree in medicine, osteopathic medicine, microbiology, chemistry, or a biological science from an accredited institution certified by the American board of microbiology or has three or more years of appropriate laboratory training and experience of which at least one year was spent acquiring proficiency in the specialty of microbiology with a laboratory director at the doctoral level of a hospital, health department, university, or medical research institution.

(b) He holds an appropriate master's degree from an accredited institution and has five years of appropriate laboratory experience of which at least two years were spent acquiring proficiency in the specialty of microbiology with a laboratory director at the doctoral level of a hospital, health department, university or research institution.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2334. Certification in serology.

Rule 34. A person shall be certified as a laboratory director in serology who meets either the filing requirements:

(a) He holds unearned doctoral degree in medicine, osteopathic medicine, microbiology, chemistry or a biological science from an accredited institution and 3 years of appropriate laboratory experience of which at least six months were spent acquiring proficiency in serology with a laboratory director at the doctoral level of a hospital, health department, university or medical research institution.

(b) He holds an appropriate master's degree from accredited institution and has five years of appropriate laboratory experience of wage at least six months were spent acquiring proficiency in serology with the laboratory director of the doctoral level of a hospital, health department, university or medical research institution.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2335 Certification in hematology.

Rule 35. A person shall be certified as a laboratory director in hematology who meets either the filing requirements:

(a) He holds an earned doctoral degree in medicine, osteopathic medicine, microbiology, chemistry, or biological science from an accredited institution and has three years of appropriate clinical laboratory training and experience, of which at least one year was spent acquiring proficiency in the specialty of hematology with the laboratory director of the doctoral level of a hospital, health department, university, or medical research institution.

(b) He holds an appropriate master's degree from accredited institution and has five years of appropriate laboratory experience of which at least one year was spent acquiring proficiency in the specialty of hematology with a laboratory director at the doctoral level of a hospital, health department, university or medical research institution.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2336 Certification of immunohematology.

Rule 36. (1) A person shall be certified as a laboratory director in immunohematology, which includes all laboratory procedures necessary for transfusion services, if he holds a earned doctoral degree in medicine or osteopathic medicine and has one-year experience in immunohematology including transfusion services.

(2) A person shall be certified as a laboratory director in immunohematology, but which excludes all laboratory procedures involving transfusion services, if he holds an earned doctoral degree or master's degree in an appropriate field from an accredited institution and has three years of appropriate laboratory experience of which at least one year was spent acquiring proficiency in the specialty of immunohematology with a laboratory director at the doctoral level of a hospital, health department, university or medical research institution.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2337 Certification in biochemistry or biophysics.

Rule 37. (1) A person shall be certified as a laboratory director in biochemistry or biophysics who meet each of the following requirements:

(a) He holds an earned doctoral degree in medicine, osteopathic medicine, microbiology, chemistry, while physics, or a biological science from an accredited institution and is certified by the American board of clinical chemistry and has three years of appropriate laboratory training and experience of which at least one year was spent acquiring proficiency in specialties of chemistry or biophysics with a laboratory director at the doctoral level of a hospital, health department, university or medical research institution.

(b) He holds an earned master's degree in appropriate field from an accredited institution and has five years of appropriate laboratory training and experience of which at least two years were spent acquiring proficiency in the specialties of chemistry or biophysics with a laboratory director at the doctoral level of a hospital, health department, university, or medical research institution.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2338 Certificates for present laboratory directors.

Rule 38. A laboratory director who was responsible for direction of a laboratory in this state for 12 months within three years before January 1, 1969, shall be issued a certificate of qualification in those fields and procedures performed in this laboratory if he meets either of the following requirements:

(a) He holds at least a bachelor's degree from an accredited institution with chemistry or a biological science as his major subject.

(b) He has achieved in fields and procedures performed a satisfactory grade in the general and specialty examinations conducted by or under the sponsorship of the United States public health service for independent laboratories under of the federal health insurance for the aged program or through examinations prescribed by the director of public health.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2339 Provisional certificates.

Rule 39. If the requirements for education, training, and experience set forth in R 325.2333 to R 325.2337 cannot be met, the director of public health with the advice of the laboratory facilities council may give provisional certification subject to a semi-annual review to a laboratory director in the specialties covered by such rules if he ascertains that the laboratory directed by this individual can be operated competently and will best serve the public health. If the conditions which led to a provisional certification change, the certification shall be considered bowl aid. This provisional certification is valid only while the individual is employed at the specific laboratory for which it was necessary to issue a provisional certificate to laboratory director.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2340. Suspension and revocation.

Rule 40. A certificate of qualification or a provisional certificate may be suspended or vote to pursuant to the procedure and based on the grounds set forth in R 325.2326.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

PART 4. LABORATORY DIRECTION AND SUPERVISION

R 325.2341 Laboratory directors; full-time and part-time.

Rule 41. A laboratory director shall serve the laboratory on either a full-time or on a regular part-time basis. If he serves on a regular part-time basis, he shall not serve as laboratory director of more than three laboratories unless he provides an associate laboratory director to serve in each laboratory either on a full-time or regular part-time basis. Such an associate may not serve more than three laboratories. However, if a laboratory director serves more than three laboratories on a part-time basis and is unable to provide an associate director to serve in the additional laboratories he directs, the director of public health with the advice of the laboratory facilities council may make an exception to this rule if any additional laboratory can be operated competently and will best serve the public health.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2342 Laboratory directors and owners; responsibilities.

Rule 42. (1) Commensurate with the laboratory workload, a laboratory director shall spend an adequate amount of time in the laboratory to direct and supervise the technical performance of the staff and shall be readily available for personal and telephone consultation.

(2) If the laboratory director is to be continuously absent for more than one month, arrangements shall be made for a qualified substitute laboratory director.

(3) The laboratory owner is responsible for the proper performance of tests made in the laboratory in the employment in in-service training of qualified laboratory personnel. The owner may delegate all or part of these responsibilities to a laboratory director.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2343 Assistance to laboratory directors; qualifications.

Rule 43. (1) A laboratory may perform tests in disciplines in which the laboratory director or associate is not qualified or where the director serves in a part-time capacity, if a person designated as an assistant to the director has either of the following qualifications:

(a) He meets the educational requirements for laboratory director in the specialty he directs pursuant to R 325.2332 to R 325.2337 in has one-year of appropriate experience.

(b) He has a combination of seven years appropriate education, training, and experience and has achieved a satisfactory grade through an examination conducted under sponsorship of the department. An examination shall be taken in each specialty performed in the laboratory that is supervised by the assistant to the director. The examination shall be offered annually or oftener if in the opinion of the director of public health the need arises. Interim approval may be given by the director public health yet the laboratory meets other requirements and the assistant to the laboratory director has indicated his intent in writing to take the examination.

(2) A person who can demonstrate that he served as an assistant to the director for 12 months within three years before January 1, 1969, may be designated as an assistant to the director without examination if he is otherwise qualified.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2344 Assistance to laboratory directors: approval.

Rule 44. Get the requirements for assistant to laboratory director cannot be met, the director public health with the advice of the laboratory facilities council may approve the assistant to the laboratory director if the director of public health ascertains that the laboratory can be operated competently and will best serve the public health.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

PART 5. LABORATORY OPERATIONS

R 325.2351 Specimen examinations.

Rule 51. (1) The laboratory may examine specimens at the request of a physician, dentist, or other person authorized by law to receive such results. A laboratory performing examinations in a community oriented screening program organized by governmental or recognized charitable organizations may examine specimens without such a request.

(2) The name of the laboratory actually performing the examinations shall be indicated on the report to the authorized person submitting the specimen. The address shall also be indicated for laboratories outside of this state.

(3) A laboratory owner or director shall not solicit either personally or through an agent referral of specimens to his or any other laboratory a manner which implies an offer of rebates to persons submitting specimens or other fee-splitting arrangements. A laboratory shall not enter into a contractual provision of laboratory services for a fixed fee, independent all of the number of specimens submitted.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2352 Specimen reports and records; identification contents.

Rule 52. A specimen received shall be numbered or otherwise appropriately identified any record or copy of the relevant report shall be kept as evidence of its receipt. The record shall contain the following:

(a) The laboratory number or other identification.

(b) The name and other identification of the person from whom the specimen was taken.

- (c) The name of the licensed physician or other authorized person or laboratory who submitted the specimen.
- (d) The date the specimen was received in the laboratory.
- (e) The condition of an unsatisfactory specimen when received, such as broken, leaked, hemolyzed or turbid.
- (f) The type of test performed.
- (g) The results of the laboratory test; the name, initials, or other symbols identifying the examiner; and the date the test was completed and reported.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2353 Specimen reports; preservation and distribution.

Rule 53. (1) The original or duplicate report shall be preserved for at least one year and shall be accessible to the authorized individual inspecting the laboratory.

(2) The results of laboratory tests or procedures or copies thereof shall not be given or sent to the patient concerned, except with the written consent of the physician or other authorized person who requested the test.

(3) A laboratory receiving specimens for examination from another laboratory shall report to the submitting laboratory.

(4) An annual report giving the number of examinations and tests performed shall be submitted before license renewal. The report shall cover the twelve month period to be designated by the laboratory director.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1954 ACS 68, Eff. June 10, 1971; 1979 AC.

R 325.2354 Personnel reports and records.

Rule 54. (1) The laboratory director shall submit lists of personnel with their technical qualifications. The director of public health shall be notified within 90 days of changes in technical personnel.

(2) Current personnel records shall be maintained either in the laboratory or personnel office. The records shall include a resume of the employee's training experience, including dates of previous concurrent employment.

History: 1954 ACS 68, Eff. June 10, 1971; 1979 AC.

R 325.2355 Facilities and equipment

Rule 55. (1) Laboratory location and facilities shall conform to local building safety and fire codes and ordinances.

(2) Space shall be adequate to perform services offered by the laboratory. Suggested standards for space and storage requirements may be recommended periodically by the director of public health.

(3) Sufficient storage space shall be provided so that it will not be necessary to store surplus supplies in working areas.

(4) Provision shall be made for sterilization of contaminated materials.

(5) Fire precautions shall be observed and unnecessary physical, chemical, and biological hazards shall be prohibited.

(6) Laboratory equipment shall be examined periodically to assure that it is precisely calibrated and is in good working order.

History: 1954 ACS 68, Eff. June 10, 1971; 1979 AC.

PART 6. PERFORMANCE EVALUATION AND QUALITY CONTROL PROCEDURES

R 325.2361 Performance evaluations.

Rule 61. (1) A review of quality control procedures, calibration of instruments, standardization of reagents, maintenance of records and safety precautions shall be made at the time of the on-site inspection survey by representative of the department.

(2) Test samples for analyses may be delivered by the department to the laboratory during an on-site inspection or by mail or common carrier.

(3) The laboratory shall examine the samples using its routine methods and personnel.

(4) Proficiency evaluation programs of recognized professional organizations such as the college of American pathologists and the American association of bioanalysts in the others approved by the director of public health, shall be excepted in lieu of state of valuation programs.

(5) Copies of reports all analyses made on test samples from these a valuation programs shall be sent to the director of public health. Analyses and reports of proficiency testing may be considered by the director of public health in making the finding under section 9 of the act.

History: 1954 ACS 68, Eff. June 10, 1971; 1979 AC.

R 325.2362 Quality control programs; general provisions.

Rule 62. (1) A laboratory shall maintain a quality control program adequate inappropriate for accuracy and reproducibility of the laboratory procedures and services.

(2) An acceptable quality control program shall include:

(a) Preventive maintenance.

(b) Periodic inspection or testing for proper operation of equipment and instruments.

(c) Evaluation of reagents and volumetric instruments.

(d) Surveillance or results.

(e) Appropriate records.

(3) Facilities, equipment and instruments shall be adequate to perform the procedures for which licensing is granted under R 325.2322.

(4) Temperature controlled spaces and equipment, including water baths, incubators and refrigerators shall be checked each day of use to assure proper performance.

(5) Reagents and solutions shall be labeled to indicate identity, titer strength or concentration and a prepared.

(6) An adequate description of analytical methods used by the laboratory shall be available at all times to those performing procedures.

(7) The laboratory director shall review the procedures used at least biennially and initial end date the master copy.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2363 Clinical chemistry standards and controls.

Rule 63. (1) Standards for clinical chemistry procedure shall include the following:

(a) A clinical chemistry procedure shall include at least one solution unknown concentration in purity (standard) with each group of specimens analyzed.

(b) Standardization shall be performed not less than once each month for procedure is not amenable to subdivision (a). Standard curves shall be labeled as to instrument, wavelength, procedure and eight calibrated.

(2) Controls for clinical chemistry procedures shall include the following:

(a) The clinical chemistry procedure shall be subject to a valuation by seum, urine or other applicable control approximating the unknown composition at least once on each day of use.

(b) Control limits for such materials shall be established and recorded.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2364 Hematology procedures.

Rule 64. (1) A hematological procedure shall be subject to a control for evaluation at least once on each day of use where applicable.

(2) Where appropriate, records shall be available which documents the routine precision of each method.

(3) Differential smears shall be kept for least 30 days.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2365 Immunohematology procedures.

Rule 65. An immunohematological procedure shall conform to the standards approved by the director of public health.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2366. Bacteriology and mycology procedures.

Rule 66. (1) A sustaining procedure shall be checked at least weekly for intended reactivity by concurrent application to smears of microorganisms with predictable staining characteristics.

(2) A record shall be The procedures for preparation of media or sources of commercially prepared media.

(3) Chemical and biological solutions, reagents and antisera shall be checked periodically to ensure that they have not deteriorated and that they maintain their proper reactivity.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2367 Parasitology procedures.

Rule 67. (1) A stain shall be prepared in used according to recorded procedures.

(2) The specific gravity of a solution used for flotation or sedimentation shall be checked to ensure that meets required specifications.

(3) An illustrated reference source of identified parasites shall be available in the laboratory for comparison with diagnostic specimens.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2368 Serology procedures.

Rule 68. (1) Where applicable, a serologic procedure performed on unknown specimens shall simultaneously included a positive control serum of known titer to insure sensitivity and a negative control serum to insure specificity of antigen reactivity.

(2) Adequate controls for all test components, such as antigens, components or erythrocyte indicator systems, shall be employed to insure reactivity or uniform titer.

(3) The new lot of reagent shall be tested in parallel with one of acceptable reactivity before the new reagent is placed in routine use.

(4) Controls of graded reactivity shall be included each time tests are performed in order to detect variations in reactivity levels. Tests shall not be performed or results reported unless the predetermined reactivity pattern of the controls is obtainable.

(5) Serologic tests for syphilis shall be run with standards in controls which conform to venereal disease research laboratory, national communicable disease center recommendations.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.

R 325.2369 Cytology procedures.

Rule 69 (1) The laboratory director or his assistant laboratory director qualified in cytopathology shall review for proper staining and interpretation a random sample of each day's specimens.

- (2) A smear suspected of being abnormal by a cytology technologists or cytotechnician Shelby reviewed in a report signed by a physician qualified in cytology.
- (3) A smear shall be preserved for at least one year.

History: 1954 ACS 61, Eff. Feb. 16, 1970; 1979 AC.