902 KAR 11:050. Equipment, methods, and samples.

RELATES TO: KRS Chapter 333
STATUTORY AUTHORITY: KRS 194.050
CERTIFICATION STATEMENT:
NECESSITY, FUNCTION, AND CONFORMITY: KRS Chapter 333 directs that all medical laboratories in Kentucky shall establish a quality control program acceptable to the Cabinet for Human Resources, and authorizes the cabinet to adopt reasonable rules and regulations to effectuate the purposes of KRS Chapter 333, including standards of performance in the examination of specimens. This administrative regulation is to ensure accuracy of test results by control of medical laboratory equipment, methods, and samples.

Section 1. Quality Control; General Practices. Each medical laboratory shall establish a quality control program covering all types of analyses performed by the laboratory for verification and assessment of accuracy, measurement of precision, and detection of error. The program shall provide for the following:

(1) Preventive maintenance, periodic inspection, and testing for proper operation of equipment and instruments as may be appropriate; validation of methods; evaluation of reagents; surveillance of results; and remedial action to be taken in response to detected defects.

(2) Adequacy of facilities, equipment, instruments, and methods for performance of the procedures or categories of procedures for which a license application is filed or granted; proper lighting for accuracy and precision; monitoring of temperature-controlled spaces and equipment, including water baths, incubators, sterilizers, and refrigerators, to ensure proper performance; evaluation of analytical measuring devices, such as photometers and radioactivity counting equipment, with respect to all critical operating characteristics.

(3) Labeling of all reagents and solutions to indicate identity and, if significant, titer, strength or concentration, recommended storage requirements, preparation or expiration date, and other pertinent information; assure that material of substandard reactivity or deteriorated materials are not used.

(4) The availability at all times, in the immediate bench area in which staff is engaged in examining specimens and performing related procedure within a category (e.g., clinical chemistry, hematology, and pathology) of current laboratory manuals or other complete written descriptions and instructions relating to:

(a) The analytical methods to be used by the staff, properly designated and dated to reflect the most recent supervisory reviews;

(b) Reagents;

(c) Control and calibration procedures; and

(d) Pertinent literature references. Textbooks may be used as supplements to the written descriptions but may not be used in lieu thereof.

(5) Written approval by the director or supervisor of all changes in laboratory procedures.

(6) Maintenance and availability to laboratory personnel and to the cabinet of records, reflecting dates and, if appropriate, the nature of inspection, validation, remedial action, monitoring, evaluation, and changes and dates of changes in laboratory procedures.

(7) Solicitation designed to provide for the collection, preservation, and transportation of specimens sufficiently stable to provide accurate and precise test results suitable for clinical interpretation.

Section 2. Quality Control for Particular Specialties and Subspecialties. In addition to the quality control provisions required under Section 1 of this administrative regulation, each medical laboratory shall provide for additional controls which pertain to the particular specialties and subspecialties in which the laboratory is involved. In establishing the controls, the following rules shall apply:

(1) If the laboratory performs tests in the specialty of microbiology, chemical and biological solutions, reagents, and antisera shall be tested and inspected each day of use for reactivity and deterioration.

(a) If the laboratory performs tests in the subspecialties of bacteriology and mycology, staining materials shall be tested for intended reactivity by application to smears of microorganisms with predictable staining characteristics; and each batch of medium shall be tested before, or concurrently with, use with selected organisms to confirm required growth, characteristics, selectivity, enrichment, and biochemical response.

(b) If the laboratory performs tests in the subspecialty of parasitology, a reference collection of slides, photographs, or gross specimens of identified parasites shall be available and used in the laboratory for appropriate comparison with diagnostic specimens; and a calibrated ocular micrometer shall be used for determining the size of ova and parasites, if size is a critical factor.

(c) If the laboratory performs tests in the subspecialty of virology, systems for the isolation of viruses and reagents for the identification of viruses shall be available to cover the entire range of viruses which are etiologically related to clinical diseases for which services are offered; 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 identify erroneous results; and if sero-diagnostic tests for virus diseases are performed, requirements for quality control as specified for serology shall apply.

(2) If the laboratory performs tests in the specialty of serology, the following controls shall be established:

(a) Serologic 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.

(b) Controls for all test components (antigens, complement, erythrocyte indicator systems, etc.) shall be employed to ensure reactivity and uniform dosage.

(c) Test results shall not be reported unless the predetermined reactivity pattern of the controls is obtained.

(d) Equipment, glassware, reagents, controls, and techniques for tests for syphilis shall conform to those recommended in the "Manual of Tests for Syphilis", American Public Health Association, 1990, incorporated by reference, or to any subsequent revisions. A copy of the "Manual of Tests for Syphilis" may be inspected or obtained at the Office of the Commissioner for Health Services, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. until 4:30 p.m.

(3) If the laboratory performs tests in the specialty of clinical chemistry:

(a) Each instrument or other device shall be recalibrated or rechecked at least once on each day of use. Records which document the routine precision of each method, automated or manual, and its recalibration schedule shall be maintained and available to laboratory personnel and the cabinet; at least one (1) standard and one (1) reference sample (control) shall be included each day of testing unknown specimens; and control limits for standards and reference samples shall be recorded and displayed and shall include the course of action to be instituted if the results are outside the acceptable limits.

(b) Screening or qualitative chemical urinalysis shall be checked daily by use of suitable reference samples.

(4) If the laboratory performs tests in the specialty of immunohematology:

(a) ABO grouping shall be performed by testing unknown red cells with anti-A and anti-B grouping serums licensed under Part 73, Title 42, Code of Federal Regulations, or possessing equivalent potency, using the technique for which the serum is

specifically designed to be effective; for confirmation of ABO grouping the unknown serum shall be tested with known A1 and B red cells.

(b) The Rho(D) type shall be determined by testing unknown red cells with anti-Rho (anti-D) typing serum licensed under 42 CFR Part 73, or possessing equivalent potency using the technique for which the serum is specifically designed to be effective; anti-Rho' (CD), anti-Rho" (DE) and anti-Rhorh'rh" (CDE) serums licensed pursuant to 42 CFR Part 73, or possessing an equivalent potency, may be used for typing donor blood; all Rho negative donor and patient cells shall be tested for the Rho variant (Du); a control system of patient's cells suspended in his own serum or in albumin shall be employed if the test is performed in a protein medium.

(c) The potency and reliability of reagents (antisera, known test cells, and antiglobulin - Coombs serum) used for ABO grouping, Rh typing, antibody detection, and compatibility determinations shall be tested for reactivity on each day of use and if a new lot of reagents is used.

(5) If the laboratory performs tests in the specialty of hematology, instruments and other devices used in hematological examination of specimens shall be recalibrated, retested, or reinspected, as may be appropriate, each day of use; each procedure shall be rechecked each day of use with two (2) levels of controls; tests such as the one (1) stage prothrombin time test shall be run in duplicate unless the laboratory can demonstrate that low frequency of random error or high precision makes the testing unnecessary; standard deviation, coefficient of variation, or other statistical estimates of precision shall be determined by random replicate testing of specimens; and the accuracy and precision of blood cell counts, hematocrit, and hemoglobin measurements shall be tested each day of use.

(6) If the laboratory performs tests in the specialties of exfoliative cytology, histopathology, or oral pathology, the following controls shall be established:

(a) If the laboratory performs tests in the specialty of exfoliative cytology, the laboratory director or supervisor qualified in cytology shall rescreen for proper staining and correct interpretation at least a ten (10) percent random sample of gynecological smears which have been interpreted to be in one (1) of the benign categories by personnel not possessing director or supervisor qualifications; all gynecological smears interpreted to be in the "suspicious" or positive categories by screeners shall be confirmed by the laboratory director or qualified supervisor and the report shall be signed by a physician qualified in pathology or cytology; all nongynecological cytological preparations, positive or negative, shall be reviewed by a director or supervisor qualified in cytology; nonmanual methods shall provide quality control similar to that in other nonmanual laboratory procedures; and all smears shall be retained for not less than five (5) years from date of examination.

(b) If the laboratory performs tests in the specialties of histopathology and oral pathology, all special stains shall be controlled for intended reactivity by use of positive slides; stained slides shall be retained for not less than two (2) years from date of examination, and blocks shall be retained for not less than one (1) year from the date of examination; and 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.

(7) If the laboratory performs tests in the specialty of radiobioassay, the counting equipment shall be checked for stability at least once each day of use, with radioactive standards or reference sources; reference samples with known activity and within expected levels of normal samples shall be processed in replicate quarterly; for each method, records which document the routine precision and the recalibration schedule shall be maintained and be available to the staff and the cabinet.

(3 Ky.R. 204; eff. 5-4-1977; 20 Ky.R. 2189; eff. 3-14-1994; eff. 3-22-2019; Crt eff. 12-29-2025.)