

NJ Dept. of Health & Senior Services – Clinical Laboratory Improvement Services  
Prelicensure Check List

At the prelicensure survey you need to have the reagents, materials, supplies, test systems, culture media, equipment and instruments that are appropriate and sufficient for the start-up of patient testing in your laboratory. We are also asking that the laboratory director and general supervisor be present during the prelicensure survey.

We are requesting that the following information be accessible and retrievable during the survey:

- Standard operating procedure manual with all test procedures (e.g., package inserts and supplemental information, as necessary);
- Reference laboratories' client services manual, if applicable;
- Personnel records, including:
  - Current and complete CL-34 Laboratory Personnel Qualification Appraisal forms
  - Diplomas, certificates, degrees;
  - Training and experience;
  - Continuing education;
  - Competency assessment policies and procedures;
  - Duties/responsibilities
  - A work schedule listing all personnel required to be onsite during hours of operation.
- Quality control records, including:
  - Package inserts for reagents, controls and calibrators;
  - Remedial action information;
  - Calibration and calibration verification records;
  - Statistical limits; and
  - Instrument maintenance and function checks records.
- Proficiency testing (PT) reports, including:
  - Test runs with PT results;
  - Direct, original instrument printouts; and
  - Remedial actions for unsatisfactory results.
- Quality system assessment plan and documentation;
- Safety policies and procedures; and
- Laboratory Information System operation
- Samples of patient testing records:
  - Requisition;
  - Work records;
  - Patient test report.
- Establishment/verification of performance specifications  
Please have documentation of the studies you performed to verify or establish the performance specifications available for our review. Documentation must include raw data, product insert if FDA approved method and step-by-step procedure used to establish or verify the performance specifications for each performance characteristic.