902 KAR 11:045. Test and specimen records.

RELATES TO: KRS Chapter 333
STATUTORY AUTHORITY: KRS 194.050
CERTIFICATION STATEMENT:
NECESSITY, FUNCTION, AND CONFORMITY: KRS Chapter 333 requires medical laboratories in Kentucky to keep records involving medical laboratory services and copies of reports of laboratory tests for the period of time and in a manner prescribed by administrative regulation. KRS Chapter 333 authorizes the Secretary for Human Resources to adopt rules and regulations to effectuate the purposes and provisions of the chapter. This administrative regulation describes the contents of test and specimen records to be maintained by the medical laboratories.

Section 1. Records of Observations. Records of observations shall be made by the medical laboratory concurrently with the performance of each step in the examination of specimens.

(1) The records shall reflect the actual results of all control procedures.

(2) Pursuant to KRS 333.180(1), all pertinent laboratory records shall be made available to inspection, examination, and copying as the cabinet may direct.

(3) All records shall be retained for a period of at least two (2) years after the date of submittal of the report, except as otherwise prescribed by law.

Section 2. Specimen Records. Daily accession records shall be maintained containing the following information:

(1) Laboratory number of the specimen or other means of identification;

(2) Name and other identification of the person from whom the specimen was taken, if available;

(3) Name of the licensed physician or other person or laboratory submitting the specimen;

(4) Date the specimen was collected by the physician or other authorized person, if available;

(5) Date the specimen was received in the laboratory;

(6) Condition of unsatisfactory specimens and packages if received (e.g., broken, leaked, hemolyzed, or turbid);

(7) Type of test performed;

(8) Result of the laboratory test; and

(9) Date the test was completed.

(3 Ky.R. 203; eff. 5-4-1977; 20 Ky.R. 2188; eff. 3-14-1994; eff. 3-22-2019; Crt eff 12-29-2025.)