
42 C.F.R. § 493.1445

Standard; 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, respectively.
- (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.
- (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;

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