

DELEGATION OF LABORATORY DIRECTOR RESPONSIBILITIES



CLINICAL LABORATORY



The Laboratory Director is responsible for the overall operation and administration of the laboratory. The director's responsibilities include employing personnel who are competent to perform test procedures, reporting test results promptly and accurately, and ensuring compliance with applicable regulations.

The Laboratory Director may delegate the performance of certain duties in writing to qualified individuals while remaining responsible for ensuring that all duties are properly performed.

The two tables below list the responsibilities of the Laboratory Director (LD) in moderate-complexity (MC) and high-complexity (HC) laboratories that may NOT be delegated and those that may be delegated and to which qualified individual they may be delegated. The relevant Accreditation Commission for Health Care (ACHC) Standard is identified with a cross-reference to the corresponding Clinical Laboratory Improvement Amendments (CLIA) regulation.

Position Key

CC Clinical Consultant	GS General Supervisor	LD Laboratory Director	TC Technical Consultant	TP Technical Personnel	TS Technical Supervisor
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Laboratory Director responsibilities that may NOT be delegated

Responsibility	ACHC Standard	Code of Federal Regulations (42 CFR)
Ensure quality services for all aspects of test performance (pre-analytic, analytic, and post-analytic).	02.01.06	HC: 493.1445 (e)(1) MC: 493.1407 (e)(1)
Ensure and provide safe environmental conditions with protection from physical, chemical, and biological hazards.	02.01.07	HC: 493.1445 (e)(2) MC: 493.1407 (e)(2)
Be accessible for on-site, telephone, or electronic consultation, as needed.	02.01.04	HC: 493.1445 (c) MC: 493.1407 (c)
Ensure that Laboratory Director-approved procedures are available to staff.	02.01.14	HC: 493.1445 (e)(14) MC: 493.1407 (e)(13)
Assign duties and responsibilities in writing for CC, TS, TC, GS, TP (job/position descriptions).*	02.01.15 & 02.05.03	HC: 493.1445 (e)(15) MC: 493.1407 (e)(14)
Ensure all delegated duties are performed properly.	02.01.03	HC: 493.1445 (a)(b) MC: 493.1407 (a)(b)
Ensure that a GS provides on-site supervision as required for personnel qualified under 493.1489(4) who perform high-complexity testing.	02.01.12	HC: 493.1445(e)(10)
Authorize test performance that is commensurate with the education, training, or experience and technical abilities of testing personnel.	02.05.03	HC: 493.1495(a) MC: 493.1425(a)

*Positions required based on test complexity of laboratory:

- High-complexity positions: LD, CC, TS, GS, TP
- Moderate-complexity positions: LD, CC, TC, TP (Note: There is no GS position.)

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Laboratory Director responsibilities that MAY be delegated to individuals in qualified position(s)

Responsibility	Qualified Positions for Delegation			Standard	Code of Federal Regulations (42 CFR)
	CC	TS/TC	GS (HC Only)		
Select methods to assure accurate results and verify procedure used (accuracy, precision, etc.).		X		02.01.08	HC: 493.1445(e)(3)(i-iii)
Ensure Proficiency Testing (PT) enrollment and timely testing in an approved program. Review PT reports and approve remedial action.		X		02.01.09	HC: 493.1445(e)(4)(i-iv) MC: 493.1407(e)(4)(i-iv)
Ensure that QC and QA programs for all areas of the laboratory covering pre-analytic, analytic, and post-analytic phases are established and maintained.		X		02.01.10	HC: 493.1445(e)(5-7) MC: 493.1407(e)(5-7)
Employ sufficient number of employees with appropriate education/training. Establish performance monitoring and identify remedial training/ continuing education needs.		X		02.01.13	HC: 493.1445(e)(11)(12)(13) MC: 493.1407(e)(10)(11)(12)
Ensure remedial action is taken to resolve technical problems and no test results are reported until all corrective actions have been taken and the system is properly functioning.		X	X	02.04.03	493.1463(b)(1-2)
Provide orientation and training to TP.		X	X	02.04.03	493.1463(b)(3)
Conduct annual evaluation and competency assessment of TP performance.		X	X	02.04.03	493.1463(b)(4)
Perform semi-annual evaluation and competency assessment of TP in the first year of their employment.		X		02.02.04	HC: 493.1451(b)(8)(i-vi),(9) MC: 493.1413(b)(8)(i-vi),(9)
Ensure that reports of test results include information required for interpretation.	X			02.01.11	HC: 493.1445(e)(8),(9) MC: 493.1407(e)(8),(9)
Ensure that consultation is available to clients relating to the quality of reported test results and their interpretation relevant to specific patient conditions.	X			02.01.11	HC: 493.1445(e)(8-9) MC: 493.1407(e)(8-9)