

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

Year 2021

Top 10 Deficiencies in the Nation – CMS Surveys

Regulatory Subpart	Regulatory Cite	Deficiency	# all labs with deficiency	% all labs with deficiency
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.	726	18.96%
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.	670	17.50%
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.	623	16.27%
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.	610	15.93%
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.	560	14.63%
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.	558	14.57%
Analytic Systems (D5429) STANDARD	493.1254(a)(1)	Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.	498	13.01%
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.	494	12.90%
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).	447	11.67%
Laboratory Director's Responsibility (D6016)	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;	392	10.24%

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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
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.	875	22.85%
Laboratory Director - Moderate (D6000) CONDITION	493.1403	The laboratory must have a director who meets the qualification requirements of § 493.1405 of this subpart and provides overall management and direction in accordance with § 493.1407 of this subpart.	697	18.20%
Analytic Systems (D5400) CONDITION	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.	375	9.79%
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.	366	9.56%
Facility Administration (D3000) CONDITION	493.1100	Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing.	275	7.18%
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.	257	6.71%
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.	224	5.85%
Reporting of SARS-CoV-2 Test Results (D1002) CONDITION	492.41	During the Public Health Emergency, as defined in § 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.	211	5.51%
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.	191	4.99%
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.	155	4.05%