12 QUALITY SYSTEM ESSENTIALS

Area	Elements	Current Processes
1. Organization and Leadership	• Scope of Service • Reporting Structure • Mission, Vision, Value • Leadership Review • Resources	• Laboratory Administration policies and procedures detail scope of service, signature authorizations and laboratory organization. • A current organization chart is maintained by Laboratory Compliance and available to laboratory staff. • Laboratory leaders serve on various hospital committees. A list is maintained by Laboratory Compliance.
2. Facilities and Safety	• Structure and Utilities • Environmental Conditions • Communications • Safety Programs • Emergency Management	• Safety policies and procedures are annually reviewed by laboratory staff. • An active laboratory safety program exists that includes a safety committee, safety training, and safety walkthroughs. • Laboratory is involved in the Environment of Care Committee and Emergency Preparedness meetings.
3. Personnel	• Staff Qualifications • Job Description • Orientation and Training • Competency • Continuing Education	• A comprehensive personnel file is maintained on all laboratory employees - documentation includes signed job description, proof of education, orientation, training, and competency assessment. • Detailed policies and templates are utilized for competency assessment and training. • Various continuing education opportunities are held throughout the year. Each laboratory employee is required to obtain CE each year.
4. Purchasing and Inventory	• Critical Materials and Services • Supplier Qualification • Supplier/Customer Agreements • Inventory Management • Market Recall	• Contracts are maintained for various suppliers – including the Red Cross and top outreach sources. • Laboratory staff carefully monitors budgets and ordering processes. • Laboratory staff responds to RASMAS alerts as needed, and the quality committee discusses important recalls and alerts.
5. Equipment	• Selection and Acquisition • Equipment Qualification • Operations and Calibration • Maintenance and Repairs	• Equipment purchases undergo a thorough evaluation process, as well as a bid process. • An accurate list of equipment is maintained for regulatory purposes. • All equipment is calibrated and methodically maintained according to laboratory regulations and manufacturers standards. • Laboratory collaborates with Clinical Engineering on ensuring documentation of preventative maintenance, which is also presented to the EOC committee.
6. Process Management	• Process Design and Development • Validation • Performance • Quality Control • Change Control	• Each laboratory follows a strict quality control plan which includes schedules, acceptable limits and corrective actions. • A method validation policy and checklist is followed for instrument validation.

Area	Elements	Current Processes
7. Documents and Records	• Document Creation • Use and Maintenance • Annual Review • Document Control • Record Quality and Review • Retention, Storage and Retrieval	• An electronic system is utilized for control of all laboratory documents, including policies, procedures and forms. All documents undergo an approval process by the laboratory medical director and division directors, and then are acknowledged by applicable laboratory staff. • The Laboratory follows a record retention policy that meets regulatory and hospital standards.
8. Information Management	• Training and Reference Guides • Software • Interface Testing	• The laboratory Information System actively maintains all software and operating system. All interfaces are thoroughly evaluated initially and tested yearly. • The laboratory training process includes guides, checklists, tests and worksheets.
9. Event Management	• Detection, Documentation and Investigation • Categorization and Analysis • External Notification • Product/Result Recall/Correction	• The laboratory participates in the hospital event reporting system and responds to applicable events. • Services Occurrence Reports and other mechanisms are used to document and investigate nonconforming events. • Notices are provided to external clients regarding change in testing.
10. Monitoring and Assessment	• Quality Indicators • Internal Audit Program • External Inspections/Assessments • Proficiency Testing • Quality Reporting	• Each laboratory monitors quality indicators, which are reviewed by the division directors and quality committee. • A laboratory scorecard is reported to hospital quality. • The laboratory participates in a comprehensive proficiency testing program. • The laboratory is accredited by the College of American Pathologists, a biennial inspection process. • The laboratory maintains continual survey readiness, through tracers, walkthroughs, monthly meetings, annotating checklists, etc.
11. Service and Satisfaction	• Needs Assessments • Customer Comments • Consultation • Complaint Resolution	• The laboratory investigates and responds to customer complaints through the Event Reporting System. • Customer Patient Satisfaction Cards are tracked and enumerated for each phlebotomy site. • Physician satisfaction is included on the biennial hospital survey. • URL Satisfaction is surveyed each year.
12. Continual Improvement	• Data Analysis • Identification of Opportunities for Improvement • Quality Management Tools • Process Improvement	• Each laboratory compiles monthly quality data and investigates metrics not meeting thresholds. • Annual quality reports list quality improvement initiatives.

QUALITY INDICATORS

Common Indicators

Critical Value Documentation
Ordering Process - Requisition Review
Proficiency Testing
Quality Control
Met Turnaround Time Expectations

Other Quality Mechanisms

- Customer Service Satisfaction
- Personnel File Audits
- Survey Readiness Tracers
- Event Reporting
- Medical Chart Reviews
- Internal Audits
- Unacceptable Specimen Tracking
- Policies and Procedure Audits

Classifications of Quality Improvement Indicators

All phases of testing are covered throughout the clinical laboratory system – preanalytic, analytic and postanalytic stages

- *Preanalytic performance indicators include:*
  - Requisition Verification
  - Unacceptable Specimens
  - Slide preparation
  - Transcription Errors

- *Analytic performance indicators include:*
  - Proficiency Testing
  - Turnaround Times
  - Quality Control documentation

- *Postanalytic performance indicators include:*
  - Critical Value Documentation
  - Corrected Reports
  - Managing Slide inventory
  - Managing specimen requests

Proficiency testing results

The laboratories participate in a wide variety of proficiency testing to ensure the accuracy of test results. We also conduct alternate assessments of performance to ensure the accuracy and reliability of patient testing when inter laboratory comparison is not available — or additional quality monitoring is desired. We comply with the regulations set forth in Clinical Laboratory Improvement Amendments (CLIA-88).

Assessment of data

Statistical methods such as charts, graphs, confidence intervals, and trend analysis are used to identify undesirable variance, trends, and opportunities for improvement. Regulatory standards, external benchmarks, clinical significance, and/or accepted standards of care are used to establish goals and targets. Annual goals are established as a means to evaluate performance.