

CHAPTER 45

CLINICAL LABORATORY SERVICES

Authority

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

Source and Effective Date

R.2000 d.123, effective March 20, 2000.
See: 32 N.J.R. 6(a), 32 N.J.R. 1059(a).

Chapter Expiration Date

In accordance with N.J.S.A. 52:14B-5.1c, Chapter 45, Clinical Laboratory Services, expires on September 16, 2005. See: 37 N.J.R. 1118(a).

Chapter Historical Note

Chapter, 45, Clinical Laboratories, was adopted as R.1976 d.201, effective July 28, 1976. See: 8 N.J.R. 64(a), 8 N.J.R. 381(a).

Pursuant to Executive Order No. 66(1978), Subchapter 1, Licensure of Clinical Laboratories expired on October 1, 1984.

Pursuant to Executive Order No. 66(1978), Subchapter 2, Laboratory Charges expired on November 1, 1984.

Chapter 45, Clinical Laboratory Services, was adopted as new rules by R.1985 d.243, effective May 20, 1985. See: 17 N.J.R. 268(a), 17 N.J.R. 1294(a).

Pursuant to Executive Order No. 66 (1978), Chapter 45, Clinical Laboratory Services, 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, Clinical Laboratory Services, was readopted as R.1995 d.126, effective February 6, 1995. See: 27 N.J.R. 32(a), 27 N.J.R. 941(a). Pursuant to Executive Order No. 66(1978), Chapter 45 expired on February 6, 2000.

Chapter 45, Clinical Laboratory Services, was adopted as new rules by R.2000 d.123, effective March 20, 2000. See: Source and Effective Date.

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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

Specialty	1-9	10-29	30-49	50-89	90 or More
Hematology	\$100	\$125	\$150	\$175	\$200
Immunohematology	\$100	\$125	\$150	\$175	\$200
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 (Absence or Presence)	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
Electrolytes only	150.00
QBC with Differential	225.00

Sperm Count	100.00
UCS with Antibiotic Susceptibility	100.00
Dipstick Urinalysis only	35.00
Urine hCG only	25.00
Urinalysis Combo	75.00
Sedimentation Rate	75.00
Whole Blood Prothrombin Time	75.00
Throat-Screen (CLIA-waived methods)	25.00
<i>H. pylori</i> Antibody	75.00
Fecal Occult Blood	25.00
C-Reactive Protein (CRP)	35.00
PSA and/or PAP	75.00
Whole Blood Glucose (CLIA Waived)	50.00
Glycohemoglobin	50.00
GGT and/or Phosphorus	50.00

(b) Laboratories shall remit an additional \$50.00 for proficiency testing enrollment renewal applications submitted after the stated enrollment deadline in order for the Department to process the renewal enrollment application.

(c) Laboratories shall pay a fee of \$50.00 per sample set for samples requested for shipment outside the routine mailing schedule for the purpose of replacement, pre-licensure, reinstatement or troubleshooting.

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) Upon November 3, 2003, the following fee-for-service cost structure shall apply to the New Jersey Department of Health and Senior Services:

Laboratory Test	
Inborn Errors of Metabolism	\$71.00
(PKU, T4 Galactosemia, Sickle Cell, Biotinidase Deficiency, CAH, Cystic Fibrosis, MSUD, MCAD, SCAD, LCAD, VLCAD, Citrullinemia, Argininosuccinic Acidemia, PA, MMA, GA-1, IVA, HMG, 3-MMC)	
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.

Amended by R.1999 d.384, effective November 15, 1999.

See: 31 N.J.R. 1588(a), 31 N.J.R. 3843(a).

In (a), substituted a reference to November 15, 1999 for a reference to November 1, 1992 in the introductory paragraph, and increased the fee for Inborn Errors of Metabolism tests.

Amended by R.2003 d.445, effective November 3, 2003.

See: 35 N.J.R. 3009(a), 35 N.J.R. 5097(a).

In (a), amended the effective date and rewrote Inborn Errors of Metabolism.