



Under Pennsylvania's Clinical Laboratory Act and Department regulations, a clinical laboratory is a place, establishment or institution organized and operated primarily for the performance of bacteriological, biochemical, microscopical, serological or parasitological tests by the practical application of one or more of the fundamental sciences to material originating from the human body, by the use of specialized apparatus, equipment and methods, for the purpose of obtaining scientific data which may be used as an aid to ascertain the state of health. The term includes, but is not limited to, independent, hospital, industrial, state, county and municipal laboratories and clinical laboratories operated in private offices and clinics of practitioners of the healing arts (physician's office laboratory/clinic laboratory). A **physician's office laboratory** performs clinical laboratory testing only on its own patients or those of the practice; it does not receive specimens from other physicians' offices or laboratories. **Clinic laboratories** perform testing under the direction of the physician(s) who treat the clinic's patients; they do not receive specimens from other physicians, clinics or laboratories. Facilities only collecting or preparing specimens (or both) and not performing testing are not considered laboratories.

REQUIREMENTS FOR ALL LABORATORIES

Must hold a Pennsylvania Clinical Laboratory Permit issued by the Department of Health, Bureau of Laboratories.

Must have a director with a doctoral level degree and experience acceptable to the Department.

Must have a General Supervisor with education and experience as defined by the Department and is present during all hours of testing.

Must have a director present during all hours that testing is performed. **See additional notes on director's presence (Instructions for Application Process and Demographic Changes).**

Must have written procedures for all tests performed (supplemental package inserts are acceptable).

Must use materials that are in date, stored and used according to the manufacturers' instructions.

Must record all quality control (QC) results so that they are traceable to the patients' test results.

Must successfully participate in an approved proficiency testing program. **See additional notes (Instructions for Application Process and Demographic Changes).**

Must notify the Bureau immediately of a change in director or location and within 30 days of a change in ownership, laboratory name or test menu.

Must agree that the Bureau reserves the right to perform an on-site inspection at any time of the premises occupied and maintained by **any** laboratory and may examine all matters related to clinical laboratory testing.

Must adhere to any additional requirements defined by the Department.