

902 KAR 11:040. Specialty test procedure.

RELATES TO: KRS Chapter 333

STATUTORY AUTHORITY: KRS 194.050

NECESSITY, FUNCTION, AND CONFORMITY: KRS Chapter 333 authorizes the Cabinet for Human Resources to issue licenses to medical laboratories in Kentucky, and directs that licenses be issued only for the performance of those medical laboratory procedures which the particular laboratory, by virtue of the educational and experience background of its laboratory personnel, is competent to perform. The cabinet is authorized to adopt reasonable rules and regulations to effectuate the purposes and provisions of KRS Chapter 333. This administrative regulation establishes standards for determining the specialty of test procedures for which a laboratory may be licensed.

Section 1. Tests Performed. The medical laboratory shall perform only those laboratory procedures and tests that are within the specialties and subspecialties the laboratory director or supervisor is qualified. The following standards shall apply:

(1) A laboratory may perform anatomical and clinical laboratory procedures and tests in all specialties if the laboratory director or a supervisor is a physician certified in both anatomical and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications equivalent to those required for certification.

(2) Unless otherwise exempted in subsection (1) of this section, a laboratory may perform tests in the specialty of:

(a) Microbiology, including the subspecialties of bacteriology, virology, mycology, and parasitology if the director or a supervisor is a physician or holds an earned doctoral or master's degree in microbiology from an accredited institution and, subsequent to graduation, had two (2) years of experience in clinical microbiology.

(b) Serology if the director or a supervisor is a physician or holds an earned doctoral or master's degree in biology, chemistry, immunology, or microbiology from an accredited institution and, subsequent to graduation, had two (2) years of experience in serology.

(c) Hematology, including gross and microscopic examination of the blood, if the director or a supervisor holds a master's or bachelor's degree in biology, immunology, microbiology, chemistry, or medical technology from an accredited institution and, subsequent to graduation, had two (2) years of experience in hematology.

(d) Immuno-hematology if the director or a supervisor is a physician with two (2) years of experience in immuno-hematology subsequent to graduation.

(e) Clinical chemistry if the director or a supervisor is a physician or holds an earned doctoral or master's degree in chemistry from an accredited institution and, subsequent to graduation, had two (2) years of experience in clinical chemistry approved by the cabinet.

(f) Radiobioassay if the director or a supervisor is a physician or holds an earned doctoral, master's, or bachelor's degree in chemistry, physics, biology, or medical technology from an accredited institution and, subsequent to graduation, had two (2) years of experience in radiobioassay approved by the cabinet.

(g) Tissue pathology, limited to skin pathology, if the director or a supervisor is a physician certified in dermato-pathology by the American Board of Dermatology or possesses qualifications equivalent to those required for certification.

(h) Diagnostic cytology if the director or a supervisor is a physician who is certified by the American Society of Cytology to practice cytopathology or possesses qualifications equivalent to those required for certification. The laboratory shall be qualified to perform the tests only on that anatomic site for which the director or supervisor is certified.

(i) Oral pathology if the director or supervisor is a dentist or physician who is certified in oral pa-

thology by the American Board of Oral Pathology or possesses qualifications equivalent to those required for certification.

(3) Unless otherwise exempted in subsections (1) and (2)(d) of this section, a laboratory may perform tests in the immunohematology subspecialties of ABO grouping and Rh typing, antibody detection, identification, and titering if the director or a supervisor holds a master's or bachelor's degree in biology, immunology, microbiology, chemistry, or medical technology from an accredited institution and, subsequent to graduation, has two (2) years of experience in immunohematology.

(4) A laboratory may perform tests in the specialty of tissue pathology if the director or a supervisor is a physician who is certified in anatomical pathology by the American Board of Pathology or possesses qualifications equivalent to those required for certification.

Section 2. Special Exceptions. (1) Unless otherwise exempted in Section 1(2)(a), (b), (c), (e), or (f) of this administrative regulation, if an individual qualifies as a medical laboratory director by reason of having served as director of a medical laboratory for twelve (12) months between January 1, 1968, and May 4, 1977, having attained a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject, and, subsequent to graduation, had six (6) years of pertinent full-time medical laboratory experience, the laboratory may perform tests in the specialty of:

(a) Microbiology if the director holds a bachelor's degree in a biological science and, subsequent to graduation, had four (4) years of experience in microbiology.

(b) Hematology if the director holds a bachelor's degree in biology, immunology, or microbiology from an accredited institution and, subsequent to graduation, had four (4) years of experience in hematology.

(c) Serology if the director holds a bachelor's degree in biology, chemistry, immunology, or microbiology and, subsequent to graduation, had four (4) years of experience in serology.

(d) Radiobioassay if the director, subsequent to graduation, had one (1) year of experience in radiobioassay.

(e) Clinical chemistry if the director holds a bachelor's degree in a chemical science or its equivalent and, subsequent to graduation, had four (4) years of experience in clinical chemistry.

(2) The laboratory may perform tests in the subspecialties of blood grouping and Rh typing, antibody detection, identification, and titering if the director holds a bachelor's degree in biology, immunology or microbiology from an accredited institution and, subsequent to graduation, had four (4) years of experience in immunohematology.

(3) The laboratory may perform tests in any of the specialties or subspecialties mentioned in subsections (1) and (2) of this section if the director holds a bachelor's degree in medical technology and, subsequent to graduation, had the designated years of specialized experience.

Section 3. Special Qualification by Examination. Unless otherwise exempted in Sections 1 and 2 of this administrative regulation, if an individual qualifies as a medical laboratory director by reason of having served as director of a medical laboratory for twelve (12) months between January 1, 1968, and May 4, 1977, and has achieved a satisfactory grade through an examination approved by the cabinet, the laboratory may perform tests in the laboratory specialties the director achieved a satisfactory grade in an examination approved by the cabinet. (3 Ky.R. 202; eff. 5-4-1977; 20 Ky.R. 2186; 2640; eff. 3-14-1994; Crt eff. 3-22-2019.)