

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

PART 450
ILLINOIS CLINICAL LABORATORIES CODE

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120 Licensed Laboratory (Repealed)

- 121 450.APPENDIX B Application for Class III Permit Laboratory (Repealed)

- 122 450.APPENDIX C Exempt, Permit, and License Requirements – An Overview
123 (Repealed)

124

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

127

128 SOURCE: Amended November 16, 1970; amended at 2 Ill. Reg., p. 87, effective November 5,
129 1978; amended at 4 Ill. Reg. 33, p. 224, 225 and 228, effective August 6, 1980; amended at 6 Ill.

130 Reg. 4151, effective April 5, 1982; amended at 7 Ill. Reg. 7643, effective June 14, 1983; codified
131 at 8 Ill. Reg. 19488; amended at 9 Ill. Reg. 20709, effective January 3, 1986; emergency
132 amendment at 10 Ill. Reg. 307, effective January 3, 1986, for a maximum of 150 days; amended
133 at 10 Ill. Reg. 10712, effective June 3, 1986; amended at 12 Ill. Reg. 10018, effective May 27,
134 1988; emergency amendment at 12 Ill. Reg. 19518, effective October 28, 1988, for a maximum
135 of 150 days; amended at 13 Ill. Reg. 4285, effective March 21, 1989; amended at 13 Ill. Reg.
136 11573, effective July 1, 1989 and September 1, 1989; emergency amendment at 13 Ill. Reg.
137 13678, effective August 14, 1989, for a maximum of 150 days; emergency rule expired January
138 11, 1990; amended at 14 Ill. Reg. 2360, effective January 26, 1990; amended at 15 Ill. Reg.
139 15727, effective October 18, 1991; amended at 44 Ill. Reg. 20004, effective December 9, 2020;
140 Subchapter d recodified at 49 Ill. Reg. 15668; amended at 50 Ill. Reg. _____, effective
141 _____.

142
143 **SUBPART A: GENERAL**

144
145 **Section 450.5 Scope and Applicability**

- 146
147 a) This Part provides regulatory oversight of all entities certified pursuant to 42 CFR
148 493, that perform analysis of human specimens for health assessment or to
149 diagnose, prevent or treat disease.
150
151 b) All certified CLIA laboratories will be regulated as set forth in 42 CFR 493 and
152 described in the State Operations Manual (Appendix C – Survey Procedures and
153 Interpretive Guidelines for Laboratories and Laboratory Services), issued by the
154 Department of Health and Human Services.
155
156 c) Clinical~~Licensed~~ Laboratory
157
158 ~~1) As set forth in this Part, a "licensed" laboratory is a laboratory licensed by~~
159 ~~the Department under the standards set forth in CLIA laws and regulations~~
160 ~~(CLIA Law) to accept and test clinical human specimens from a person, in~~
161 ~~accordance with Article VII of the Act.~~
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163 12) The clinical~~icensed~~ laboratory shall maintain certification status in good
164 standing as required by CLIA Law.
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166 2) A clinical laboratory shall examine specimens only at the request of:
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168 A) A licensed physician,
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170 B) A licensed dentist,
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172 C) A licensed podiatric physician,

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- 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

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

218
219 ~~"Approved Clinical Laboratory"—a laboratory certified under the federal Clinical~~
220 ~~Laboratory Improvement Amendments (CLIA) of 1988.~~

221
222 "CLIA Law" – the Clinical Laboratory Improvement Amendments of 1988
223 (amendments to the Public Health Service Act (42 USC 263a)) and the related
224 federal regulations. Establishes quality standards for laboratory testing performed
225 on specimens from humans, such as blood, body fluid, and tissue, for the purpose
226 of diagnosis, prevention, or treatment of disease, or of assessment of health.

227
228 "*Clinical Laboratory*" or "*Laboratory*" – a facility, [certified by the Centers for](#)
229 [Medicare and Medicaid Services, that](#) ~~which~~ [performs laboratory tests under the](#)
230 [standards set forth in CLIA Law to accept and test clinical human specimens from](#)
231 [a person, in accordance with Article VII of the Act, or issues reports resulting](#)
232 [from tests.](#) For the purposes of this Part, "Clinical Laboratory" or "Laboratory"
233 does not include forensic laboratories. (Section 2-103 of the Act)

234
235 "Controlled Substance" – a drug, substance, or immediate precursor as defined in
236 the Illinois Controlled Substances Act.

237
238 "Demonstration of Proficiency" – when a laboratory meets the standards for
239 acceptable proficiency testing as stated in Section 450.720(a) by means of on site
240 analysis of specimens sent to the laboratory by agencies approved by the
241 Department for that purpose.

242
243 "[Dentist](#)" – a person who is licensed as a dentist under the [Illinois Dental Practice](#)
244 [Act.](#)

245
246 "Department" – *the Department of Public Health of the State of Illinois.* (Section
247 2-105 of the Act)

248
249 "Director" – the Director of the Department of Public Health.

250
251 "*Director of Clinical Laboratory*" or "*Laboratory Director*" – *an individual who*
252 *administers the technical and scientific operation of a clinical laboratory,*
253 *including the reporting of the findings of clinical laboratory tests.* (Section 2-104
254 of the Act)

255
256 "FDA" – Food and Drug Administration within the United States Department of
257 Health and Human Services (HHS).

258

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

262
263 *"Health Screening" – tests or categories of tests set forth in the Act and this Part*
264 *that are performed for the purpose of assessing a phase of the general state of*
265 *health of human subjects (Section 2-120 of the Act).*

266
267 "HHS" – the United States Department of Health and Human Services.

268
269 "Optometrist" – a person who is licensed as an optometrist under the Illinois
270 Optometric Practice Act of 1987.

271
272 "Owner" – a person who has ownership or control interest in an Illinois laboratory
273 as ownership or control interest is defined in 42 CFR 420.201.

274
275 ~~"Licensed Clinical Laboratory" – a laboratory licensed by DPH based on~~
276 ~~certification by the Centers for Medicare & Medicaid Services (CMMS) in~~
277 ~~accordance with CLIA.~~

278
279 *"Physician" – unless otherwise indicated in the Act and this Part, a person*
280 *licensed by the Department of Professional Regulation, pursuant to the*
281 *requirements of the Medical Practice Act of 1987; (i.e., a physician licensed to*
282 *practice medicine in all its branches and a chiropractic physician) or a person*
283 *licensed as a physician under the laws of another state or territory of the United*
284 *States. (Section 2-116 of the Act).*

285
286 "Physician Assistant" – a person who is licensed as a physician assistant under the
287 Physician Assistant Practice Act of 1987.

288
289 "Podiatric physician" – a person who is licensed as a podiatric physician under
290 the Podiatric Medical Practice Act of 1987.

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

296
297 "Single Practice" – a medical, dental or podiatric practice, or a partnership,
298 professional service corporation, or medical corporation of one or more licensed
299 practitioners who share facilities, personnel, income and expenses for a clinical
300 laboratory that is used solely as an adjunct to the care of patients of the members
301 of the single practice.

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"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~~~~icensed~~ 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 \[625 ILCS 5\]](#)

- 345 9) [Nurse Practice Act \[225 ILCS 65\]](#)
346
347 10) [Illinois Optometric Practice Act of 1987 \[225 ILCS 84\]](#)
348
349 11) [Pharmacy Practice Act \[225 ILCS 85\]](#)
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351 12) [Physician Assistant Practice Act of 1987 \[225 ILCS 95\]](#)
352
353 13) [Genetic Counselor Licensing Act \[225 ILCS 135\]](#)
354
355 b) The following State of Illinois Regulations are referenced in this Part:
356
357 1) Sewer Discharge Criteria (35 Ill. Adm. Code 307)
358
359 2) Standards for Owners and Operators of Hazardous Waste Treatment,
360 Storage, and Disposal Facilities (35 Ill. Adm. Code 724)
361
362 3) Solid Waste Disposal: General Provisions (35 Ill. Adm. Code 809)
363
364 c) The following federal guidelines, statutes, federal regulations, and other materials
365 are incorporated by reference:
366
367 1) Federal Regulations and Statutes:
368
369 A) [42 CFR 420.201, Definitions \(October 1, 2024\)](#)
370
371 B~~A~~) 42 CFR 493, Laboratory Requirements (CLIA regulations)
372 (October 1, ~~2023~~[2018](#))
373
374 C~~B~~) 21 CFR 600-680, Biologics (April 1, ~~2024~~[2018](#))
375
376 D~~E~~) Health Insurance Portability and Accountability Act of 1996
377 (HIPAA), Public Law 104-191, Title II – Preventing Health Care
378 Fraud and Abuse; Administrative Simplification; Medical Liability
379 Reform, Section 264 – Recommendations with Respect to Privacy
380 of Certain Health Information (August ~~2021~~, 1996), Assistant
381 Secretary for Planning and Evaluation, Room 415F, U.S.
382 Department of Health and Human Services, 200 Independence
383 Avenue, SW, Washington DC 20201
384 Also available online at: [https://aspe.hhs.gov/report/health-](https://aspe.hhs.gov/report/health-insurance-portability-and-accountability-act-1996)
385 [insurance-portability-and-accountability-act-1996](https://aspe.hhs.gov/report/health-insurance-portability-and-accountability-act-1996)
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387 ~~D)~~ ~~42 USC 263a, Certification of Laboratories (January 12, 2018)~~

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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/clsiclsigp17a3?srsltid=AfmBOoo7vY39kKr8biBOV3Zterkul_VizhwnHSb1cNeTLj47gYKTWQl
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/eliac/pdf/Addenda/eliac0910/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 20242016 – An International System for Human Cytogenetic Nomenclature (20242016), 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

- 431 a) Complete records ~~for in regard to~~ each specimen examined shall be kept on file in
432 the laboratory for not less than five years. The records shall contain:
433
- 434 1) Laboratory number or other identification of the specimen.
435
 - 436 2) The name of the person from whom the specimen was taken, except in
437 cases of anonymous HIV testing or of anonymous or coded premarital
438 syphilis testing. The names and addresses of persons who have chosen to
439 have HIV testing done anonymously may not be recorded in the files,
440 except that any existing records referring to testing done before anonymity
441 was chosen may be retained without linkage to the anonymous testing.
442
 - 443 3) The name of the ~~licensed physician or other~~ authorized person, clinical
444 laboratory, or blood bank submitting the specimen.
445
 - 446 4) The date the specimen was collected and the date the specimen was
447 received in the laboratory.
448
 - 449 5) When a specimen is forwarded to another clinical laboratory for tests, the
450 name, the date when the specimen was forwarded to the laboratory, the
451 date it was tested, and the date the report of the findings of the test was
452 received from the laboratory.
453
 - 454 6) In case the specimen is an unsatisfactory specimen, the condition of the
455 specimen when received.
456
 - 457 7) The types and numbers of tests performed annually.
458
 - 459 8) The results of the test conducted by the laboratory, the method used, the
460 signature of the examiner.
461
 - 462 9) *Clinical laboratory test results may be reported or transmitted to:*
463
 - 464 A) *The authorized person~~licensed physician, the patient if requested,~~*
465 *~~or other authorized person~~ who requested the test, or the patient, if*
466 *requested, their designee, or both;*
467
 - 468 B) *Any health care provider who is providing treatment to the patient;*
469 ~~or~~
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 - 471 C) *An electronic health information exchange for the purposes of*
472 *transmitting, using, or disclosing clinical laboratory test results in*
473 *any manner required or permitted by HIPAA; and;*

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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 _____)