



42 CFR 493 Laboratory Requirements

Subpart K Quality System for Nonwaived Testing - General Laboratory Systems

Instructions		Notes: (Pass/Fail)
Quality System		
1.	Are there policies and procedures in place to implement and monitor a quality system for all phases of total testing process and general laboratory systems?	
2.	Does the ongoing monitoring system identify, evaluate and resolve problems in the performance and services of the laboratory?	
3.	Are components of the quality system appropriate for the specialties and subspecialties of testing the lab performs, services the lab offers and clients the lab serves?	
Patient Information		
4.	How is patient information secured?	
5.	Are policies and procedures written and followed to maintain confidentiality?	
6.	Are personnel educated or trained to maintain confidentiality?	
7.	How does the laboratory handle breaches of confidentiality?	
8.	Are these events documented, investigated and reviewed?	
Specimen Identification (ID) and Integrity		
9.	How is identification and integrity of patient specimen maintained from receipt through completing of testing and reporting?	
10.	Are policies and procedures written and followed to maintain specimen integrity?	
11.	Are personnel educated or trained to maintain specimen integrity?	
12.	How does the laboratory handle specimen identification errors?	
13.	Are these events documented, investigated and reviewed?	
Complaints and Problems		
14.	How does the laboratory handle complaints and problems?	
15.	What procedures are in place to identify and document problems that occur as a result of testing?	
16.	Are investigations of complaints documented?	
17.	Are complaints and related investigations documented?	
Employee and Consultant Competency		
18.	How does the laboratory conduct employee and consultant competency?	
19.	Does the qualifications of the employee or consultant fulfill the minimum requirements of the job position? Are their credentials verified?	
20.	Are employees or consultant trained and/or tested to perform the minimum requirements of the job position?	
21.	Is the competency of each employee and consultant documented?	
Quality Assessment		
22.	How does the laboratory conduct quality assessment (QA)?	
23.	Are policies and procedures written and followed for quality assessment?	
24.	Is the revision of policies and procedures to prevent recurrence of problems reviewed?	
25.	Are corrective actions to resolve problems reviewed?	
26.	Is the appropriate staff involved in assessing QA measures?	
27.	Are all the components of the QA documented?	