New York Exempt State Presentation to Clinical Laboratory Improvement Advisory Committee



January 1, 2022, through December 31, 2022

Top Ten CLIA Deficiencies Cited

NYS STANDARD	CLIA EQUIVALENT	# TIMES CITED	PERCENTAGE OF SURVEYS
Human Resources Standard of Practice 8 (HR S8): Competency Assessment - Testing Personnel	493.1413(b)(8)	77	12.2
Reporting Sustaining Standard of Practice 2 (Reporting S2): Test Report Content	493.1291(c)	74	11.7
Document Control Standard of Practice 1 (DC S1): Availability	493.1251(a)	73	11.5
Quality Management System Sustaining Standard of Practice 3 (QMS S3): Quality Indicators	493.1200(a)	64	10.1
Reagent and Media Standard of Practice 1 (RGM S1): Reagent and Media Records	493.1252(c)	58	9.2
Laboratory Equipment and Instrument Standard of Practice 3 (LEI S3): Function Checks and Performance Verification of Instruments, Equipment and Test Systems	493.1254(a) and 493.1255(b)	53	8.4
Document Control Standard of Practice 2 (DC S2): Compliance	493.1251(a)	42	6.6
Director Standard of Practice 4 (DR S4): Director Responsibilities	493.1445(e)	38	6.0
Quality Management System Standard of Practice 5 (QMS S5): System and Process Audits	493.1200(b)	36	5.7
Test Procedure Content Standard of Practice 1 (TPC S1): Test Procedure Content	493.1251(b)	33	5.2

<u>Outreach</u>: A Top Ten List of Deficiencies is presented at a variety of laboratory association events across the state each year. A description of the most common underlying causes for the deficiencies is provided as part of this ongoing laboratory education effort.