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QSE 7: Process Management

Policy	The laboratory documents and validates all processes in the pre-analytic, analytic, and post-analytic activities path of workflow.
Purpose	This policy provides direction for the processes and procedures necessary to ensure that testing procedures are correctly performed, the environment is suitable for reliable testing, testing methods work as expected to yield reliable results, and governmental and other regulations are met. It also provides direction to effectively manage the laboratory's processes such that all impacts of the changes on customers and other processes are considered and dealt with accordingly.
Responsibility	The Laboratory Director is responsible for ensuring process control is monitored for customer satisfaction. The Laboratory Supervisor is responsible for the development and validation of specimen handling processes. The Lead Technologists and Quality Manager are responsible for documenting and monitoring internal quality control.
Process Identification and Validation	The laboratory documents and validates all processes in the path of workflow prior to implementation.
Specimen Management	Specimen handling processes in pre-analytic, analytic, and post-analytic activities are designed and validated to ensure they work as intended.
Method Verification/Validation	All pre-analytic, analytic, and post-analytic activities utilize methods that have been verified or validated and have established and verified reportable ranges and reference intervals.
Internal Quality Control	Process and statistical measurements are made to identify random and special causes of process variations.
Supporting Documents	The following processes support this policy: • Process Identification and Validation • Specimen Management • Method Verification/Validation • Internal Quality Control

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Process for Process Identification and Validation

What Happens	Who's Responsible	Procedures
The laboratory identifies and documents all processes in the path of workflow and for each QSE	• Laboratory Supervisor • Lead Technologists • Quality Manager	• Process Identification, Documentation, and Validation • Specimen Tracking and Handling • Test-Specific SOPs
The laboratory performs validation of all processes prior to implementation to ensure that they work as intended	• Laboratory Director • Laboratory Supervisor • Lead Technologists • Quality Manager	• Process Identification, Documentation, and Validation • Specimen Tracking and Handling • Test-Specific SOPs
The laboratory identifies and documents any problems or deficiencies in the processes based on validation activities	• Laboratory Director • Laboratory Supervisor • Lead Technologists • Quality Manager	• Process Identification, Documentation, and Validation • Specimen Tracking and Handling • Test-Specific SOPs
The laboratory revises any processes as necessary to correct problems or deficiencies	• Laboratory Supervisor • Lead Technologists • Quality Manager	• Process Identification, Documentation, and Validation • Specimen Tracking and Handling • Test-Specific SOPs

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Process for Specimen Management

What Happens	Who's Responsible	Procedures
The laboratory establishes written policies and procedures for specimen submission, handling, and referral	• Laboratory Supervisor • Lead Technologists • Laboratory Director	• Specimen Tracking and Handling
The laboratory receives a written or electronic request for patient testing from an authorized person	• Patient Physicians • Specimen Processors	• Specimen Tracking and Handling
The laboratory ensures the specimens meet established written requirements	• Specimen Processors	• Specimen Tracking and Handling • Test-Specific SOPs
Specimens are processed and stored prior to testing procedures	• Specimen Processors • Technicians/Technologist	• Specimen Tracking and Handling • Test-Specific SOPs
Specimens are tested following analyte-specific SOPs	• Technicians/Technologist	• Specimen Tracking and Handling • Test-Specific SOPs
Specimens are stored after testing	• Technicians/Technologist	• Specimen Tracking and Handling • Test-Specific SOPs
The laboratory establishes and follows written policies and procedures for ongoing mechanisms to monitor, assess, and correct problems identified in specimen management	• Quality Manager • Laboratory Manager • Lead Technologists • Technicians/Technologist	• Specimen Tracking and Handling • Test-Specific SOPs • Quality Management

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Process for Method Verification/Validation, Reportable Ranges, and Reference Intervals

What Happens	Who's Responsible	Procedures
The laboratory verifies/validates all methodology prior to implementing testing	• Laboratory Supervisor • Quality Manager • Technicians/Technologists • Laboratory Director	• Verification/Validation Procedures • Test-Specific SOPs
The laboratory establishes/verifies reportable ranges and biological reference intervals prior to implementing testing	• Laboratory Supervisor • Quality Manager • Technicians/Technologists • Laboratory Director	• Establishing Reportable Ranges • Establishing Reference Intervals • Test-Specific SOPs

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Process for Internal Quality Control

What Happens	Who's Responsible	Procedures
Internal Quality Control Policy is established	• Laboratory Director • Quality Manager	• Laboratory Quality Control
Control materials are selected and obtained for all analytic procedures	• Lead Technologist • Quality Manager • Purchasing Department	• Laboratory Quality Control • Test-Specific SOPs • Hospital Purchasing Department Policies and Procedures • Inventory of Reagents
Control materials are stored for all analytic procedures	• Lead Technologist • Laboratory Supply Manger	• Inventory of Reagents • Test-Specific SOPs
Control materials are tested and results documented as described in Test-Specific SOPs	• Lead Technologist • Quality Manager	• Test-Specific SOPs • Laboratory Quality Control
Quantitative Control values are monitored for acceptability following pre-established acceptability criteria (such as Westgard rules where applicable)	• Quality Manager • Lead Technologist • Technicians/Technologists • Laboratory Supervisor	• Laboratory Quality Control • Test-Specific SOPs
Qualitative Control values are monitored for acceptability following pre-established acceptability criteria	• Quality Manager • Lead Technologist • Technicians/Technologists • Laboratory Supervisor	• Laboratory Quality Control • Test-Specific SOPs
Corrective actions are completed and documented for all QC failures	• Quality Manager • Lead Technologist • Laboratory Supervisor • Technicians/Technologists	• Laboratory Quality Control • Test-Specific SOPs • Corrective Action Logs
QC issues are discussed at monthly Quality Assurance Meetings	• Laboratory Director • Quality Manager • Quality Management Team	• Laboratory Quality Control • Quality Management