

# **POLICY**

## **Laboratory Director Operation and Administration Delegated Responsibility - Farmington Hills, Grosse Pointe, and Troy**

**This Policy is Applicable to the following Corewell Health sites:**

Corewell Health Beaumont Grosse Pointe Hospital, Corewell Health Beaumont Troy Hospital, Corewell Health Farmington Hills Hospital

<b>Applicability Limited to:</b>	N/A
<b>Reference #:</b>	33338
<b>Version #:</b>	2
<b>Effective Date:</b>	11/07/2025
<b>Functional Area:</b>	Clinical Operations, Laboratory
<b>Lab Department Area:</b>	Lab - General, Laboratory Policies

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### **1. Purpose**

To define responsibilities delegated to approved laboratory staff by the Lab Medical Director.

### **2. Policy**

The Laboratory Medical Director has the authority to delegate responsibility for the operation and administration of areas within the lab to approved/qualified laboratory staff.

1. The designee's skill and competency as it pertains to assigned duties and responsibilities will be assessed annually using form attached: Assessment of Delegated Duties.

### **3. Frequency of On-Site Visits**

A. Lab Medical Directors not routinely on-site must, make periodic on-site visits at a minimum frequency of at least every six months (with at least four months between the two on-site visits.).

1. Examples of documentation confirming on-site visits may include:
  - a. Signed onsite log/form or attendance sheet/schedule.
  - b. Site visit reports or inspection checklists.
  - c. Meeting minutes referencing the visit.
  - d. Completed Laboratory Director On-Site Visit Form (attached)

### **4. Delegated Responsibilities**

- A. Ensure testing systems needed for analytic and post-analytic phases are performed properly.
- B. Ensure verification procedures for test methodologies are adequate to determine accuracy, precision, and other pertinent performance characteristics.
- C. Ensure laboratory personnel are performing the test methods as required for accurate and reliable results.
- D. Ensure that the laboratory is enrolled and participating in an appropriate proficiency testing program.
- E. Monitoring and reviewing PT results, reports, and corrective actions.
- F. Ensure that the quality control and quality assessment programs are established and maintained,  
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- 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 established performance specifications are identified.
  - I. Ensure test results are reported only when testing systems are functioning properly.
  - J. Prior to testing patient samples, ensure that all personnel receive and demonstrate competency assessment annually for the type and complexity of services to be performed by those personnel.
  - K. 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.
  - L. Ensure that an approved procedure manual is available to all testing personnel.
  - M. Specify in writing the responsibilities and duties of each person engaged in the performance of pre-analytic, Analytic, and post-analytic phases of testing.
  - N. Ensure proper selection of laboratory equipment and supplies.
  - O. Complete Annual audit of each section's Personnel Evaluation Roster. Assure they are complete and accurate.
5. Functions that may not be delegated include the following:
- A. Provision of appropriately trained supervisory and technical staff and the identification of their responsibilities
  - B. Personal on-site visits, including assessment of physical and environmental conditions and the adequacy of staffing on a periodic basis, as defined in written policy
  - C. Approval of new technical policies and procedures, as well as substantial changes to existing documents (except as defined in COM.10250 for laboratories not subject to US regulations)
  - D. Approval of individualized quality control plans (IQCP).
6. **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:  
If current Designee/Alternate Designee does not meet the personnel qualifications under the CLIA defined roles then the Site Lab Medical Director will assume the role.
    - 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 Administrative and Employee-related; Training/Education as appropriate

**Table 1** Procedures/Policies/Workflows/Publicized documents

Document Type	New/Substantially Revised	Review at Least Every 2 Years	Minor Revisions
Technical	<u>By Site</u> Laboratory Medical Director	<u>By Site Department</u> Site Lab Medical Director Manager/Supervisor/Designee	<u>By Site Department</u> Manager/Supervisor/Designee
Non-Technical	<u>By Site</u> Site Operations Director	<u>By Site Department</u> Manager/Supervisor/Designee	<u>By Site Department</u> Manager/Supervisor/Designee

**C. Site Designee Charts**

See attached

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**7. Revisions**

Corewell Health reserves the right to alter, amend, modify or eliminate this document at any time without prior written notice.

- 8. Policy Superseded and Replaced:** This Policy supersedes and replaces the following procedures as of the effective date of this procedure: [33441 Corewell Health East – Laboratory Operation and Administration Delegated Responsibility Policy]

**9. Policy Development and Approval****Document Owner:**

Laura Judd (Operations Specialist)

**Writer(s):**

Tracie Rusicka (Operations Specialist)

**Reviewer(s):**

Jennifer Yaker (Mgr, Laboratory), Kelly Walewski (Mgr, Laboratory), Kristin Russell (Mgr, Laboratory)

**Approver:**

Elzbieta Wysteppek (Dir, Laboratory Services), Hassan Kanaan (OUWB Clinical Faculty), John Pui (Chief, Pathology), Laura Judd (Operations Specialist), Masood Siddiqui (Staff Pathologist), Ryan Johnson (OUWB Clinical Faculty), Sarah Britton (VP, Laboratory Svcs), Subhashree Mallika Krishnan (Staff Physician)

**10. Keywords**

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