



State of New Jersey
DEPARTMENT OF HEALTH

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Governor

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Lt. Governor

www.nj.gov/health

DR. RAYNARD E. WASHINGTON
Commissioner

The Department of Health's (Department) Clinical Laboratory Licensing Program (CLLP) is aware of your interest in operating an independent collection service. Before commencing operations, a collection service must apply for, and be granted, a clinical collection station license by the Department.

The New Jersey Clinical Laboratory Improvement Act, N.J.S.A. 45:9-42.27a, defines a collection station as "any facility used for the collection, processing and transmission of specimens to another facility for the performance of clinical tests."

The application, including instructions for initial applicants, and the above-referenced law and the Department's rules can be found at <http://www.nj.gov/health/phel/clinical-lab-imp-services/>.

Please be advised that the unlicensed collection of specimens or performance of clinical testing by a laboratory may result in the Department's initiation of enforcement proceedings, including the imposition of a fine of up to \$1,000 for each violation of the New Jersey Clinical Laboratory Improvement Act, N.J.S.A. 45:9-42.26, et seq. Each sample assayed or specimen collected could constitute a separate violation of the Act.

A complete application for initial licensure must include all the items listed below and be submitted to CLLP via email to CLLP@doh.nj.gov or by mail (PO Box 361, Trenton, NJ, 08625) as a single complete package. CLLP will return incomplete applications.

- License application form CL-18
- \$200 collection station fee for each fixed location or each mobile collection service
- Ownership form CL-9 for all owner(s)
- A separate document listing the name and contact information for the individual who will serve as Laboratory Director (licensed MD/DO or Bioanalytical Laboratory Director)
- Documentation reflecting the training, education, competency, or qualifications for collectors
- A copy of the floor plan or a photograph of the area of the facility/vehicle used for record retention, phlebotomy and storage of supplies

After CLLP has received the complete application with all required documents and required fees, CLLP may contact you to arrange a pre-licensure inspection of the facility at a mutually convenient date and time.

If you have any questions, please contact CLLP at 609-718-8077. Thank you for your cooperation.

Sincerely,

Jacquelyn Guthrie

Jacquelyn Guthrie, MLS (ASCP)^{CM}
Clinical Laboratory Evaluator 2
Clinical Laboratory Licensing Program
Public Health and Environmental Laboratories