

Laboratory Compliance Section

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CLINICAL LABORATORY DIRECTOR RESPONSIBILITIES FOR MODERATE AND HIGH COMPLEXITY TESTING

The laboratory Director is responsible for the overall operation and administration of the laboratory, including the employment of competent personnel, equipment, safety, laboratory policies, quality assurance, all testing (including proficiency testing) and test reports. (42 CFR 493.1407 and 493.1445) The Director may, if qualified, perform the duties of the technical consultant, technical supervisor, clinical consultant, general supervisor and testing personnel. Some duties may be delegated in writing to other qualified individuals. The Director must ensure that delegated duties are properly performed and must be accessible to provide on site, telephone, or electronic consultation.

The following Director responsibilities may NOT be delegated:
Ensure quality services for all aspects of service
Ensure safe environmental conditions
Ensure Director approved procedures are available to staff
Employ sufficient number of employees with appropriate education/training
Write duties of CC, TC, TS, GS, TP (position descriptions)
Ensure all delegated Director duties are properly performed
Ensure general supervisor provides on site supervision as required for high complexity testing personnel qualified under 493.1489(4)
Ensure test performance only within the limitations of the clinical laboratory license

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The following Director responsibilities MAY be delegated to the individual(s) designated as clinical consultant, technical consultant, technical supervisor or general supervisor as indicated below:

	Director	CC	TC	TS*	GS*
Select methods to assure accurate results	X		X	X	
Verify methods (accuracy, precision, etc)	X		X	X	
Assure proficiency testing enrollment (in approved program)	X		X	X	
Review proficiency test reports and approve remedial action	X		X	X	
Assure appropriate on site supervision of high complexity test performance	X			X	
Ensure that a quality control and quality assurance program is established and maintained	X		X	X	
Resolve technical problems (not a specific director responsibility)			X	X	
Ensure remedial action taken to resolve technical problems	X		X	X	X
Ensure no test results are reported until all corrective actions have been taken and the test system is properly functioning	X		X	X	X
Assure personnel competency & training	X		X**	X**	X
Evaluate testing personnel annually	X		X	X	X
Assure reports include pertinent information for interpretation	X	X			
Ensure that an approved procedure manual is available to all staff responsible for testing.	X		X	X	
Consult with patient regarding lab results	X	X			

Key: CC=Clinical Consultant TC=Technical Consultant TS=Technical Supervisor GS=General Supervisor

*High Complexity Testing only

**Identify training needs