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Laboratory Operations and Administration Delegated Responsibility

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

To define delegated responsibilities to approved laboratory staff by the Lab Medical Directors for Dearborn, Taylor, Trenton, and Wayne Labs. List qualifications and responsibilities of Section Director (Technical Supervisor) and Supervisors/general supervisors.

II. FREQUENCY OF ON-SITE VISITS:

If the activities of the medical director are routinely conducted remotely they will make periodic on-site visits at a minimum frequency of:

A. Dearborn, Taylor, Trenton, and Wayne - once per month.

B. Canton - once per quarter.

III. DIRECTOR RESPONSIBILITY - DELEGATION OF FUNCTIONS

The College of American Pathologists (CAP) requires that if specific laboratory director functions or responsibilities are delegated, the delegation is in writing (by name or job title) and the director ensures that the functions or responsibilities are properly performed by a qualified individual.

A. **Examples of functions that may be delegated include the following:**

1. Review of Quality Assurance (QA), Proficiency Testing (PT) performance, competency assessment, and test methodology performance studies.

B. **Functions that may NOT be delegated include the following:**

1. Provision of appropriately trained supervisory and technical staff and the identification of their

responsibilities.

2. Personal on-site assessment of physical and environmental conditions and the adequacy of staffing on a periodic basis, as defined in written policy.
3. Approval of new technical policies and procedures, as well as substantial changes to existing documents.
4. Approval of individualized Quality control plans (IQCP)

C. For CLIA required roles not performed by the director,, the director delegates those responsibilities to qualified individuals. The responsibilities and duties of supervisors, consultants and testing personnel involved in pre-analytic, analytic, and post-analytic phases of testing must be defined in writing, with records of authorization to perform testing, and the level of supervision required, as applicable.

IV. DELEGATED RESPONSIBILITIES:

A. Ensure testing systems needed for analytic and post-analytic phases are performed properly.

B. Ensure the physical area is appropriate for testing, the environment is safe for employees, and is in compliance with good practice and applicable regulations.

C. Ensure verification procedures for test methodologies are adequate to determine accuracy, precision and other pertinent performance characteristics.

D. Ensure laboratory personnel are performing the test methods as required for accurate and reliable results.

E. Ensure that the laboratory is enrolled in appropriate proficiency testing program.

F. Ensure that the quality control and quality assessment programs are established and maintained, and failures in quality are identified.

G. Ensure the establishment and maintenance of acceptable levels of analytic performance for each test.

H. Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratories establish performance specifications are identified.

I. Ensure test results are reported only when testing systems are functioning properly.

J. Ensure that reports of test results include pertinent information required for interpretation.

K. Ensure that consultation is available to the laboratory's clients on the matter of quality and the test results reported and their interpretation.

L. Employ sufficient number of personnel, appropriate education and experience to properly supervise and accurately perform tests and report tests results.

M. Ensure that prior to testing patient specimens, all personnel have appropriate education and experience commensurate with the type and complexity of testing they perform.

N. Prior to testing patient samples, ensure that all personnel receive adequate training for the type and complexity of services to be performed by those personnel.

O. Ensure that policies and procedures are established and signed by authorized personnel for monitoring individuals who conduct pre-analytic, analytic, and post-analytic phases of testing to assure competency.

P. Ensure that an approved procedure manual is available to all testing personnel.

Q. Specify in writing the responsibilities and duties of each person engaged in the performance of pre-analytic, analytic, and post-analytic phases of testing.

R. Ensure proper selection of laboratory equipment and supplies.

V. DESIGNEES:

A. Per College of American Pathologists (CAP) guidelines for high complexity testing, designees may be appointed by the Technical Supervisor to an individual meeting the qualifications of a General Supervisor for the following:

1. Review and provide an authorizing signature for various documents. These documents and items may include, but are not limited to policies, procedures, quality control documents, quality assurance documents, personnel review and competency records, etc.
2. Assuring remedial actions are taken when test systems deviate from the laboratory's established performance specifications.
3. Training and orientation of testing personnel.
4. Competency assessment of testing personnel.

B. **Procedures/Policies/Workflows** Technical includes Phlebotomy, Quality Systems, and Training/ Education as appropriate. Non-technical includes Outreach, Administrative and Employee-related; Training/Education as appropriate.

Approver/Designee

Document Type	New/ Substantially Revised	Review at Least Every 2 Years	Minor Revisions
Technical	By Site	By Site Department	By Site Department
	Laboratory Medical Director	Site Lab Medical Director or Manager/Supervisor	Manager/Supervisor, Coordinator, Operations Specialist or Medical Technologist Lead
Non-Technical	By Site	By Site Department	By Site Department
	Site Operations Director	Manager/Supervisor	Manager/Supervisor, Coordinator, Operations Specialist or Medical Technologist Lead

C. **Monthly Review of Instrument Maintenance, Internal Reference Guides, Forms**
Technical and Non-technical: Manager/Supervisor/Coordinator/Medical Technologist Lead

D. **Forms, Internal Reference Guides**
Technical and Non-technical: By site department Manager/Supervisor/Coordinator/Medical Technologist Lead/Operations Specialist (as indicated by site title)

E. **Personnel Training/Competency Records**
Technical and Non-technical: Manager/Supervisor/Coordinator/Medical Technologist Lead

DEARBORN LAB DESIGNEE CHART

Laboratory Section	Medical Director	Designee	Alternate Designee
Laboratory Administration	Site Lab Medical Director	Operations Director	Operations Specialist
Transfusion Medicine	Blood Bank Site Lab	BB Supervisor	BB Medical

Laboratory Section	Medical Director	Designee	Alternate Designee
	Medical Director, Site Lab Medical Director		Technologist Lead
Chemistry	Site Lab Medical Director	Chemistry Supervisor	Chemistry Medical Technologist Lead
Point of Care (POC)	Site Lab Medical Director	Chemistry Supervisor	POC Medical Technologist Lead
Hematology/Coagulation/ Urinalysis	Site Lab Medical Director	Hematology Supervisor	Hematology Medical Technologist Lead
Surgical Pathology/ Cytology Processing	Site Lab Medical Director	Anatomic Pathology (AP) Coordinator	Pathologist Assistant Designate
Phlebotomy	Site Lab Medical Director	Phlebotomy Manager	Laboratory Support Tech Lead
Specimen Processing	Site Lab Medical Director	Specimen Processing Manager	Laboratory Support Tech Lead

Taylor, Trenton, Wayne/Canton Designee Chart

Laboratory Section	Medical Director	Designee	Alternate Designee
Lab Administration	Site Lab Medical Director	Operations Director	Operations Specialist
Chemistry/Toxicology	Site Lab Medical Director	Site Laboratory Manager	Chemistry Medical Technologist Lead
Hematology/Coagulation/ Urinalysis	Site Lab Medical Director	Site Laboratory Manager	Hematology Medical Technologist Lead
Microbiology	Site Lab Medical Director	Site Laboratory Manager	Medical Technologist Lead
Phlebotomy/Processing/ Outpatient Lab	Site Lab Medical Director	Processing/Phlebotomy Supervisor	Laboratory Support Tech Lead
Point of Care	Site Lab Medical Director	POC Medical Technologist Lead	Medical Technologist
Quality/Safety	Site Lab Medical Director	Operations Specialist	Operations Director
Transfusion Medicine	Site Lab Medical Director	BB Medical Technologist Lead	Blood Bank Supervisor
Surgical Pathology/Cytology Processing	Site Lab Medical Director	Lab Processing Supervisor	AP Coordinator

F. The designee's skills and competency will be assessed annually. See the attached Delegated Duties Annual Assessment Checklist.

G. See the following procedures with delegated attachments:

1. Laboratory Proficiency Testing

2. Laboratory Policy/Procedure and Quality Review and Approval

VI. SECTION DIRECTOR (TECHNICAL SUPERVISOR) QUALIFICATIONS AND RESPONSIBILITIES:

For high complexity testing, one or more individuals qualified as a technical supervisor must be identified on the CAP's Laboratory Personnel Evaluation Roster.

A. The Technical Supervisor must meet the following requirements:

1. MD or DO licensed to practice (if required) in the jurisdiction where the laboratory is located with certification in anatomic pathology or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications equivalent to those required for certification.
    a. If responsible for anatomic pathology or cytopathology must be board certified in anatomic pathology or possess equivalent qualifications
    b. If responsible for clinical pathology must be board certified in clinical pathology or possess equivalent qualifications
    c. If responsible for anatomic pathology and/or cytopathology, and clinical pathology, must be board certified in both anatomic and clinical pathology or possess equivalent qualifications OR
2. For specialties other than Anatomic Pathology and Cytopathology, an individual will meet the qualifications of a technical supervisor providing the following qualifications are met:
    a. MD or DO licensed to practice (if required) in the jurisdiction where the laboratory is located with at least one year of training and/or experience in high-complexity testing*; or
    b. Doctoral degree in chemical, physical, biological or clinical laboratory science from an accredited institution with at least one year of laboratory training and/or experience in high complexity testing*; or
    c. Master's degree in a chemical, physical, biological, or clinical laboratory science or medical technology from an accredited institution with at least two years of laboratory training and/or experience in high complexity testing*; or
    d. Bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution with at least four years of laboratory training and/or experience in high complexity testing*.
    e. The technical supervisor's training and experience must be in the designated specialty or subspecialty area of service for which the individual is responsible.
    f. For laboratories subject to US regulations, alternate qualifications for the following specialty areas can be found in Fed Register. 1992 (Feb 28): 7177-7180 [42CFR493.1449]: bacteriology, mycobacteriology, mycology, parasitology, virology, cytology, ophthalmic pathology, dermatopathology, oral pathology, and radiobioassay.
    g. If more stringent state or local regulations are in place for supervisory qualifications, including requirements for state licensure, they must be followed.
    h. For laboratories subject to US regulations, credentials for all personnel trained outside of the US must be reviewed and recorded to ensure that their training and

qualifications are equivalent to CLIA requirements. The equivalency evaluations should be performed by a nationally recognized organization. The following types of records may also be used to show equivalency: 1) license to practice medicine issued by the state in which the laboratory is located; or 2) laboratory personnel license in states where laboratory personnel licensure is required and qualifications are at least as stringent as CLIA. Department of Defense laboratories must evaluate equivalency using a process approved by the Center for Laboratory Medicine Services.

i. The section director, as designated by the laboratory director, must be accessible to the laboratory as needed for on-site, telephone, or electronic consultation and is responsible for the technical and scientific oversight of the laboratory. The section director is responsible for performing and recording competency assessment for high complexity testing. The duties for performing the competency assessment may be delegated, in writing, to individuals meeting general supervisor qualifications for high complexity testing. Other responsibilities of the technical supervisor include:
    i. Selection of test methodology
    ii. Establishment or verification of laboratory test performance specifications
    iii. Enrollment and participation in proficiency testing
    iv. Establishment of a quality control program to monitor ongoing test performance
    v. Resolution of technical problems and ensuring that remedial actions are taken
    vi. Ensuring that patient/client results are not reported until corrective actions are taken and test systems are functioning properly
    vii. Identification of training needs

j. For functions that are delegated, such as review of quality control data, assessment of competency, or review of proficiency testing performance, delegation must be in writing and the technical supervisor is responsible to ensure that those functions are properly carried out by a qualified individual.

VII. GENERAL SUPERVISOR QUALIFICATIONS/ RESPONSIBILITIES:

For high complexity testing, one or more individuals qualified as a general supervisor must be defined on the CAP's Laboratory Personnel Evaluation Roster.

A. *Supervisors who do not qualify as a laboratory director or section director/technical supervisor must qualify as testing personnel and possess the minimum of a:*
    1. *Bachelor's degree in a chemical, physical, biological or clinical laboratory science or medical technology with at least one year of training and/or experience in high complexity testing*; or*
    2. *Associate degree in a laboratory science or medical technology or equivalent education and training as defined in 42CFR493.1489(b)(2)(ii), with at least two years of training and/or experience in high complexity testing*; or*
    3. *Have previously qualified or could have qualified as a general supervisor prior to February 28, 1992*

B. *The general supervisor's training and experience must be in the designated discipline or area of service for*

which the individual is responsible.

C. *Requirements for the supervisors/general supervisors of cytopathology, cytogenetics, histocompatibility, and molecular pathology are more stringent and are found in the Cytopathology, Cytogenetics, Histocompatibility, and Molecular Pathology Checklists.*

D. *If more stringent state or local regulations are in place for supervisory qualifications, including requirements for state licensure (eg, California), they must be followed.*

E. *For laboratories subject to US regulations, credentials for all personnel trained outside of the US must be reviewed and recorded to ensure that their training and qualifications are equivalent to CLIA requirements. The equivalency evaluations should be performed by a nationally recognized organization. The following types of records may also be used to show equivalency: 1) license to practice medicine issued by the state in which the laboratory is located; or 2) laboratory personnel license in states where laboratory personnel licensure is required and qualifications are at least as stringent as CLIA. Department of Defense laboratories must evaluate equivalency using a process approved by the Center for Laboratory Medicine Services.*

F. *The supervisor of high-complexity testing must be accessible to the laboratory as needed for on-site, telephone, or electronic consultation and is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. Individuals meeting the qualifications of a general supervisor for high complexity testing may assess the competency of high complexity testing personnel, if this duty is delegated, in writing, by the section director. Other responsibilities of the general supervisor include:*

    1. *Resolution of technical problems in accordance with policies and procedures established by the laboratory director or technical supervisor*
    2. *Monitoring of test performance*
    3. *Ensuring that remedial actions are taken when test systems deviate from the laboratory's established performance specifications*
    4. *Providing orientation of testing personnel*

VIII. REFERENCES:

College of American Pathologists (CAP) Lab General Checklist GEN.53400 and GEN.53600

Attachments

Assessment of Delegated Duties Checklist.docx

Approval Signatures

Step Description	Approver	Date
Medical Directors	Jeremy Powers: Chief, Pathology	8/28/2024
Medical Directors	Muhammad Arshad: Chief, Pathology	8/27/2024

Policy and Forms Steering Committee Approval (if needed)	Kimberly Cole: Spec, Operations	8/21/2024
Site Laboratory Leaders	Christopher Ferguson: Dir, Lab Services	8/21/2024
	Kimberly Cole: Spec, Operations	8/21/2024

Applicability

Dearborn, Taylor, Trenton, Wayne

Corewell Health

East – Dearborn, Taylor, Trenton, Wayne, and Canton Laboratory

Delegated Duties Annual Assessment

Name: _____ Date: _____

Section: _____

Instructions to Laboratory Director

1. Assess the employee for each of the responsibilities below as they apply to their area of accountability. Enter Not Applicable (NA) if responsibility does not apply.
2. Record a "✓" for Meets Expectation or Needs Improvement.
3. If Needs Improvement is selected, document a corrective action plan in the Recommendations section.

Responsibility	Meets Expectation	Needs Improvement
Performs training of employees.		
Ensures remedial actions are taken when test systems deviate from the laboratory's established performance specifications.		
Ensures policies are developed for all testing performed.		
Develops and/or monitors quality improvement indicators.		
Ensures competency is assessed for all employees.		
Identifies and develops process improvement projects as needs arise.		
Ensures Proficiency Testing (PT) results are submitted before their due date.		
Reviews PT results and performs investigation and corrective action, if necessary.		
Ensures patient test results are not reported until all corrective actions have been taken and the test system functions properly.		
Signs the PT attestation of the PT reporting form in the absence of the Medical Director.		
Performs Quality Record Review.		
Analyzes current workflows/processes and communicates best practices to staff.		
Enforces accreditation and regulatory standards to ensure the area of responsibility is in compliance.		
Provides leadership, mentoring, coaching and education to develop and maintain and effective, well-trained staff.		
Performs review of technical policies at least every 2 years.		

Recommendations:

Employee Signature: _____ Date: _____

Medical Director Signature: _____ Date: _____