Marion County Public Health Department Laboratory
CLIA JOB RESPONSIBILITIES for LABORATORY DIRECTOR

Laboratory Name on CLIA License	Location	CLIA #
Marion County Health Department Laboratory	3838 N Rural St. Indianapolis, IN 46205	15D0647159
Action Health Center Laboratory	2868 N Pennsylvania St. Indianapolis, IN 46205 4825 N Arlington Ave. Indianapolis, IN 46226 2405 S. Madison Ave. Indianapolis, IN 46225 10101 E. 38th St. Indianapolis, IN 46235 1140 Dr. Martin Luther King Jr. St. Indianapolis, IN. 46202	15D0694961
Bell Flower Clinic Laboratory	1101 W. 10th St. Indianapolis, IN 46202	15D0684048

Responsibilities outlined below are for High Complexity testing. Please note these responsibilities also apply to Moderate Complexity testing.

493.1445 Laboratory Director Responsibilities:

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.

a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487

   Commentary: An individual qualified as laboratory director under 493.1443 may not qualify as technical supervisor in a particular specialty or subspecialty unless he or she has the required training or experience. If the director of high complexity testing is not qualified to perform the duties of the technical supervisor or clinical consultant, he or she must employ individual(s) meeting the respective qualifications.

b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.
c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.
d) Each individual may direct no more than five laboratories.

Commentary: An individual may serve as director of 5 nonwaived certified laboratories. However, an individual may serve as technical consultant, clinical consultant, or technical supervisor for any number of laboratories.

e) The laboratory director must—

1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

Commentary: If the director cannot practically provide personnel, on-site supervision, it must be demonstrated that the director:

- *Provides direction and consultation electronically or by telephone, as necessary; or*
- *Delegates to qualified personnel specific responsibilities as provided in the regulations.*

The laboratory director may reapportion to a technical supervisor in writing, the responsibilities in 493.1445e (3), (4), (5), (6), (7), (12), (13), and (14).

The only responsibilities that may be delegated to the general supervisor are listed at 493.1463(b)(1)-(4)- ***See General Supervisor CLIA Responsibilities****.*

2) 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;
3) **(May be Delegated to Technical Supervisor)** Ensure that—
    i. The test methodologies selected have the capability of providing the quality of results required for patient care;
    ii. Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and
    iii. Laboratory personnel are performing the test methods as required for accurate and reliable results;
4) **(May be Delegated to Technical Supervisor)** Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that—
    i. The proficiency testing samples are tested as required under Subpart H of the regulations;
    ii. The results are returned within the timeframes established by the proficiency testing program;

iii. All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and
iv. An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory;

5) **(May be Delegated to Technical Supervisor)** Ensure that the quality control and quality assurance programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;
6) **(May be Delegated to Technical Supervisor)** Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;
7) **(May be Delegated to Technical Supervisor)** Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and that patient test results are reported only when the system is functioning properly;
8) Ensure that reports of test results include pertinent information required for interpretation;
9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific conditions;
10) Ensure that a general supervisor provides onsite supervision of high complexity test performance by testing personnel qualified under Section IV, qualification code TPH7;
11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with personnel responsibilities;
12) **(May be Delegated to Technical Supervisor)** Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;
13) **(May be Delegated to Technical Supervisor)** Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;
14) **(May be Delegated to Technical Supervisor)** Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and
15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and

postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

Approved By:

Joan, Trendell, Bureau Chief, Bureau of Population Health (Signature/Date)

Employee Acknowledgement:

I have read and understand the qualifications and job responsibilities for the Clinical Consultant as per the Clinical Laboratory Improvement Act of 1988 and it's subsequent acts. I agree to follow the job responsibilities.

Bonny Lewis Van, PhD, FACB; Director-Public Health Laboratory (CLIA Laboratory Director)

Employee Signature/Date