

Lab Quality Confab

Accrediting Agencies Top Ten Deficiencies 2016

October 19, 2016



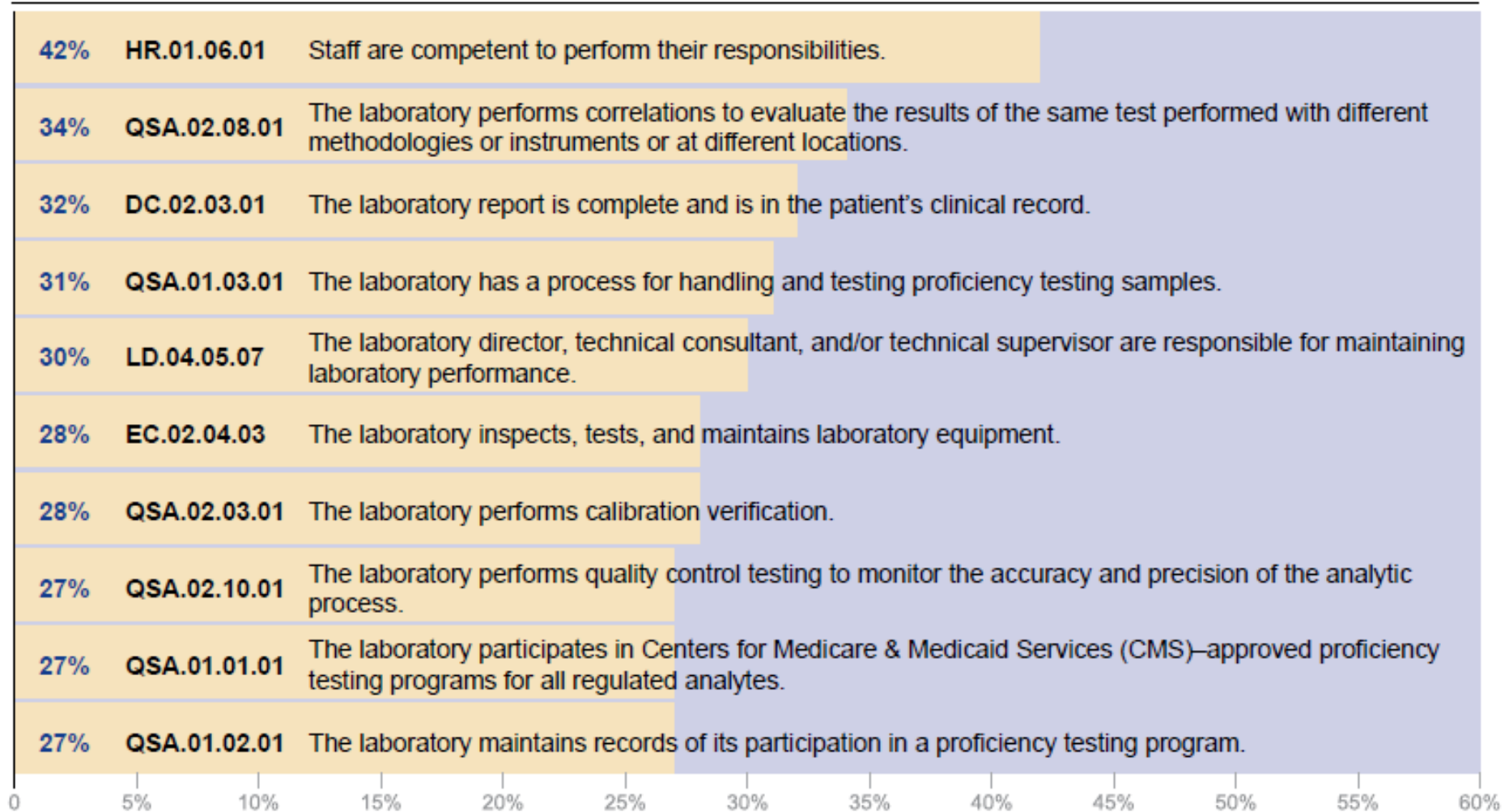
Nora L. Hess, MBA, MT(ASCP), Senior Consultant

	Item Number	Description
1	493.1252 b,d	Test systems reagent storage and monitoring
2	493.1255	Calibration, calibration verification and documentation
3	493.801	Enrollment and testing of PT
4	493.1235	Training and competency criteria and documentation
5	493.1291	Test report format policy and inclusion of all required elements
6	493.1105 (a)(3)(i)	2X per year method specification verification
7	493.1251(b)	Procedure Manuals
8	493.1253(b)1	Performance specifications comparable to manufacturer
9	493.1253(b)2	Performance specifications for modified test systems
10	493.1239(a-c)	Quality policies, documentation, corrective actions

	Item Number	Description
1	GEN.55500	Competency Records
2	COM.01200	Accurate Activity Menu
3	COM.10000	Procedure Manual
4	COM.04200	Instrument/Equipment Record Review
5	COM.10100	Procedure Manual Review
6	COM.30300	Reagent Labeling
7	COM.30600	Maintenance/function Checks
8	COM.01700	PT Evaluation
9	COM.01400	PT Attestation Statement
10	COM.40000	Method Validation and Verification

	Item Number	Description
1	PER 5	Lack of complete or current competency records
2	LDR 5	Lab Director not fulfilling responsibility for QC/QA
3	PT16	Lack of documented review of PT
4	LDR 4	Lab Director not fulfilling responsibility for PT
5	PER 4c	Technical Consultant or Technical Supervisor not fulfilling responsibilities
6	WAV 2	Waived testing QC not performed per manufacturer
7	QC 16	Lack of quantitative QC review using graphs or statistical tools
8	PER 4e	Testing staff not fulfilling responsibilities
9	CA 2	Lack of Calibration Verification
10	PT 4	Lack of 2X per year accuracy verification for unregulated analytes

TOP STANDARDS COMPLIANCE DATA FOR FIRST HALF OF 2016 LABORATORY AND POINT-OF-CARE TESTING



Note: The data determined for the laboratory program were derived from an average of 383 applicable surveys.