

**Division of Clinical Laboratory Improvement and Quality
Centers for Medicare & Medicaid Services**

October 2018

Top 10 Deficiencies in the Nation – CMS Surveys

Regulatory Subpart	Regulatory Cite	Deficiency	# all labs with deficiency	% all labs with deficiency	# POLS with deficiency	% POLS with deficiency
Analytic Systems (D5413) STANDARD	493.1252(b)	The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented.	804	4.8%	503	4.6%
General Lab Systems (D5217) STANDARD	493.1236(c)(1)	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I or this part.	726	4.3%	517	4.8%
Personnel Competency Assessment (D5209) STANDARD	493.1235	As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.	691	4.1%	442	4.1%
Analytic Systems (D5791) STANDARD	493.1289(a)	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems	675	4.0%	289	2.7%
Analytic Systems (D5403) STANDARD	493.1251(b)	The procedure manual must include the requirements for specimen acceptability, microscopic examination, step-by-step performance of the procedure, preparation of materials for testing, etc.	671	4.0%	414	3.8%
Post Analytic Systems (D5805) STANDARD	493.1291(c)	The test report must indicate the following: for positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number, the name and address of the laboratory location where the test was performed, and other requirements specified in 493.1291(c).	589	3.5%	394	3.6%
Procedure Manual (D5401) STANDARD	493.1251(a)	Written procedure manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel.	544	3.2%	344	3.2%
Analytic Systems (D5429) STANDARD	493.1254(a)(1)	Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.	523	3.1%	300	2.8%
Analytic Systems (D5417) STANDARD	493.1252(d)	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of	521	3.1%	329	3.0%
Verification of Performance Specifications (D5421) STANDARD	493.1253(b)(1)	Each laboratory that introduces an unmodified, FDA-cleared or approved test system must demonstrate that it can obtain performance specifications comparable to those established by the manufacturer.	478	2.8%	244	2.2%

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Top 10 Conditions in the Nation – CMS Surveys

Regulatory Subpart	Regulatory Cite	Deficiency	# all labs with deficiency	% all labs with deficiency	# POLs with deficiency	% POLs with deficiency
Personnel Moderate Complexity (D6000) CONDITION	493.1403	The laboratory must have a director who meets the qualification requirements of 493.1405 and provides overall management and direction in accordance with 493.1407.	417	2.48%	264	2.49%
Personnel High Complexity (D6076) CONDITION	493.1441	The laboratory must have a director who meets the qualification requirements of 493.1443 and provides overall management and direction in accordance with 493.1445.	266	1.58%	85	0.80%
Analytic Systems (D5400) CONDITION	493.1250	Laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283.	236	1.41%	127	1.20%
Personnel Moderate Complexity (D6063) CONDITION	493.1421	The laboratory must have sufficient number of individuals meeting the qualifications of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.	185	1.10%	108	1.02%
Personnel Moderate Complexity (D6033) CONDITION	493.1409	The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 and provides technical oversight in accordance with 493.1413.	189	1.13%	110	1.04%
Proficiency Testing (D2000) CONDITION	493.801	Each laboratory must enroll in a PT program that meets the criteria in subpart I and is approved by HHS. The laboratory must enroll for each specialty and subspecialty, and must test the samples in the same manner as patients' specimens.	179	1.07%	98	0.92%
Proficiency Testing (D2016) CONDITION	493.803	Each laboratory performing nonwaived testing must successfully participate in a PT program approved by CMS as described in subpart I of this part for each specialty, subspecialty and analyte or test in which the laboratory is certified under CLIA.	117	0.70%	70	0.66%
Personnel High Complexity (D6168) CONDITION	493.1487	The laboratory must have sufficient number of individuals who meet the qualification requirements concerning State licensure, if applicable, and the educational requirements for High complexity personnel as defined in 493.1489.	92	0.55%	45	0.42%
Hematology Quality Systems (D5024) CONDITION	493.1215	If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269 and 493.1281 through 493.1299.	65	0.39%	26	0.25%
Personnel High Complexity (D6108) CONDITION	493.1447	Have a technical supervisor who meets the qualification requirements as defined in 493.1449 and provides technical supervision in accordance with 493.1451.	59	0.35%	25	0.24%