BID SPECIFICATIONS
For
CLIA Director
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 requires a CLIA Director to provide oversight for all laboratory testing operations in each of the 3 laboratories. The CLIA Director shall provide oversight for the operation and administration of the Newborn Screening (NBS) and other applicable laboratory testing at IDPH laboratories located in Chicago, Springfield and Carbondale, Illinois. The selected candidate will be able to perform required CLIA duties from a remote location or on-site at any of the three laboratory locations. The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation, as needed.

The position is expected to be for three years, with workdays being Monday – Friday and in accordance with the State calendar. Schedule will be determined with the successful applicant, based on workload and availability and subject to IDPH approval. The anticipated start date is February 1, 2022.

CLIA Director Qualifications

Per 42 CFR 493 Subpart F 493.1443 the following qualifications must be met:
(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and
(b) The laboratory director must—(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification;
or(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or(ii) Have at least 2 years of experience directing or supervising high complexity testing;
or(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution and—(i) Be certified and continue to be certified by a board approved by HHS; or(ii) Before February 24, 2003, must have served or be serving as a director of a laboratory performing high complexity testing and must have at least—(A) Two years of laboratory training or experience, or both; and(B) Two years of laboratory experience directing or supervising high complexity testing.
(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or(5) On or before February 28, 1992, be qualified under State law to direct a

laboratory in the State in which the laboratory is located; or(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

Interested and qualified candidates should respond to this bid request with a per hour rate for these services along with a Resume/Curriculum Vitae (CV) and credentials showing their ability to meet the criteria to act as a CLIA Director.

CLIA Director Duties

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.) Review and learn 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 NBS and all clinical diagnostic testing done in the IDPH laboratories located in Chicago, Carbondale, and Springfield. See addresses in laboratory locations.

4.) At a minimum, provide oversight for the following areas:

a) Testing systems in the laboratory provide quality services in all aspects of test performance, i.e., the pre-analytic, analytic, and post-analytic phases of testing and are appropriate for patient population(s)
b) Physical and environmental conditions of the laboratory are adequate and appropriate for the testing performed
c) The environment for employees is safe from physical, chemical, and biological hazards and safety and biohazard requirements are followed
d) A general supervisor (high complexity testing) is available to provide day-to-day supervision of all testing personnel and reporting of test results as well as provide on-site supervision for specific minimally qualified testing personnel when they are performing high complexity testing
e) Sufficient numbers of appropriately educated, experienced, and/or trained personnel are available who provide appropriate consultation, properly supervise, and accurately perform tests and report test results in accordance with the written duties and responsibilities specified by you, are employed by the laboratory
f) New test procedures are verified or validated per regulations prior to implementation including all necessary paperwork, included in the procedure manual, and followed by personnel
g) Each employee's responsibilities and duties are specified in writing and monitored.

5.) Ensure 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.

6.) Ensure that laboratory standard operating procedures (SOPs) meet CLIA requirements. Review and approved SOPs as necessary.

7.) Review qualifications of laboratory personnel to determine suitability as testing and supervisory staff. Review and approve personnel assessments initially and as needed.

8.) Recommend improvement actions, based on the requirements under CLIA, for any deficiency noted in internal or external audits, or that arise during normal operations.

9.) Ensure that the Division of Laboratories utilizes a quality system approach to laboratory testing that provides accurate and reliable test results.

Laboratory Locations:

IDPH Springfield Lab
825 N Rutledge 3rd Floor
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 Resume/Curriculum Vitae (CV) and credentials showing their ability to meet the criteria to act as a CLIA Director.

Date of Bid	Name of Qualified Candidate	Availability by Hours per Week	Firm Price per Hour
			$

Selected vendor must submit and complete FORM A prior to contract execution. See attachment of FORM A on RFP publication site.

Please submit Bids to: Sean McAuliff at Sean.M.McAuliff@Illinois.gov

Bids are due on **Wednesday, December 29, 2021** no later than **3:00 p.m**. Central Standard Time