

CLIA Director and Clinical Consultant Positions NBS RFP

Under the Clinical Laboratory Improvement Amendments (CLIA)

Congress passed the Clinical Laboratory Improvement Amendments ([CLIA – 42CFR 493](#)) to establish quality standards for all laboratories testing patient specimens by ensuring accuracy, reliability, and timeliness of test results. The law specifies that the clinical laboratory must have access to a CLIA Director who must be qualified to manage and direct the laboratory personnel and performance of tests. It further specifies that the CLIA Director must be eligible to be an operator of a laboratory and meet educational and experience qualifications ([Subpart F - §493.1443](#)). The Illinois Department of Public Health, Division of Laboratories has three CLIA accredited laboratories which require a CLIA Director. In addition to federal law, the Illinois Clinical Laboratories Code ([77 Ill. Admin. Code 450](#)) stipulates the qualifications of a CLIA Director of Clinical Laboratory, along with the requirement of a CLIA Director's supervision to operate a clinical laboratory.

The Illinois Department of Public Health (IDPH) Division of Laboratories is seeking a CLIA Director and a Clinical Consultant, both of which must meet the requirements of the lab director position under CLIA. Each position will require approximately 25 hours per week. These positions will provide oversight and consultation for the newborn screening (NBS) testing unit and other clinical laboratory testing operations in each of the three laboratories. The selected candidates shall be able to perform the duties listed below from a remote location or on-site at any of the three laboratory locations.

The CLIA Director position will be responsible for the clinical regulatory requirements. The CLIA Director shall provide oversight for the clinical operations of the IDPH laboratories located in Chicago, Springfield and Carbondale, Illinois as needed by the Division of Laboratories. The primary responsibility of the CLIA Director is to oversee clinical laboratory testing and processes within the Division.

CLIA Director duties include:

- 1.) Complete and submit paperwork and documentation necessary to qualify as the Laboratory Director for clinical testing to all applicable federal and state entities.
- 2.) Orient to the general operations, policies, procedures, and framework of the Division of Laboratories through meetings with technical laboratory supervisors.
- 3.) Provide oversight for the operation and administration of the IDPH laboratories located in Chicago, Carbondale, and Springfield. See addresses below.
- 4.) Coordination with laboratory managers, the CLIA Director will ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards.
- 5.) Ensuring that test methodologies selected have the capability of providing the quality of results required for patient care and evaluate verification/validation procedures to determine the accuracy, precision, and other pertinent performance characteristics of the methods.
- 6.) Ensuring that the laboratories are enrolled in an HHS approved proficiency testing program for the testing performed and that the results are returned within the timeframes established by the proficiency testing program.
- 7.) Ensuring that laboratory standard operating procedures (SOPs) meet CLIA requirements. Review and approve clinical SOPs as necessary.
- 8.) Review qualifications of laboratory personnel to determine suitability as testing and supervisory staff. Review and approve personnel assessments initially and as needed.

- 9.) Oversee and facilitate resolution of improvement actions, based on the requirements under CLIA, for any deficiency noted in internal or external audits, or that arise during normal operations.
- 10.) Ensure that the Division of Laboratories utilizes a quality system approach to laboratory testing that provides accurate and reliable test results.
- 11.) Be accessible to all the laboratories to provide onsite, telephone or electronic consultation, as needed.

The Clinical Consultant position will be responsible for providing consultation, advice, and rendering opinions to each of the laboratory’s clients, supervisors, administration, and to the CLIA Director. The Clinical Consultant shall also serve as a back-up to the CLIA Director as needed by IDPH.

Clinical Consultant duties include:

- 1.) Fulfill CLIA Director duties listed above in the event of serving as back up CLIA Director.
- 2.) Provide test ordering and interpretation of test result consultation to the laboratory’s clients.
- 3.) Assist laboratory personnel in ensuring appropriate testing to meet clinical expectations.
- 4.) Provide consultation and communication to laboratory personnel, administration, and the CLIA Director related to quality of testing, new test development, and technical expertise on clinical diagnostic testing.

Laboratory Locations:

IDPH Springfield Lab
 825 N Rutledge Street
 Springfield, IL 62702

IDPH Chicago Lab
 2121 W. Taylor Street
 Chicago, IL 60612

IDPH Carbondale Lab
 1155 South Oakland Avenue
 Carbondale, IL 62901

Interested and qualified candidates should respond to this bid request with a per hour rate for these services along with a Curriculum Vitae and credentials demonstrating their ability to meet the criteria required for these positions. Please include weekly availability for each position application. Forms A will be required for the awarded vendor as a part of the contracting process. A sample for your review can be found at this link: <https://www2.illinois.gov/cpo/general/Pages/SolicitationandContractTemplates.aspx>

Date of Bid	Name of Qualified Candidate	Price per hour	Hours Available per Week

Offeror’s Signature