

CHAPTER 45
CLINICAL LABORATORY SERVICES

Authority

N.J.S.A. 45:9-42.30, 26:1A-33.

Source and Effective Date

R.1995 d.126, effective February 6, 1995.
See: 27 N.J.R. 32(a), 27 N.J.R. 941(a).

Executive Order No. 66(1978) Expiration Date

Chapter 45, Clinical Laboratory Services, expires on February 6, 2000.

Chapter Historical Note

The original Chapter, 45, Clinical Laboratories, was filed and became effective July 28, 1976 as R.1976 d.201. See: 8 N.J.R. 64(a), 8 N.J.R. 381(a). Amendments were filed and became effective October 5, 1979 as R.1979 d.398. See: 11 N.J.R. 437(c), 11 N.J.R. 549(d). Further amendments became effective January 4, 1982 as R.1981 d.493. See: 13 N.J.R. 653(a), 14 N.J.R. 45(b). The prior rules concerning licensure of clinical laboratories expired October 1, 1984 and rules concerning laboratory charges expired November 1, 1984 pursuant to Executive Order 66(1978). This new chapter "Clinical Laboratory Services" became effective May 20, 1985 as R.1985 d.243. See: 17 N.J.R. 268(a), 17 N.J.R. 1294(a). Pursuant to Executive Order No. 66 (1978), Chapter 45 was readopted as R.1990 d.145, effective February 7, 1990. See: 21 N.J.R. 3708(b), 22 N.J.R. 846(a).

Pursuant to Executive No. 66(1978), Chapter 45 was readopted as R.1995 d.126. See: Source and Effective Date. See, also, section annotations.

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SUBCHAPTER 1. LICENSURE OF CLINICAL LABORATORIES

8:45-1.1 Initial licensure

(a) Application for an initial license to conduct a clinical laboratory, as required under the provisions of Chapter 166, P.L. 1975, commonly known as the New Jersey Clinical Laboratory Improvement Act, shall be made on forms provided for that purpose by the New Jersey State Department of Health.

(b) Each license to operate a clinical laboratory will specify those laboratory procedures or categories of procedures which the laboratory is authorized to perform.

(c) No license issued under these regulations shall be transferable.

(d) A new license shall be obtained whenever the location, ownership or director of a clinical laboratory is changed.

(e) The license shall be conspicuously displayed by the licensee on the premises of a clinical laboratory.

(f) A separate license shall be required for each location.

8:45-1.2 Annual renewal of licensure

(a) All clinical laboratory licenses shall be issued on or before January 1 in each calendar year and shall expire December 31 in each calendar year.

(b) The Department will provide applications for licensure renewal on or before October 1 of each year to be completed properly and returned to the Department, together with appropriate licensure renewal fee, on or before the succeeding November 1. The Department will mail license renewals to clinical laboratories not later than January 1, of the succeeding year.

8:45-1.3 Licensure fees

(a) Initial and annual renewal licensure fees shall be identical and are prescribed by the following table. Fees noted shall be payable per each specialty.

Total Number of Employees of Entire Laboratory¹

Specialty	1-9	10-29	30-49	50-89	90 or More
Urinalysis	\$100	\$125	\$150	\$175	\$200
Mycobacteriology	\$100	\$125	\$150	\$175	\$200
Parasitology	\$100	\$125	\$150	\$175	\$200
Mycology	\$100	\$125	\$150	\$175	\$200
Bacteriology	\$100	\$125	\$150	\$175	\$200
Virology	\$100	\$125	\$150	\$175	\$200
Serology	\$100	\$125	\$150	\$175	\$200
Hematology	\$100	\$125	\$150	\$175	\$200
Immunohematology	\$100	\$125	\$150	\$175	\$200

Specialty	1-9	10-29	30-49	50-89	90 or More
Routine Chemistry	\$100	\$125	\$150	\$175	\$200
Endocrinology	\$100	\$125	\$150	\$175	\$200
Toxicology	\$100	\$125	\$150	\$175	\$200
Cytology	\$100	\$125	\$150	\$175	\$200
Cytogenetics and/or tissue typing	\$100	\$125	\$150	\$175	\$200
Collection Station only	\$100 per site				
Waived Tests only	\$ 50 per site				

¹ Exclusive of director, trainees in approved medical technologist schools, clerical and maintenance employees. Part-time employees are to be included, prorated to full-time equivalents.

(b) Laboratories shall remit an additional \$50.00 for renewal applications submitted after December 31 in order for the Department to process the renewal application.

(c) Laboratories shall pay a fee of \$50.00 for replacement of a license due to a change of address.

Amended by R.1995 d.126, effective March 6, 1995.
See: 27 N.J.R. 32(a), 27 N.J.R. 941(a).
Amended by R.1998 d.423, effective August 17, 1998.
See: 30 N.J.R. 1705(a), 30 N.J.R. 3100(a).
Rewrote the section.

8:45-1.4 Proficiency testing fees

(a) Those laboratories enrolled in the State's Clinical Laboratory Improvement Service analytical proficiency testing program will be assessed an annual fee by specialty/sub-specialty/procedure according to the following table:

Bacteriology	\$250.00
Throat Culture only	150.00
Gram Stain Only	150.00
Throat Screen (DAT)	100.00
Pinworms	25.00
Dermatophyte Screen	75.00
KOH Prep	25.00
Vaginal Wet Prep	25.00
Sperm	25.00
Urine Culture Screen	75.00
Urine Microscopy	25.00
Syphilis	150.00
Diagnostic Immunology	340.00
Rubella and/or Rheumatoid Factor	280.00
ASO and/or IM and/or hCG	280.00
Antinuclear Antibody	285.00
Endocrinology	190.00
Routine Chemistry	275.00
Lipids/Glucose Only	175.00
Blood Gases	200.00
Erythrocyte Protoporphyrin	225.00
Drugs of Abuse in Urine	250.00
CBC with Blood Cell ID	225.00
Hemoglobin or Hematocrit only	125.00
Blood Cell ID only	100.00
Coagulation	225.00

Comprehensive Blood Banking and Immunohematology	350.00
Limited Immunohematology	210.00
Monitoring Other PT Surveys	50.00

New Rule, R.1990 d.145, effective February 7, 1990.
See: 21 N.J.R. 3708(b), 22 N.J.R. 846(a).
Amended by R.1995 d.126, effective March 6, 1995.
See: 27 N.J.R. 32(a), 27 N.J.R. 941(a).

SUBCHAPTER 2. LABORATORY CHARGES

8:45-2.1 Fees; generally

(a) Effective November 1, 1992, the following fee-for-service cost structure shall apply to the New Jersey State Department of Health:

Laboratory Test	
Inborn Errors of Metabolism (PKU, T4, Galactosemia, Sickle Cell)	\$27.00
Toxoplasmosis	\$15.00
Rubella Screen	\$10.00
Blood Lead	\$12.00
Mycobacteriology (TB)	\$30.00
Water Bacteriology	\$15.00
Bacteriology Culture	\$30.00
Susceptibility Studies (TB)	\$30.00
Isolation of Special Pathogens	\$30.00
Parasitology	\$15.00
Lyme Disease	\$20.00

(b) Effective November 1, 1992, the following additional fee-for-service charges shall also apply:

Bacteriology	
Lyme Disease	\$20.00
Specimen Transport Kits (each kit)	\$ 1.00

Amended by R.1990 d.145, effective February 7, 1990.
See: 21 N.J.R. 3708(b), 22 N.J.R. 846(a).
Tests added; fees raised.
Amended by R.1992 d.427, effective October 19, 1992.
See: 24 N.J.R. 2508(a), 24 N.J.R. 3725(c).
All fees increased.