

CLIA UPDATE – August 2007
Division of Laboratory Services
Centers for Medicare and Medicaid Services
Top 10 Deficiencies in the Nation – CMS Surveys

Regulatory Subpart	Regulatory Cite	Deficiency	# labs with deficiency	% labs with deficiency
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.	1,087	5.80%
Analytic Systems (D5411) STANDARD	493.1252(a)	Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.	1,066	5.69%
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 specified in 493.1251 through 493.1283.	1,018	5.43%
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.	965	5.15%
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.	925	4.93%
General Lab Systems (D5291) STANDARD	493.1239(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 general laboratory systems requirements in 493.1231 through 493.1236.	789	4.21%
Postanalytic Systems (D5805) STANDARD	493.1291(c)	The test report must indicate positive patient identification, name and address of the laboratory where the test was performed, the report date, test performed, specimen source, result and units of measurement or interpretation.	761	4.06%
Personnel Moderate Complexity (D6021) STANDARD	493.1407(e)(5)	The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided.	713	3.80%
Analytic Systems (D5787) STANDARD	493.1283(a)	The laboratory must maintain an information or record system that includes positive identification of the specimen, date and time of specimen receipt, condition and disposition of specimens that do not meet the laboratory's criteria for acceptability, the records and dates of all specimen testing including the identity of the personnel who performed the test.	638	3.40%
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 substandard quality.	633	3.38%

Total number of laboratories surveyed = 18,746
Data based on the most current survey conducted on or after January 12, 2004
OSCAR data as of 8/10/2007

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Centers for Medicare and Medicaid Services
Top 10 Conditions in the Nation – CMS Surveys

Regulatory Subpart	Regulatory Cite	Deficiency	# labs with deficiency	% labs 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.	603	3.22%
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.	423	2.26%
Analytic Systems (D5400) CONDITION	493.1250	Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.	347	1.85%
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.	241	1.29%
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.	180	0.96%
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.	151	0.81%
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.	100	0.53%
General Laboratory Systems (D5200) CONDITION	493.1230	Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.	98	0.52%
Endocrinology Quality Systems (D5020) CONDITION	493.1212	If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.	83	0.44%
Preanalytic Systems (D5300) CONDITION	493.1240	Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.	52	0.28%

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