**Section 450.1010 Necessary Records**

a) Complete records in regard to each specimen examined shall be kept on file in the laboratory for not less than five years. The records shall contain:

1) Laboratory number or other identification of the specimen.

2) The name of the person from whom the specimen was taken, except in cases of anonymous HIV testing or of anonymous or coded premarital syphilis testing. The names and addresses of persons who have chosen to have HIV testing done anonymously may not be recorded in the files, except that any existing records referring to testing done before anonymity was chosen may be retained without linkage to the anonymous testing.

3) The name of the licensed physician or other authorized person, clinical laboratory, or blood bank submitting the specimen.

4) The date the specimen was collected and the date the specimen was received in the laboratory.

5) When a specimen is forwarded to another clinical laboratory for tests, the name, the date when the specimen was forwarded to the laboratory, the date it was tested, and the date the report of the findings of the test was received from the laboratory.

6) In case the specimen is an unsatisfactory specimen, the condition of the specimen when received.

7) The types and numbers of tests performed annually.

8) The results of the test conducted by the laboratory, the method used, the signature of the examiner.

9) *Clinical laboratory test results may be reported or transmitted to*:

A) *The licensed physician,* the patient if requested, *or other authorized person who requested the test, their designee, or both;*

B) *Any health care provider who is providing treatment to the patient*; or

C) *An electronic health information exchange for the purposes of transmitting, using, or disclosing clinical laboratory test results in any manner required or permitted by HIPAA.*

10) *No interpretation, diagnosis, prognosis, or suggested treatment shall appear on the laboratory report form, except that a report made by a physician licensed to practice medicine in Illinois, a dentist licensed in Illinois, or an optometrist licensed in Illinois may include that information.*

11) *Nothing in this* Part *prohibits the sharing of information as authorized in Section 2.1 of the Department of Public Health Act.* (Section 7-102 of the Act)

b) Reports to be submitted to the Department.

A laboratory shall submit reports containing information and data concerning its technical operations, as may be requested by the Department. These reports shall be notarized and signed by the owner and director of the laboratory.

(Source: Amended at 44 Ill. Reg. 20004, effective December 9, 2020)