Division of Clinical Laboratory Improvement and Quality
Year 2024
Top 10 Standard-Level Deficiencies

Standards D-tag and Regulatory Subpart	Regulatory Citation	Deficiency	Number of all labs with deficiency	% of all labs with deficiency
D5413 Analytic Systems	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.	818	5.0%
D5209 Personnel Competency Assessment	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.	778	4.8%
D5401 Procedure Manual	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.	635	3.9%
D5403 Analytic Systems	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.	609	3.7%
D5417 Analytic Systems	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.	607	3.7%
D5217 General Lab Systems	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.	548	3.4%
D5421 Verification of Performance	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.	451	2.8%
D6016 Laboratory Director Responsibilities	493.1407(e)(4)(i)	Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that (i) The proficiency testing samples are tested as required under subpart H of this part;	451	2.8%
D5429 Analytic Systems	493.1254(a)(1)	Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.	449	2.8%
D5805 Post Analytic Systems	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).	417	2.6%

Division of Clinical Laboratory Improvement and Quality
Year 2024
Top 10 Condition-Level Deficiencies

Conditions D-tag and Regulatory Subpart	Regulatory Citation	Deficiency	Number of all labs with deficiency	% of all labs with deficiency
D2016 Successful Participation	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.	738	4.39%
D6000 Personnel Moderate Complexity	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.	709	4.22%
D6076 Personnel High Complexity	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.	388	2.31%
D5400 Analytic Systems	493.1250	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.	340	2.02%
D2000 Proficiency Testing	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.	218	1.30%
D6063 Personnel Moderate Complexity	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.	182	1.08%
D6033 Personnel Moderate Complexity	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%
D6168 Personnel High Complexity	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.	172	1.02%
D6108 Personnel High Complexity	493.1447	The laboratory must have a technical supervisor who meets the qualification requirements as defined in 493.1449 and provides technical supervision in accordance with 493.1451.	110	0.65%
D5300 Preanalytic Systems	493.1240	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.	82	0.49%