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Laboratory Quality Policy

Document Type: Policy

I. PURPOSE AND OBJECTIVE:

This document outlines the laboratory quality program.

II. POLICY STATEMENT:

The laboratories at Corewell Health East are dedicated to quality. A department quality system program has been established to provide the highest possible standard of laboratory services. This quality program is not meant to supersede lab section or hospital quality programs but is intended to enhance these programs.

III. ORGANIZATION:

A. The laboratory has defined the responsibility, authority and inter-relationships of staff who manage, perform, or verify work-affecting quality.

B. The ultimate goal is to deliver the highest possible standard of laboratory services within the resources of the laboratory, and in accordance with the College of American Pathologists (CAP) standards. High quality laboratory services are achieved by:

1. Providing maximum laboratory accuracy.
2. Providing expedient reporting of test results,
3. Detecting and preventing errors in operational processes,
4. Reducing process variations that can cause errors,
5. Improving effectiveness and efficiency of processes,

6. Staffing adequate numbers of qualified employees,
7. Providing appropriate employee training programs,
8. Developing and maintaining a competent staff,
9. Responding to patient/clinical staff needs in provision of services,
10. Securing effective communications with clinical / nursing staff, and
11. Complying with all required regulations and accreditation standards.

C. Laboratory management support of the quality system

1. Laboratory site Medical Directors, section Medical Directors, Operations Directors, Managers, Supervisors, Medical Technologist Leads, and Operations Specialist are responsible to verify quality system standards are implemented and maintained.

D. Approval, revision, review, and maintenance of the laboratory Quality Manuals

1. Quality manuals contain various documents that describe and support the laboratory quality program. These documents are reviewed and approved by the site Medical Director or designee, at least, biennially. Site Operations Specialists are responsible to maintain these manuals.
2. The site Medical Director or designee is responsible for periodic review of the quality program for appropriateness and effectiveness.

IV. PERSONNEL:

The laboratory employs adequate number of qualified individuals who have the education, training and experience necessary to perform assigned tasks in a quality manner as defined in job descriptions.

A. Employee Qualifications, Job Descriptions, and Scheduling

1. Staff meets minimum education and training requirements defined by the organization and the laboratory.
2. Job descriptions are written and maintained by laboratory management.
3. Staffing plans (schedules) are maintained by each lab section.
4. Refer to Laboratory Education - Testing Personnel Credential Verification.

B. Job Orientation

1. New employees are provided orientation to Corewell Health, the laboratory, and to their assigned laboratory section.
2. Refer to:
    a. Laboratory Education - New Hire Orientation
    b. Color-Blindness Testing for Laboratory Employees

C. Training and Training Verification

1. The assigned lab section provides training. Training is specific to assigned tasks and includes Safety, Computer (Laboratory Information Systems/Health Information Systems), Quality, Technical, and other skills as needed.

2. Staff development is provided to meet laboratory needs, individual needs, regulatory and accreditation requirements, and the changing needs of the hospital.
3. Training is considered adequate when the individual demonstrates sufficient knowledge and skills to effectively perform the assigned job tasks.
4. Training records are maintained by the assigned lab section, per defined retention guidelines.
5. Refer to:
    a. Laboratory Education - Employee Training
    b. EPIC Beaker Training and Security Access
    c. Laboratory Department-Specific Education Program

D. Assessment of Competence
1. Acceptable work performance criteria are determined by section managers
2. New employee competence is assessed throughout job training.
3. All staff participates in an ongoing, section specific, competency program
4. Section management staff identifies retraining needs.
5. Competency is evaluated as part of annual performance appraisal.
6. Section management staff maintains documentation of competency assessments.
7. Prior to starting patient testing and prior to reporting patient results for new methods or instruments, each individual must have training and be evaluated for proper test performance. During the first year of an individual's duties, competency must be assessed at least semiannually. After an individual has performed his/her duties for one year, competency must be assessed annually. Retraining and reassessment of competency must also occur when problems are identified with an individual's performance. [A]
8. Refer to Laboratory Education - Employee Competency Assessment.

E. Continuing Education (CE)
1. Participation in educational classes, professional meetings, teleconferences and seminars is encouraged.
2. A minimum annual continuing education requirement is established for this laboratory. A laboratory Continuing Medical Laboratory Education form is provided for use in documenting each employee's annual CE.
3. Refer to Laboratory Education - Continuing Medical Laboratory Education (CMLE).

F. Performance Appraisal
1. A performance review based on job responsibilities, objective measures, and pre-defined standards, is completed for each employee. Time lines of these reviews is defined by Corewell Health Human Resources.
2. Refer to the system-wide policy Performance and Development.

G. Trainer Qualifications

1. Select individuals, who satisfy criteria set by section leadership, qualify to function as lab section trainers.

V. EQUIPMENT:

A. Selection and Installation

1. Individual lab sections (Medical, Technical Directors) set acceptable criteria for the selection of new equipment and determine if the supplier meets those specifications.
2. The supplier may take an active role in the installation process, to include training.
3. Refer to Medical Equipment Management Program: Incoming Equipment.

B. Validation and Calibration

1. The laboratory verifies the performance of all instruments and equipment prior to initial use, after major maintenance or service, and after relocation to ensure that they run according to expectations.
2. All measurement devices, new or repaired, are calibrated according to operating procedures written in accordance with manufacturer's recommendations, regulatory requirements, and accreditation standards.
3. The laboratory completes validation (method comparison study, precision study, analytic sensitivity, analytical specificity, interferences, Analytical Measurement Range (AMR), with director approval) studies prior to implementing the use of new equipment.
4. The reportable range (analytic measurement range) is verified/established for each analytic procedure before implementation.
5. Biomedical staff and the lab section maintain records of equipment identity, results of scheduled calibrations, actions taken, and final disposition.

C. Preventive Maintenance

1. Manufacturers' recommendations, regulatory requirements, accreditation standards, and lab section policy are used in determining preventive maintenance needs/schedules.
2. Documentation of maintenance is maintained by the lab section or by Biomedical staff. This includes findings, actions, and follow-up activities.

D. Defective Equipment

1. Defective equipment is identified and removed from service. It is either repaired or replaced, as is determined by inspection.

VI. PURCHASING AND INVENTORY:

A. Qualifying Equipment, Supplies, and Services

1. Each lab section is responsible to define characteristics or functional requirements

for equipment, supplies, or services for that section.

B. Contract Review and Approved Supplier List

1. Where applicable, agreements to obtain products and/or services are reviewed by hospital Purchasing, Value Analysis Team (VATS) committee and by the section management staff to identify that each party's expectations are defined and agreed upon.
2. The Purchasing and/or the lab section manager maintain a list of suppliers.
3. Refer to Policy for Purchasing Sponsored Programs Supplies, Equipment or Services.

C. Receipt, Inspection, Testing, Documentation, Storage of Incoming Supplies

1. Each lab section has a process to receive, inspect, test (where required), and properly store incoming supplies at the proper temperatures as specified by the manufacturer's recommendation.
2. All reagents (chemicals, stains, controls, media, antibodies, test strips, testing cartridges, etc.) are used within their indicated expiration date. If the reagent does not have an expiration date indicated by the manufacturer, the laboratory will assign an expiration date based on known stability, frequency of use, storage conditions and risk of deterioration.

D. Refer to Laboratory Procedure for the Management of Vendor Notifications of Defects/ Issues for product recalls/issues.

VII. PROCESS CONTROL:

Process control measures include:

A. Each lab section has developed standard operating procedures. These procedures include, but not limited to, the following:

1. Principle and clinical significance
2. Requirements for patient preparation; specimen collection, labeling, handling storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection
3. Microscopic examination, including the detection of inadequately prepared slides
4. Step-by-step performance of the procedure, including test calculations and interpretation of results
5. Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing
6. Calibration and calibration verification procedures
7. The analytic measurement range for test results for the test system, if applicable
8. Control procedures
9. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability

10. Limitations in the test methodology, including interfering substances
11. Reference intervals (normal values)
12. Imminently life-threatening (critical) test results
13. Pertinent literature references
14. The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the procedure for reporting imminently life-threatening (critical) results
15. Description of the course of action to take if a test system becomes inoperable

B. Specimen Collection, Processing and Transport
    1. Specimen collection manuals are available for the proper collection, processing and transport of specimens, including any special instructions for patient preparation or specimen handling.
    2. Refer to the Lab Test Directory.

C. Maintenance of equipment and facilities
    1. Each lab section has an established process to verify proper functioning of equipment and a safe and adequate work environment.

D. Process validation for new or changed processes or procedures
    1. Each section is responsible to monitor processes perform as intended.
    2. Validation or revalidation is done if process changes occur that may affect the outcome of a process, or as defined by accrediting bodies.
    3. Retrospective validation is performed for well-established processes using historical data, when appropriate.

E. Preparation of quality assurance reports used to monitor and control processes
    1. Operational system quality monitors are established and used to capture information for numerical data analysis.
    2. Quality assurance metrics are presented at regularly scheduled laboratory meetings.

F. Proficiency testing (PT), training, and competency assessment
    1. Proficiency testing is used to measure and compare testing systems with outcomes of testing performed by other laboratory peers.
    2. Each lab section participates in proficiency testing programs (as mandated by the College of American Pathologists [CAP]) appropriate for its level of testing.
    3. The PT program includes designation of testing personnel, frequency of challenges, routine review, and documented corrective action.
    4. Each lab section provides training and competence assessment for testing staff.

G. Quality Control (QC)
    1. Each lab section has established processes and schedules for QC testing.

H. Internal and external operational and quality system assessments

1. Each lab section participates in both internal and external assessments of laboratory quality.

VIII. INFORMATION MANAGEMENT:

A. Corewell Health Information Technology (IT) provides the laboratory with Laboratory Information System (LIS) staff and other technical support persons for all computer-related activities.

B. Patient Report Elements

1. The paper and/or the electronic report includes the following elements:

a. Name and address of testing laboratory (see note below)

b. Patient name and identification number, or unique patient identifier and identification number

c. Name of physician of record, or legally authorized person ordering test, as appropriate

d. Name of the test(s) performed

e. Date of specimen collection, and if appropriate, time of collection

f. Date of release of report (if not on the report, this information should be readily accessible)

g. Time of release of report, if applicable (if not on the report, this information should be readily accessible)

h. Specimen source, when applicable

i. Test result(s) and units of measurement, when applicable

j. Reference intervals, as applicable

k. Conditions of specimen that may limit adequacy of testing

IX. DOCUMENTS AND RECORDS:

A. Document Control

1. Each section follows standard laboratory procedure to ensure that new and substantially revised procedures are approved by the site Medical Director and that all operating procedures are reviewed by the section Medical Director or designee, at least biennially.

B. Records Management: Generating, reviewing, retaining, and retrieving records

1. Records are retained according to regulatory requirements, accreditation standards, and internal specifications.

2. Records are stored in a manner that maintains integrity and facilities retrieval.

C. Refer to Laboratory Document Management and Record Retention Procedure.

X. OCCURRENCE MANAGEMENT:

A. Occurrence reporting, classification, tracking-and trending, and analysis

1. The laboratory uses the hospital on-line RL Solutions Event Report Summary (ERS) system to document and investigate Specimen and Laboratory-related events. A formal Root Cause Analysis is performed for all Sentinel Event occurrences.
2. Internal variances may also be used to document and track unexpected events associated with certain sub-processes.
3. SOFT Express is also used for occurrence reporting. It is primarily used for Outreach reporting.

B. Tracking and Trending

1. The laboratory and Blood Bank Process Owners maintain databases for ERS reports related to their respective areas.

C. Hospital management review

1. General lab and Blood Bank monthly ERS Summary Reports are completed by site Process Owners and shared with laboratory leadership.

D. Refer to:

1. Procedure for Laboratory Employees to Communicate Concerns Regarding Test Quality and Laboratory Safety
2. Laboratory RL Solutions Quality/Safety Reports

XI. ASSESSMENTS:

A. External and internal assessments

1. The laboratory is routinely inspected by the CAP biennially. In alternate years, the laboratory performs a formal self-inspection, with those results being sent to the CAP.
2. In addition to the CAP, the Royal Oak, Troy and Grosse Pointe Blood Bank departments are also inspected by the American Association for Blood Banks (AABB).
3. Assessment findings are addressed by section leadership and actions taken are reviewed for appropriateness by section Medical Director.

XII. PROCESS IMPROVEMENT:

A. The following activities serve as a source of ideas for process improvements:

1. External regulatory and accreditation assessment findings
2. The findings from operational system quality monitors and internal quality audits and assessments
3. Reports of patient and clinical staff complaints

4. Analysis of ESR reports
5. Review of any selected process to determine if the process can be made more efficient and effective
6. Staff, manager, director recommendations

B. Corewell Health embraces a Just Culture system approach to assessing problems and reviewing incidents. Additionally, incident review/follow-up includes:
    1. Identification, prioritization, and selection of problems to be resolved,
    2. Staff training in process improvement procedures,
    3. Use of data collection and data analysis tools,
    4. Implementation of process changes, where appropriate,
    5. Review of applied solutions for effectiveness in solving the problem, and
    6. Periodic reporting and follow-up monitoring.

XIII. SERVICE AND SATISFACTION:

A. Corewell Health has established service standards for all patient care areas and support departments. The laboratory accepts and implements these standards.

B. Satisfaction surveys are conducted by the laboratory and by the hospitals on a periodic basis. These survey outcomes are reviewed by laboratory leadership, and the necessary action plans developed and implemented.

XIV. FACILITIES AND SAFETY:

A. As part of the Corewell Health and the laboratory safety management programs, laboratory staff is provided with on-line procedures and training programs that focus on general safety issues, Health Insurance Portability and Accountability Act (HIPAA), chemical hygiene plan, standard precautions, emergency / disaster plan, (non-inclusive list).

B. Each lab section works to provide the safest environmental working conditions.

XV. REFERENCES:

A. Lab General Checklist, College of American Pathologists, Northfield, IL, current version.

B. All Common Checklist, College of American Pathologists, Northfield, IL, current version.

C. CLSI, Quality Management System: Leadership and Management Roles and Responsibilities, Approved Document, QM 14-A, Wayne, PA, Jan 25, 2013.

D. A Model Quality System for Transfusion Services, American Association of Blood Banks, Transfusion Service Quality Assurance Committee, Bethesda, Maryland, 1997.

E. Laboratory Quality Assurance Plan

F. Laboratory Annual Safety Assessments

Approval Signatures

Step Description	Approver	Date
CLIA Site Licensed Medical Directors	Muhammad Arshad: Chief, Pathology	9/27/2024
CLIA Site Licensed Medical Directors	Ann Marie Blenc: System Med Dir, Hematopath	9/26/2024
CLIA Site Licensed Medical Directors	Jeremy Powers: Chief, Pathology	9/26/2024
CLIA Site Licensed Medical Directors	Hassan Kanaan: OUWB Clinical Faculty	9/23/2024
CLIA Site Licensed Medical Directors	Ryan Johnson: OUWB Clinical Faculty	9/16/2024
CLIA Site Licensed Medical Directors	Subhashree Mallika Krishnan: Staff Physician	9/16/2024
CLIA Site Licensed Medical Directors	Masood Siddiqui: Staff Pathologist	9/16/2024
CLIA Site Licensed Medical Directors	John Pui: Chief, Pathology	9/16/2024
CLIA Site Licensed Medical Directors	Kurt Bernacki: System Med Dir, Surgical Path	9/16/2024
Policy and Forms Steering Committee Approval (if needed)	Michele Sedlak: Lab Quality Coord	9/16/2024
	Sarah Britton: VP, Laboratory Svcs	9/9/2024
Operations Directors	Joan Wehby: Dir, Lab Services	9/3/2024
Operations Directors	Brittnie Berger: Dir Sr, Lab Operations	8/14/2024
Operations Directors	Amy Knaus: Dir, Pathology Service Line	8/9/2024
Operations Directors	Christopher Ferguson: Dir, Lab Services	8/9/2024
Operations Directors	Elzbieta Wystepek: Dir, Lab Services	8/8/2024
	Michele Sedlak: Lab Quality Coord	8/8/2024

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne