TITLE 77: PUBLIC HEALTH
CHAPTER I: DEPARTMENT OF PUBLIC HEALTH
SUBCHAPTER e: LABORATORIES AND BLOOD BANKS

PART 450
ILLINOIS CLINICAL LABORATORIES CODE

SUBPART A: GENERAL

SUBPART B: DIRECTORS OF CLINICAL LABORATORIES

SUBPART C: LOCATION, CONSTRUCTION AND SANITATION

SUBPART D: QUALIFICATIONS OF PERSONNEL

SUBPART E: EQUIPMENT

SUBPART F: OUT OF STATE LABORATORIES

SUBPART G: PROFICIENCY SURVEY PROGRAM AND INSPECTION OF FACILITIES

SUBPART H: SPECIAL REQUIREMENTS PERTAINING TO BLOOD BANKS

SUBPART I: PROHIBITED PRACTICE

SUBPART J: RECORDS AND REPORTS

SUBPART K: QUALITY CONTROL

SUBPART L: HIV CONTAMINATED BLOOD AND HUMAN TISSUE

SUBPART M: HEALTH SCREENING

AUTHORITY: Implementing and authorized by the Illinois Clinical Laboratory and Blood Bank Act [210 ILCS 25].

SOURCE: Amended November 16, 1970; amended at 2 Ill. Reg., p. 87, effective November 5, 1978; amended at 4 Ill. Reg. 33, p. 224, 225 and 228, effective August 6, 1980; amended at 6 Ill.

Reg. 4151, effective April 5, 1982; amended at 7 Ill. Reg. 7643, effective June 14, 1983; codified at 8 Ill. Reg. 19488; amended at 9 Ill. Reg. 20709, effective January 3, 1986; emergency amendment at 10 Ill. Reg. 307, effective January 3, 1986, for a maximum of 150 days; amended at 10 Ill. Reg. 10712, effective June 3, 1986; amended at 12 Ill. Reg. 10018, effective May 27, 1988; emergency amendment at 12 Ill. Reg. 19518, effective October 28, 1988, for a maximum of 150 days; amended at 13 Ill. Reg. 4285, effective March 21, 1989; amended at 13 Ill. Reg. 11573, effective July 1, 1989 and September 1, 1989; emergency amendment at 13 Ill. Reg. 13678, effective August 14, 1989, for a maximum of 150 days; emergency rule expired January 11, 1990; amended at 14 Ill. Reg. 2360, effective January 26, 1990; amended at 15 Ill. Reg. 15727, effective October 18, 1991; amended at 44 Ill. Reg. 20004, effective December 9, 2020; Subchapter d recodified at 49 Ill. Reg. 15668; amended at 50 Ill. Reg. _____, effective _____.

SUBPART A: GENERAL

Section 450.5 Scope and Applicability

a) This Part provides regulatory oversight of all entities certified pursuant to 42 CFR 493, that perform analysis of human specimens for health assessment or to diagnose, prevent or treat disease.

b) All certified CLIA laboratories will be regulated as set forth in 42 CFR 493 and described in the State Operations Manual (Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services), issued by the Department of Health and Human Services.

c) Clinical~~Licensed~~ Laboratory

~~1)~~ ~~As set forth in this Part, a "licensed" laboratory is a laboratory licensed by the Department under the standards set forth in CLIA laws and regulations (CLIA Law) to accept and test clinical human specimens from a person, in accordance with Article VII of the Act.~~

1~~2~~) The clinical~~licensed~~ laboratory shall maintain certification status in good standing as required by CLIA Law.

2) *A clinical laboratory shall examine specimens only at the request of:*

A) *A licensed physician,*

B) *A licensed dentist,*

C) *A licensed podiatric physician,*

D) *A licensed optometrist,*

E) *A licensed physician assistant,*

F) *A licensed advanced practice registered nurse,*

G) *An authorized law enforcement agency or, in the case of blood alcohol, at the request of the individual for whom the test is to be performed in compliance with Sections 11-501 and 11-501.1 of the Illinois Vehicle Code,*

H) *A genetic counselor with the specific authority from a referral to order a test or tests pursuant to subsection (b) of Section 20 of the Genetic Counselor Licensing Act, or*

I) *A* licensed *pharmacist in accordance with Section 43.5 of the Pharmacy Practice Act.* (Section 7-101 of the Act)

d) Physicians, corporations, individuals, local health authorities, and others that intend to conduct clinical tests on human specimens for health assessments or to diagnose, prevent or treat disease shall obtain certification status from the Centers for Medicare and Medicaid Services~~by the Department~~ in accordance with CLIA Law. Health screening activities under Section 2-120 of the Act may be conducted by a clinical~~licensed~~ laboratory at the laboratory location listed on the CLIA certificate; however, health screening events shall be conducted in accordance with Sections 450.1300, 450.1310, and 450.1330.

(Source: Amended at 50 Ill. Reg. _____, effective _____)

Section 450.10 Definitions

"Act" or "Clinical Laboratory Act" − the Illinois Clinical Laboratory and Blood Bank Act.

"Advanced Practice Registered Nurse" – a person who is licensed as an advanced practice registered nurse under the Nurse Practice Act.

"Authorized Person" – A physician, dentist, optometrist, physician assistant, or advanced practice registered nurse, an authorized law enforcement agency, or, in the case of blood alcohol, an individual for whom the test is to be performed in compliance with Sections 11-501 and 11-501.1 of the Illinois Vehicle Code, a genetic counselor with the specific authority from a referral to order a test or tests

pursuant to subsection (b) of Section 20 of the Genetic Counselor Licensing Act, or a pharmacist, in accordance with Section 43.5 of the Pharmacy Practice Act.

~~"Approved Clinical Laboratory" – a laboratory certified under the federal Clinical Laboratory Improvement Amendments (CLIA) of 1988.~~

"CLIA Law" – the Clinical Laboratory Improvement Amendments of 1988 (amendments to the Public Health Service Act (42 USC 263a)) and the related federal regulations. Establishes quality standards for laboratory testing performed on specimens from humans, such as blood, body fluid, and tissue, for the purpose of diagnosis, prevention, or treatment of disease, or of assessment of health.

"Clinical Laboratory" or "Laboratory" – a facility, certified by the Centers for Medicare and Medicaid Services, that ~~*which*~~ *performs laboratory tests* under the standards set forth in CLIA Law to accept and test clinical human specimens from a person, in accordance with Article VII of the Act, *or issues reports resulting from tests.* For the purposes of this Part, "Clinical Laboratory" or "Laboratory" does not include forensic laboratories. (Section 2-103 of the Act)

"Controlled Substance" – a drug, substance, or immediate precursor as defined in the Illinois Controlled Substances Act.

"Demonstration of Proficiency" – when a laboratory meets the standards for acceptable proficiency testing as stated in Section 450.720(a) by means of on site analysis of specimens sent to the laboratory by agencies approved by the Department for that purpose.

"Dentist" – a person who is licensed as a dentist under the Illinois Dental Practice Act.

"Department" – *the Department of Public Health of the State of Illinois*. (Section 2-105 of the Act)

"Director" – the Director of the Department of Public Health.

"Director of Clinical Laboratory" or "Laboratory Director" – *an individual who administers the technical and scientific operation of a clinical laboratory, including the reporting of the findings of clinical laboratory tests.* (Section 2-104 of the Act)

"FDA" – Food and Drug Administration within the United States Department of Health and Human Services (HHS).

"Full-time Experience" − experience in the field being referred to consisting of at least 35 hours per week conducting activities required by the specific position or field such as conducting the tests referred to in Section 2-103 of the Act.

"Health Screening" – tests or categories of tests set forth in the Act and this Part *that are performed for the purpose of assessing a phase of the general state of health of human subjects* (Section 2-120 of the Act).

"HHS" – the United States Department of Health and Human Services.

"Optometrist" – a person who is licensed as an optometrist under the Illinois Optometric Practice Act of 1987.

"Owner" – a person who has ownership or control interest in an Illinois laboratory as ownership or control interest is defined in 42 CFR 420.201.

~~"Licensed Clinical Laboratory" – a laboratory licensed by DPH based on certification by the Centers for Medicare & Medicaid Services (CMMS) in accordance with CLIA.~~

"Physician" − unless otherwise indicated in the Act and this Part, *a person licensed by the Department of Professional Regulation, pursuant to the requirements of the Medical Practice Act of 1987;* (i.e., a physician licensed to practice medicine in all its branches and a chiropractic physician) *or a person licensed as a physician under the laws of another state or territory of the United States.* (Section 2-116 of the Act).

"Physician Assistant" – a person who is licensed as a physician assistant under the Physician Assistant Practice Act of 1987.

"Podiatric physician" − a person who is licensed as a podiatric physician under the Podiatric Medical Practice Act of 1987.

"Prepackaged Reagent Analyzer" − an automated instrument in which a specimen or a diluted specimen is reacted with reagents contained within individual packet(s) containing all of the measured reagents required for the analysis for a given analyte.

"Single Practice" − a medical, dental or podiatric practice, or a partnership, professional service corporation, or medical corporation of one or more licensed practitioners who share facilities, personnel, income and expenses for a clinical laboratory that is used solely as an adjunct to the care of patients of the members of the single practice.

"Test" − laboratory examinations and issuance of reports resulting from the biological, microbiological, serological, chemical, immunohematological, radioimmunological, hematological, biophysical, cytological, pathological, toxicological or other examination of materials derived from the human body for the purposes of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of, the health of humans including determining drug use by humans. (Section 2-117 of the Act).

"Toxicology Laboratory" − a clinical~~licensed~~ laboratory that performs tests to detect drug abuse in the workplace, among job applicants, or for other similar purposes.

"Waived Test" – a test system, assay or examination that HHS has determined meets the CLIA statutory criteria as specified for waiver under 42 CFR 493.15~~Section 353(d)(3) of the Public Health Service Act~~ that has been determined to be so simple as to pose no risk of harm if performed incorrectly.

(Source: Amended at 50 Ill. Reg. _____, effective _____)

Section 450.50 Incorporated and Referenced Materials

The following materials are incorporated or referenced in this Part:

a) The following State of Illinois Statutes are referenced in this Part:

1) Illinois Clinical Laboratory and Blood Bank Act [210 ILCS 25]

2) Illinois Dental Practice Act [225 ILCS 25]

3) Hospital Licensing Act [210 ILCS 85]

4) Medical Practice Act of 1987 [225 ILCS 60]

5) Podiatric Medical Practice Act of 1987 [225 ILCS 100]

6) Code of Civil Procedure, Article III (Administrative Review Law) [735 ILCS 5/Art. III]

7) Illinois Controlled Substances Act [720 ILCS 570]

8) Illinois Vehicle Code [625 ILCS 5]

9) Nurse Practice Act [225 ILCS 65]

10) Illinois Optometric Practice Act of 1987 [225 ILCS 84]

11) Pharmacy Practice Act [225 ILCS 85]

12) Physician Assistant Practice Act of 1987 [225 ILCS 95]

13) Genetic Counselor Licensing Act [225 ILCS 135]

b) The following State of Illinois Regulations are referenced in this Part:

1) Sewer Discharge Criteria (35 Ill. Adm. Code 307)

2) Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities (35 Ill. Adm. Code 724)

3) Solid Waste Disposal: General Provisions (35 Ill. Adm. Code 809)

c) The following federal guidelines, statutes, federal regulations, and other materials are incorporated by reference:

1) Federal Regulations and Statutes:

A) 42 CFR 420.201, Definitions (October 1, 2024)

B~~A~~) 42 CFR 493, Laboratory Requirements (CLIA regulations) (October 1, 2023~~2018~~)

C~~B~~) 21 CFR 600-680, Biologics (April 1, 2024~~2018~~)

D~~C~~) Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, Title II – Preventing Health Care Fraud and Abuse; Administrative Simplification; Medical Liability Reform, Section 264 – Recommendations with Respect to Privacy of Certain Health Information (August 20~~21~~, 1996), Assistant Secretary for Planning and Evaluation, Room 415F, U.S. Department of Health and Human Services, 200 Independence Avenue, SW, Washington DC 20201
Also available online at: https://aspe.hhs.gov/report/health-insurance-portability-and-accountability-act-1996

~~D) 42 USC 263a, Certification of Laboratories (January 12, 2018)~~

2) Federal Guidelines and Other Materials:

A) GP17-A3 Clinical Laboratory Safety; Approved Guideline – Third Edition, Clinical and Laboratory Standards Institute (CLSI) (June 2012), 950 West Valley Road, Suite 2500, Wayne PA 10987 Also available online at: https://webstore.ansi.org/standards/clsi/clsigp17a3?srsltid=AfmBOoo7vY39kKr8biBOV3Zterkul_VizhwnHSbl1cNeTLj47gYKTWQl ~~https://clsi.org/media/1381/ gp17a3_sample.pdf~~

B) Centers for Medicare and Medicaid Services State Operations Manual – Appendix C (January 23, 2025), available at: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107ap_c_lab.pdf ~~Public Health Service Act, Subpart 2, Section 353 – Clinical Laboratories, Certification of Laboratories (1997), Public Health Law, CDC, 1600 Clifton Road, Atlanta GA 30329-4027 Also available online at: https://wwwn.cdc.gov/cliac/pdf/Addenda/cliac0910/Addendum%20C_Yost.pdf~~

C) Cytogenic and Genome Research~~Reference Volume for Human Cytogeneticists, Molecular Geneticists, Technicians, and Students for the Interpretation and Communication of Human Cytogenetic and Molecular Cytogenomic Nomenclature~~: ISCN 2024~~2016~~ − An International System for Human Cytogenetic Nomenclature (2024~~2016~~), available at: https://karger.com/cgr/article-abstract/164/Suppl.%201/1/916357/ISCN-2024-An-International-System-for-Human?redirectedFrom=PDF or from S. Karger AG, Medical and Scientific Publishers, P.O. Box CH-4009 Basel, Switzerland

d) All incorporations by reference of federal regulations and the standards of nationally recognized organizations refer to the regulation and standards on the date specified and do not include any additions or deletions subsequent to the date specified.

(Source: Amended at 50 Ill. Reg. _____, effective _____)

SUBPART J: RECORDS AND REPORTS

Section 450.1010 Necessary Records

a) Complete records for~~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 authorized person~~licensed physician, the patient if requested, or other authorized person~~ who requested the test,* or the patient, if requested, *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; and~~.~~*

D) *A pharmacist in accordance with Section 43.5 of the Pharmacy Practice Act.*

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 50 Ill. Reg. _____, effective _____)