

CHAPTER 45**CLINICAL LABORATORY SERVICES****Authority**

N.J.S.A. 26:1A-33, 45:9-42.30, and 45:9-42.35;
and Reorganization Plan No. 003-2005.

Source and Effective Date

Effective: November 20, 2013.
See: 45 N.J.R. 2601(c).

Chapter Expiration Date

Chapter 45, Clinical Laboratory Services, expires on November 20, 2020.

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: 32 N.J.R. 6(a), 32 N.J.R. 1059(a).

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

In accordance with N.J.S.A. 52:14B-5.1d, the expiration date of Chapter 45, Clinical Laboratory Services, was extended by gubernatorial directive from September 16, 2005 to September 15, 2006. See: 37 N.J.R. 4020(a).

Chapter 45, Clinical Laboratory Services, was readopted as R.2007 d.49, effective January 9, 2007. See: 38 N.J.R. 2564(a), 39 N.J.R. 450(a).

In accordance with N.J.S.A. 52:14B-5.1b, Chapter 45, Clinical Laboratory Services, was scheduled to expire on January 9, 2014. See: 43 N.J.R. 1203(a).

Chapter 45, Clinical Laboratory Services, was readopted, effective November 20, 2013. See: Source and Effective Date.

CHAPTER TABLE OF CONTENTS**SUBCHAPTER 1. LICENSURE OF CLINICAL LABORATORIES**

8:45-1.1 Initial licensure

8:45-1.2 Annual renewal of licensure

8:45-1.3 Licensure fees

8:45-1.4 (Reserved)

SUBCHAPTER 2. LABORATORY CHARGES

8:45-2.1 Fees; generally

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	\$200.00	\$250.00	\$300.00	\$350.00	\$400.00
Mycobacteriology	\$200.00	\$250.00	\$300.00	\$350.00	\$400.00
Parasitology	\$200.00	\$250.00	\$300.00	\$350.00	\$400.00
Mycology	\$200.00	\$250.00	\$300.00	\$350.00	\$400.00
Bacteriology	\$200.00	\$250.00	\$300.00	\$350.00	\$400.00
Virology	\$200.00	\$250.00	\$300.00	\$350.00	\$400.00
Serology	\$200.00	\$250.00	\$300.00	\$350.00	\$400.00
Hematology	\$200.00	\$250.00	\$300.00	\$350.00	\$400.00
Immunohematology	\$200.00	\$250.00	\$300.00	\$350.00	\$400.00
Routine Chemistry	\$200.00	\$250.00	\$300.00	\$350.00	\$400.00
Endocrinology	\$200.00	\$250.00	\$300.00	\$350.00	\$400.00
Toxicology	\$200.00	\$250.00	\$300.00	\$350.00	\$400.00
Cytology	\$200.00	\$250.00	\$300.00	\$350.00	\$400.00
Cytogenics and/or tissue typing	\$200.00	\$250.00	\$300.00	\$350.00	\$400.00
Collection Station only	\$200.00 per site				
Waived Tests only	\$200.00 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 fee of \$100.00 for renewal applications submitted after December 31 in order for the Department to process the renewal application.

(c) Laboratories shall pay a fee of \$100.00 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.

Amended by R.2009 d.362, effective December 7, 2009.

See: 41 N.J.R. 2871(a), 41 N.J.R. 4434(a).

In the table in (a), updated the fees throughout; in (b), substituted "fee of \$100.00" for "\$50.00"; and in (c), substituted "\$100.00" for "\$50.00".

8:45-1.4 (Reserved)

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).

Repealed by R.2009 d.362, effective December 7, 2009.

See: 41 N.J.R. 2871(a), 41 N.J.R. 4434(a).

Section was "Proficiency testing fees".

SUBCHAPTER 2. LABORATORY CHARGES

8:45-2.1 Fees; generally

(a) 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	\$90.00
(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.

Amended by R.2008 d.329, effective November 3, 2008.

See: 40 N.J.R. 2181(a), 40 N.J.R. 6457(a).

In the introductory paragraph of (a), substituted "The" for "Upon November 3, 2003, the"; and, in the entry for "Inborn Errors of Metabolism" in the fee list, substituted "\$90.00" for "\$71.00".