

		2	Quality Management							50750
			A	Definitions of Quality						50775
			B	Preanalytic Risks and Risk Mitigation						50800
				1	Selection of a laboratory service					50825
				2	Communication, Preanalytic					50850
			C	Analytic Risks and Risk Mitigation						50875
				1	Verification and Validation					50900
				2	Ongoing Quality Control					50925
				3	Communication, Analytic					50950
			D	Postanalytic Risks and Risk Mitigation						50975
				1	Communication, Postanalytic/Lab reports/Critical values					51000
				2	Interpretation					51025
					a	Reference Range Determinations				51050
					b	Other Interpretation, postanalytic risks/risk mitigation				51075
					c	Test Performance Characteristics, specificity, sensitivity, predictive value, etc.				51080
			E	Products Dispensed by Laboratories – Risks and Risk Mitigation						51100
			F	Oversight of Quality						51125
				1	Quality Assurance, Management, and Improvement					51150
				2	Process and Workflow Management					51175
				3	Management of non-conformances, exceptions, and incidents					51200
				4	Change Control					51225
				5	Guidelines					51250

	4	Human Resources										52250
		A	Employees									52275
				1	Job Descriptions							52300
				2	Hiring, termination							52325
				3	Initial Orientation and Training							52350
				4	Ongoing Education and Training							52375
				5	Competency and Performance Assessment							52400
				6	Other employees, HR, employees							52425
		B	Independent Contractors									52450
	5	Customers										52500
		A	Types of Customers									52525
		B	Customer Satisfaction									52550
		C	Marketing									52575
		D	Communication with Customers									52600
	6	Suppliers										52750
		A	Supplier Qualification									52775
		B	Types of Supplies									52800
				1	Analytical Equipment							52825
				2	Kits, Reagents, and Consumables							52850
				3	Blood and Blood Products							52875
				4	Other, Management, Supplies							52900
		C	Supplier Agreements									52925
		D	Inventory Management									52950
		E	Recalls									52975

	9	Laws and Regulations									54000		
		A	Laboratories and Testing								54025		
					1	CLIA					54050		
					2	CAP					54075		
					3	Proficiency Testing				54100			
					4	FDA Testing Regulations				54125			
					5	Regulation of Laboratory Financial Practices				54150			
					6	ISO 15189				54175			
					7	Public Health reporting				54200			
					8	Joint Commission				54225			
		B	Physician Relations (specific laws i.e. Stark and anti-kickback)								54250		
		C	Environmental and Worker Safety -OSHA								54275		
		D	Regulation of Information and Information Management (HIPAA)								54300		
		E	Employment Law								54325		
		F	Law pertaining to Charitable (non-profit) Organizations								54350		
		G	Other Bodies of Law and Regulation HPDB, OIG								54375		
		H	Tort Law (Malpractice)								54400		
	10	Professionalism and Ethics								54500			
		A	Medical Profession-Professionalism								54525		
					1	Autonomy				54550			
					2	Beneficence				54575			
					3	Integrity				54600			
					4	Non-Malfeasance				54625			
					5	Conflict of interest				54650			
					6	Informed Consent				54675			
					7	Confidentiality				54700			
					8	Justice				54725			
		B	Other Ethical Systems								54750		
					1	Biomedical Ethics				54775			
						a	Patient care				54800		
						b	IRB/Research/Belmont Report				54825		