



42 CFR 493 Laboratory Requirements

Subpart H Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

Instructions		Notes: (Pass/Fail)
Enrollment in Proficiency Testing (PT) Program		
1.	List all the PT program/s the lab is enrolled in and the analytes/tests in each specialty and subspecialty under each program. (Use separate sheet.)	
2.	Did the Lab participate in its PT program/s for at least one year?	
3.	Did the Lab switch to a new PT program on any of its specialties or subspecialties? If so, was Centers for Medicare and Medicaid services (CMS) notified?	
4.	List all the analytes/tests performed in the lab. (Use separate sheet.)	
5.	Compare items listed in 1 and 4. Are all analyte/tests performed in the Lab submitted to a PT program?	
5a.	If not, are the analytes/tests excluded in 42CFR493 or not covered by CMS CLIA-approved PT providers?	
5b.	Are the analytes/tests verified twice a year for accuracy?	
6.	Did the Lab successfully participate in all of its PT programs?	
Routine Processing of PT Samples		
7.	Select 5 PT samples from different specialties to review (must be more than 6 months old.)	
8.	Were the samples treated as patients?	
9.	Entered to LIS system and given	
10.	Sample processed into re	
11.	Sample tested as in	
12.	Results recor	
13.	Sample	
Documentation		
14.	Results of PT samples were reviewed, evaluated, verified and documented.	
15.	Are there any analytes, specialties or subspecialties assigned a PT score that did not reflect laboratory test performance, received a zero score for nonparticipation, had a late return of results or otherwise, failed?	
16.	If so, were these analytes verified for accuracy?	
17.	Copy of patient testing record of each sample included in file. (Records are kept for a minimum of 2 years.)	
Evaluation of PT Samples		
18.	Results of PT samples were reviewed, evaluated, verified and documented.	
19.	Are there any analytes, specialties or subspecialties assigned a PT score that did not reflect laboratory test performance, received a zero score for nonparticipation, had a late return of results or otherwise, failed?	
20.	If so, were these analytes verified for accuracy?	