

# Beaumont

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Contact Spec, Operations  
Area Laboratory-  
Quality  
Applicability Grosse Pointe,  
Troy

## Operation and Administration Delegated Responsibility Policy - Grosse Pointe, Troy and Lenox

Document Type: Policy

### I. PURPOSE AND OBJECTIVE:

To define responsibilities delegated to approved laboratory staff by the Lab Medical Director for Grosse Pointe, Lenox and Troy Laboratory's.

### II. POLICY STATEMENT:

- A. 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.
- B. The designee's skill and competency will be assessed annually.

### III. FREQUENCY OF ON-SITE VISITS:

The Lab Medical Director will make periodic on-site visits at a minimum frequency of:

- A. Grosse Point and Troy once per month
- B. Lenox once per quarter

These visits will be documented on the Director Visit form, attachment A.

### IV. 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 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, 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. 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 sections Personnel Evaluation Roster. Assure that these are complete and accurate.

## 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:

**NOTE: 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 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	<u>By Site</u> Laboratory Medical Director	<u>By Site Department</u> Site Lab Medical Director Manager/Supervisor	<u>By Site Department</u> Manager/Supervisor/ Operations Specialist Medical Technologist Lead
Non-Technical	<u>By Site</u> Site Operations Director	<u>By Site Department</u> Manager Supervisor	<u>By Site Department</u> Manager/Supervisor Coordinator

**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/Medical Technologist Lead/Operations Specialist (as indicated by site title)

**E. Personnel Training/Competency Records**

Technical and Non-technical: Manager/Supervisor/Operations Specialist/Medical Technologist Lead

**F. Troy Lab Designee Chart**

Laboratory Section	Medical Director	Designee	Alternate Designee
Lab Administration	Site Lab Medical Director	Operations Director	Operations Specialist
Transfusion Medicine	Blood Bank Site Lab Medical Director, Site Lab Medical Director	BB Supervisor	BB Medical Technologist Lead
Chemistry	Site Lab Medical Director	Chemistry Supervisor	Chemistry Medical Technologist Lead
Point of Care (POC)	Site Lab Medical Director	POC Medical Technologist Lead	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
Microbiology	Site Lab Medical	Microbiology	Lab Manager -

Laboratory Section	Medical Director	Designee	Alternate Designee
	Director	Medical Technologist Lead	Microbiology
Outpatient Lab	Site Lab Medical Director	Phlebotomy Manager	Laboratory Support Tech Lead
Specimen Reception (SR)/Phlebotomy	Site Lab Medical Director	Phlebotomy Manager	Laboratory Support Tech Lead

**G. Grosse Pointe (GP) 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	Chemistry Medical Technologist Lead	Clinical Pathology Manager
Hematology/Coagulation/Urinalysis	Site Lab Medical Director	Clinical Pathology Manager	Hematology Medical Technologist Lead
Microbiology	Site Lab Medical Director	Clinical Pathology Manager	Medical Technologist Lead
Phlebotomy/Processing/Outpatient Lab	Site Lab Medical Director	Phlebotomy Manager	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, Blood Bank Site Lab Medical Director	BB Medical Technologist Lead	Blood Bank Supervisor
Surgical Pathology/Cytology Processing	Site Lab Medical Director	AP Coordinator	Operations Director

**H. Lenox Designee Chart**

Laboratory Section	Medical Director	Designee	Alternate Designee
Lab Administration	Site Lab Medical Director	Operations Director	Operations Specialist
Chemistry	Site Lab Medical Director	Site Medical Technologist Lead	Chemistry Medical Technologist Lead
Hematology/Coagulation/Urinalysis	Site Lab Medical Director	Site Medical Technologist Lead	Clinical Pathology Manager
Microbiology	Site Lab Medical Director	Site Medical Technologist Lead	Clinical Pathology Manager
Point of Care	Site Lab Medical Director	Site Medical Technologist	POC Medical Technologist Lead
Outpatient Lab/Phlebotomy	Site Lab Medical Director	Outreach Phlebotomy Supervisor	
Quality/Safety	Site Lab Medical Director	Operations Specialist	Operations Director

## VI. REFERENCES:

College of American Pathologists (CAP) Checklist.

## Attachments

[Assessment of Delegated Duties.docx](#)

[Laboratory Director On Site Visit Form.pdf](#)

## Approval Signatures

Step Description

Approver

Date

Policy and Forms Steering Committee Approval (if needed)	Subhashree Mallika Krishnan: Staff Physician	5/1/2024
	Masood Siddiqui: Staff Pathologist	5/1/2024
	Hassan Kanaan: OUWB Clinical Faculty	5/1/2024
	Tracie Rusicka: Spec, Operations	5/1/2024
	Elzbieta Wysteppek: Dir, Lab Operations B	4/30/2024
	Tracie Rusicka: Spec, Operations	4/30/2024

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## Applicability

Grosse Pointe, Troy

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