**Section 450.10 Definitions**

"Act" or "Clinical Laboratory Act" − the Illinois Clinical Laboratory and Blood Bank 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 which performs laboratory tests 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.

"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](https://searchhealthit.techtarget.com/definition/Health-and-Human-ServicesHHS)).

"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.

"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).

"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 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 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 44 Ill. Reg. 20004, effective December 9, 2020)