Quality System Assessment for Nonwaived Testing (QSA)

The table below lists the elements of performance (EPs) and correlated sample policies, procedures, protocols, or plans (P&Ps) included in *2023 PolicySource Laboratory and Point-of-Care Testing*.

For more information on written documentation requirements, refer to "Clarifying Required Documentation" in **Get Started** and the "Required Written Documentation" (RWD) chapter in the *CAMLAB* or its E-dition® counterpart. Check the *CAMLAB* or E-dition applicability in your setting or refer to the **Applicability Grid**.

Note: This table is accurate as of January 1, 2023.

Standard	EP	Description	Sample	Basis for Inclusion	What's New
QSA.01.03.01	1	Written policies and procedures for testing proficiency testing samples	Proficiency Testing Policy	EP requires written documentation	
QSA.02.01.01	6	Written quality control procedures for each testing system or methodology	Test, Method, and Instrument Quality Verification Policy	EP requires written documentation	
QSA.02.04.01	1	Written individualized quality control plan (IQCP) that includes a risk assessment, quality control plan, and quality assessment	Individualized Quality Control Plan	EP requires written documentation	
QSA.02.08.01	1	Written policy and procedures on correlations between analytes when they are tested using different methodologies or instruments at different locations	Analyte Correlation Performance Policy	EP requires written documentation	
QSA.02.11.01	1	Written policy and procedures for surveillance activities as part of quality control program	Individualized Quality Control Plan	EP requires written documentation	
			Surveillance Activities Policy		
QSA.02.12.01	1	Written policy and procedures for monitoring, assessing, and correcting problems in preanalytic, analytic, and postanalytic processes	Corrective Actions Policy	EP requires written documentation	
QSA.02.13.01	1	Written policy and procedures for storing, preparing, evaluating, and tracking reagents	Reagent Management Policy	EP requires written documentation	

Standard	EP	Description	Sample	Basis for Inclusion	What's New
QSA.04.06.01	1	Written policies and procedures to isolate and identify bacteria, mycobacteria, and fungi from potential sites of infection	Procedures to Identify Bacteria, Mycobacteria, and Fungi from Potential Infection Sites	EP requires written documentation	Added new policy
QSA.05.02.01	1	Written policy and procedures on maintaining minimum inventory of blood and blood components	Blood Product Inventory Management Policy	EPs require written documentation	
QSA.05.02.03	1	Written policies and procedures for obtaining blood or blood components in urgent or emergent situations			
QSA.05.03.03	1	Written policy and procedures for controlling transport, storage, and return of unused blood	Unused Blood Product Management Policy	EP requires written documentation	
QSA.05.04.03	2	Written policy and procedures describe response to activation of blood-storage alarms for refrigerators and freezers	Blood Bank Alarm Policy	EP requires written documentation	
QSA.05.06.01	1	Written policy and procedure on reagent activity testing	Reagent Reactivity Testing Policy	EP requires written documentation	
QSA.05.08.01	1	Written policy and procedures addressing donor and recipient blood testing for ABO blood group and Rh type	Donor and Recipient Blood Testing Policy	EPs require written documentation	
QSA.05.10.01	1	Written policy and procedures for identifying donor blood and recipient blood			
QSA.05.09.01	1	Written policy and procedures on compatibility testing of donor's blood with recipient's blood	Blood Compatibility Testing Policy	EP requires written documentation	
QSA.05.13.01	1	Written policies and procedures for the administration of Rh immune globulin	Perinatal Testing and Rh Immune Globulin Procedures	EP requires written documentation	
QSA.05.14.01	1	Policy and procedures for modification of blood and blood components	Blood Modification Policy	Recommended inclusion	
QSA.05.14.03	1	Written policy and procedures on processing of plasma products	Plasma Product Processing Policy	EP requires written documentation	

Standard	EP	Description	Sample	Basis for Inclusion	What's New
QSA.05.17.01	1	Written policy and procedures on blood transfusion–related activities	Blood Transfusion Policy	EP requires written documentation	
QSA.05.19.03	1	Written policies and procedures for investigating a suspected transfusion- related adverse event, including the protocol for a transfusion reaction workup	Procedures for Investigating Suspected Transfusion- Related Adverse Events	EP requires written documentation	
QSA.05.20.01	2	Written policy and procedures for notification of blood recipients of potential HIV infection	Potentially Infected Recipient Notification Policy	EP requires written documentation	
QSA.05.21.01	2	Written policy and procedures address notification of blood recipients of potential hepatitis C infection	Potentially Infected Recipient Notification Policy	EP requires written documentation	
QSA.06.03.03	1	Written quality control and testing procedures for maternal amniotic fluid alpha fetal protein (AFAFP)	Procedures for Maternal Amniotic Fluid Alpha Fetal Protein (AFAFP) Tests	EP requires written documentation	
QSA.06.04.05	1	Written quality control and testing procedures for mass spectrometry	Quality Control Procedures for Mass Spectrometry	EP requires written documentation	Added new policy
QSA.08.02.01	1	Written policy and procedures on cytology specimen collection, identification, preservation, transport, and evaluation	Cytology Specimen Collection Policy	EP requires written documentation	
QSA.08.03.01	1	Written quality improvement plan to measure, assess, and improve cytology services	Cytology Services Quality Improvement Plan	EP requires written documentation	
QSA.08.04.01	1	Written policy and procedures on cytology workload limits	Cytology Workload Limits Policy	EP requires written documentation	
QSA.09.01.01	1	Written policies and procedures for processing cytogenetic specimens	Cytogenetic Specimen Processing Procedures	EP requires written documentation	
QSA.09.03.01	2	Written quality control and testing procedures for conventional chromosomal analyses studies	Conventional Chromosomal Analyses Studies Policy	EP requires written documentation	
QSA.09.03.05	1	Written quality control and testing procedures for fluorescence in situ hybridization (FISH)	Procedures for Fluorescence in Situ Hybridization (FISH) Tests	EP requires written documentation	

Standard	EP	Description	Sample	Basis for Inclusion	What's New
QSA.10.01.01	1	Written procedures for each test performed that follow recommendations from the American Society for Reproductive Medicine (ASRM) for embryo transfer	Embryology Testing Procedures	EP requires written documentation	
QSA.10.02.01	1	Written procedures for method validation	Embryology Method Validation Policy	EP requires written documentation	
QSA.10.06.01	1	Written policy and procedures for receipt or transfer of cryopreserved specimens	Cryopreserved Embryology Specimen Policy	EP requires written documentation	
QSA.11.02.01	10	Written policies and procedures based on an approved clinical guideline to collect specimens for the performance of plasma- based coagulation assays	Procedures to Collect Specimens for Plasma-Based Coagulation Assays	EP requires written documentation	
QSA.12.04.01	1	Written procedures for histocompatibility testing	Histocompatibility Testing Procedures	EP requires written documentation	
QSA.13.05.01	1	Written policies and procedures addressing precautions related to radiation and electrical hazards of an electron microscope	Electron Microscope Use Policy	EP requires written documentation	
QSA.13.08.01	1	Written quality management plan that addresses documentation of verbal orders and reports; management of all consultation and peer case review; prevention of cross-contamination during grossing; criteria for adequacy of each surgical slide specimen; correlation with ancillary studies; authentication of interpretive surgical pathology reports; quality of the stains used; and periodic maintenance of equipment	Histopathology Laboratory Quality Management Plan	EPs require written documentation	

Standard	EP	Description	Sample	Basis for Inclusion	What's New
	2	Written policies and procedures for Mohs surgery that specify processing of Mohs frozen sections, reporting of each Mohs surgical procedure, and associated quality control procedures			
	3	Written policies and procedures for surveillance activities that include a review of the correlation of the intraoperative consultation with the final pathology diagnosis report			
QSA.15.01.01	1	Written policy and procedures for molecular testing	Molecular Testing Policy	EP requires written documentation	
QSA.17.01.01	1	Written procedures for calibrating and using the ocular micrometer for size measurements of ova and parasites	Ocular Micrometer Procedures	EP requires written documentation	