

Beaumont

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Spec, Operations
Area Laboratory-
Operations
Applicability Dearborn, Taylor,
Trenton, Wayne

Laboratory Policy/Procedure and Quality Review and Approval

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The purpose of this policy is to provide instructions for obtaining approval for new policies and procedures, revisions, and review. It also provides details for Change of Laboratory Director and designees of the Laboratory Director that can change and/or review them.

II. PROCEDURE:

A. Acceptance of New Policies and Procedures:

The Laboratory Director reviews and approves all new policies and procedures including specimen collection and handling procedures before implementation, as well as substantial changes to existing procedures. All new policies must show the date written and approved by the Laboratory Director. Subsequent review is to be conducted by the Laboratory Director or designee at the discretion of the Laboratory Director every two years. In addition, information regarding any test method, or changes to any test method, are provided to clients upon request.

B. Revisions to Existing Procedures and Policies:

The Laboratory Section Manager, Supervisor, Medical Technologist Lead, or Lab Quality Coordinator may make minor changes or revisions to policies and procedures which have been previously approved by the Laboratory Director. The Laboratory Manager, Supervisor, Medical Technologist Lead, or Lab Operations Specialist must initial and date all such changes. Any substantial changes to existing procedures for specimen collection and handling must be approved by the Laboratory Director. All new documents will be put in the policy management system.

- C. **Laboratory Policy Review:**
Any major change to a technical procedure must have the written approval of the Laboratory Director. Policy and procedure manuals can be reviewed and signed by a designee such as the Administrative Laboratory Director, Laboratory Manager, Supervisor, Medical Technologist Lead, or Lab Operations Specialist.
- D. **Change of Laboratory Director:**Following a change in laboratory directorship, the new laboratory director approves the laboratory policies and procedures within three months of the change of directorship. If the procedure approval process is going to exceed three months, document a written plan to complete the procedure review process as indicated in the [Laboratory Document Management and Record Retention Procedure](#)
- E. **Designee of Laboratory Director for Quality Control Review Documentation:**
The Laboratory Director empowers the function of Quality Control review and sign-off to various Laboratory Managers, Supervisors, Medical Technologist Lead, or Lab Operations Specialist, Technologists, Registered Nurses and other specified qualified staff in order to meet the required review and sign-off frequencies. All such designees meet the minimum requirements for a general supervisor under Clinical Laboratory Improvement Amendments (CLIA) as specified in 42 CFR 493.1449 or in 42CFR 493.1461 (See attachment A for list of Dearborn Department Specific Designee's)

III. REFERENCES:

[Laboratory Document Management and Record Retention Procedure](#)

Attachments

[Dearborn Laboratory Designee Table Policies and Procedures](#)

[Taylor and Trenton Laboratory Designee Table Policies and Procedures](#)

[Wayne and Canton Laboratory Designee Table Policies and Procedures](#)

Approval Signatures

Step Description	Approver	Date
Medical Directors	Muhammad Arshad: Chief, Pathology	4/11/2024
Medical Directors	Jeremy Powers: Chief, Pathology	4/9/2024

Policy and Forms Steering
Committee Approval (if
needed)

Kimberly Cole: Spec,
Operations

3/25/2024

Site Laboratory Leaders

Christopher Ferguson: Mgr,
Laboratory

3/19/2024

Kimberly Cole: Spec,
Operations

3/18/2024

Applicability

Dearborn, Taylor, Trenton, Wayne

COPY

**Dearborn Laboratory Designee Table for
Policy and Procedure Manual Review and Approval**

Laboratory Section	Designee
Administration	Christopher Ferguson, Laboratory Director Kimberly Cole, Laboratory Operations Specialist
Chemistry/Serology/Immunology	Stephanie Mullins, Supervisor Michelle Alexander, Medical Technologist Lead
Hematology/Coagulation/Urinalysis	Helga Groat, Supervisor Lilly Reid, Medical Technologist Lead
Microbiology	Vacant, Manager Migena Haldeda, Medical Technologist Lead Julie Backus, Medical Technologist Lead
Transfusion Services	Kelly Sartor, Supervisor Melissa Bajcz, Medical Technologist Lead Mercy Jaksim, Medical Technologist
Histology/Cytology	Shanno Griffin, Anatomic Pathology Tech Coordinator
Phlebotomy	Lori Saad, Phlebotomy Manager Kimberly Cole, Laboratory Operations Specialist
Processing	Kylene McIntosh, Manager Kimberly Cole, Laboratory Operations Specialist
Client Services	Thomas O'Shaughnessy, Manager Josie Ingraham, Supervisor Bianca Robidoux, Lab Customer Service Rep Lead
Laboratory Computer Services	Joann Logue-O'Malley, Manager IT LIS Debra Dent, System Analyst SR
Safety	Deborah Poloch, Medical Technologist Lead Kimberly Cole, Laboratory Operations Specialist
Point of Care Testing	Stephanie Mullins, Supervisor Rina Patel, Medical Technologist Lead Avani Shah, Medical Technologist Lead Sara Hermiz, Medical Technologist Lead Aliaa Alnasiry, Medical Technologist Lead Jessica Czinder, System Manager
Quality Assurance	Kimberly Cole, Laboratory Operations Specialist
Patient Service Centers	Tyler Swift, PSC Manager Nadine Alawieh, Supervisor