Beaumont

Origination:	*7/28/2020*
Effective:	*9/16/2021*
Last Approved:	*9/16/2021*
Last Revised:	*9/16/2021*
Next Review:	*9/16/2023*
Document Contact:	*Jennie Green: Mgr Laboratory*
Area:	*Laboratory-Quality*
Key Words:	
Applicability:	*Royal Oak*

Laboratory Director Operation and Administration Delegated Responsibility-Royal Oak

Document Type: Policy

I. PURPOSE AND OBJECTIVE:

To identify the delegated responsibilities of the laboratory medical director.

II. POLICY STATEMENT:

The laboratory medical director has delegated responsibility for the operation and administration of areas within the Royal Oak Clinical Pathology or the Royal Oak Anatomic Pathology laboratory.

III. DELEGATED RESPONSIBILITIES:

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

B. Ensure the physical plant is appropriate for testing.

C. Ensure the environment is safe for employees.

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

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

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

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

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

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

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

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

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

M. Employ sufficient number of personnel, appropriate education and experience to properly supervise and

accurately perform tests and report tests results.

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

O. 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.

P. 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.

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

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

S. Ensure proper selection of laboratory equipment and supplies.

IV. DESIGNEES:

Per College of American Pathologists (CAP) guidelines, designees may be appointed to 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.

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 Non-Technical	**By Site** Chief Laboratory Medical Director **By Site** Site Administrative/ Operations Director	**By Site Department** Section Medical Director Delegated Pathologist Delegated PhD **By Site Department** Manager Supervisor	**By Site Department** Manager Supervisor Coordinator Lead Technologist **By Site Department** Manager, Supervisor, etc. (as indicated by site title)
Monthly Review of Instrument Maintenance, Internal Reference Guides, Forms			
Technical and Non-technical	By site department: Manager, Supervisor, Coordinator, Lead Technologist		

Stat Test, Critical Call and Reflex Testing Reference Guides	1. All sites Medical Directors related to section being revised
Laboratory Bulletins	1. Section Medical Director(s), PhD applicable to each site 2. Chair, Pathology and Laboratory Medicine 3. System Operations Director
Lab Test Directory (LTD)	Section Medical Director or designee

Publicized documents: Includes reference guides, educational documents, marketing material and web site pages

Technical Non-Technical	Chair, Pathology & Laboratory Medicine Section Medical Director Administrative/ Operations Director	Pathologist PhD Site Operations Director	Manager, Supervisor, Coordinator (as indicated by site title)

Personnel Training/Competency Records	
Technical and Non-technical	Manager/Supervisor / Coordinator/ Lead Tech

As indicated in the accrediting guideline, the table below provides evidence of written authorization by all section Medical Directors as to the authorized reviewers and designees within their areas of responsibility.

AUTHORIZED REVIEWERS/DESIGNEES FOR PROCEDURES/POLICIES: See attached

DELEGATION OF RESPONSIBILITY: See attached

V. REFERENCES

A. College of American Pathologists Checklists, Current Version

B. Laboratory Document Management and Record Retention Procedure

Attachments

BL RO Delegation of Responsibilities.pdf
BL RO Authorized Reviewers_Designee for Policies and Procedures.pdf

Approval Signatures

Step Description	Approver	Date
	Mitual Amin: Chair, Pathology - OUWB	9/16/2021
	Ann Marie Blenc: System Med Dir, Hematopath	9/14/2021
Policy and Forms Steering Committee Approval (if needed)	Jennie Green: Mgr Laboratory	9/14/2021
Policy and Forms Steering Committee	Ilene Hirsch: Project Mgr Policy	9/14/2021

Step Description	Approver	Date
Approval (if needed)		
	Brittnie Berger: Dir, Lab Operations C	9/14/2021
	Joan Wehby: Dir, Lab Operations C	9/13/2021
	Amy Knaus: Dir, Lab Operations C	9/13/2021
	Jennie Green: Mgr Laboratory	9/13/2021

Applicability

Royal Oak