NOTICE TO ALL APPLICANTS FOR A CLINICAL LABORATORY LICENSE:
Under the provisions of N.J.S.A. 45:9-42.26 et seq. and N.J.A.C. 8:44-2.1 et seq., the signed Application for a Clinical Laboratory License, and all requested attachments, must be completed in full. A license issued under N.J.S.A. 45:9-42.26 et seq. and N.J.A.C. 8:44-2.1 et seq. IS NOT TRANSFERABLE.

INITIAL OR RENEWAL ‘WAIVED TESTS ONLY SPECIALTY’ LICENSURE PROCESS

NOTE: Fill in Calendar Year and check □ INITIAL or □ RENEWAL box on top of Page 1 of application for “Type of Application.” The fee for an initial or renewal application is $200.

ALL FIELDS MUST BE COMPLETED – APPLICATIONS WILL NOT BE PROCESSED IF DATA IS MISSING

1. Complete Laboratory Information section
2. Complete Laboratory Director Information section
   • Submit completed Personnel Qualification form (CL-34) with initial applications only
3. Complete Primary General Supervision Information section
   • Submit completed Personnel Qualification form (CL-34) with initial applications only
4. Complete Ownership Information section
   • Submit ownership form (CL-9) with Initial applications only.
5. Complete List of CLIA Waived Tests and NJ State Waived Tests Performed section
   • Indicate the proficiency testing survey provider(s)
   • Initial license applications must include PT results for those tests performed
   • Need to know if your laboratory’s instrument or test kit is CLIA Waived? Please refer to the website below:
     http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm
   • NJ State Waived Tests
     ♦ Dipstick or tablet urinalysis (non-automated)
     ♦ Spun microhematocrit
     ♦ Fecal occult blood
     ♦ Ovulation test – visual color comparison tests for human luteinizing hormone
     ♦ Erythrocyte sedimentation rate- (non-automated)
     ♦ Hemoglobin – copper sulfate (non-automated)
     ♦ Blood glucose- by glucose monitoring devices cleared by FDA specifically for home use
     ♦ Urine pregnancy test – visual comparison tests
6. Submit plan of the premises or photograph of the area to be occupied for the operation of the laboratory with initial applications only.
7. Enclose a check for $200 or e-payment receipt
   • Electronic payments may be submitted under License-Clinical Laboratory/ Collection Station on the Clinical Laboratory Improvement Services website (http://www.nj.gov/health/phel/epayments.shtml) to expedite processing.
   • Paper checks or money orders should be made payable to the “New Jersey Department of Health” (NJDOH) and include the CLIS ID number. Please include a photocopy of your check, money order, or electronic payment receipt.
   • There is a $100 late fee for renewal applications received after December 31.

NOTE: The issued license shall be conspicuously displayed by the licensee on the laboratory premises.
PHEL Addresses

Please enclose a return mailing label or envelope with all applications for accurate delivery of the license.

**US Postal Service**
Joan Mikita, Licensing Unit
PHEL/Clinical Laboratory Improvement Services
New Jersey Department of Health
P.O. Box 361
Trenton, NJ 08625-0361

**For Overnight Delivery (FedEx/UPS)**
Joan Mikita, Licensing Unit
PHEL/Clinical Laboratory Improvement Services
New Jersey Department of Health
3 Schwarzkopf Drive
Ewing, NJ 08628

Alternatively, a completed application and all requested attachments may be electronically e-mailed to clislicensing@njlns.net along with e-payment.

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**Required Notification**

The NJDOH must be notified in writing within 14 calendar days of the following laboratory changes:

- Ownership
  *Change in ownership requires a reapplication for licensure including licensure fees.*
- Director
- Hours
- Termination of Tests
- Name
- Address (Must include $100 fee)

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**Questions or Concerns?**

Please contact us at:
- Telephone: 609-406-6830
- Fax: 609-406-6863

Visit Our Website at: [www.nj.gov/health/phel/clinical-lab-imp-services/](http://www.nj.gov/health/phel/clinical-lab-imp-services/)