

**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).

Executive Order No. 66(1978) Expiration Date

Chapter 45, Clinical Laboratory Services, expires on March 20, 2005.

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) Effective November 15, 1999, 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 —(PKU, T4, Galactosemia, Sickle Cell) | \$34.00 |
| Toxoplasmosis | \$15.00 |
| Rubella Screen | \$10.00 |
| Blood Lead | \$12.00 |
| Mycobacteriology (TB) | \$30.00 |
| Water Bacteriology | \$15.00 |
| Bacteriology Culture | \$30.00 |

| | |
|--------------------------------|---------|
| Laboratory Test | |
| Susceptibility Studies (TB) | \$30.00 |
| Isolation of Special Pathogens | \$30.00 |
| Parasitology | \$15.00 |
| Lyme Disease | \$20.00 |

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.

(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.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.