

	Johns Hopkins Medicine	Policy Number	ADM013
	Pathology Volume II - General Policy Manual Documents and Records	Effective Date	04/24/2015
		Approval Date	N/A
		Page	1 of 6
	Subject Document Management	Supersedes	07/19/2013

Keywords: Policies, procedure manual, technical procedures, Quality Management Documents, Document Control, HPO

Table of Contents	Page Number
I. PRINCIPLE/PURPOSE	1
II. RESPONSIBILITIES	1
III. DEFINITIONS	2
IV. PROCESS	4
V. SUMMARY/CONCLUSION	6
VI. SUPPORTING DOCUMENTATION	6
VII. REFERENCES	6
VIII. SIGNATURES	6
Appendix A: CLIA Director Approval Form	Click Here
Appendix B: DOCUMENT TEMPLATES	Click Here
Appendix C: Obtaining an Electronic Signature (HPO)	Click Here
Appendix D: SIGNATURE PAGE TEMPLATE	Click Here
Appendix E: DOCUMENT CONTROL LOG	Click Here
Appendix F: CLIA Director Signature Form (Non- HPO Technical SOPs)	Click Here

I. PRINCIPLE/PURPOSE

The purpose of this policy is to provide guidelines on managing document control within the clinical laboratory.

This policy is designed to ensure that:

- All laboratory procedures/policies and related documents are generated in accordance with the laboratory's quality management system, federal regulations and accreditation requirements.
- New documents and substantial changes to these documents are controlled and handled appropriately.

Document management applies to all policies, procedures, forms, work/job aids and quality management documentation within the path of workflow.

II. RESPONSIBILITIES

It is the responsibility of the CLIA Laboratory Director to review and approve all technical policies and procedures that are new and those that already exist but have undergone substantial changes. All documents must be approved and reviewed before they can be implemented.

It is the responsibility of the laboratory area manager/supervisor to ensure that:

- All copies of policies and procedures are current and accessible
- All personnel have read the documents relevant to their job activities and ensure evidence of said review
- All new technical policies/procedures have been authorized and signed by the CLIA Laboratory Director before implementation
- All policies and procedures are reviewed at least every 2 years by the laboratory director or designee. More frequent reviews may be determined / defined by the laboratory section.
- Any changes to a document are made by authorized personnel who are listed on a delegation document.
- Any changes to a document are dated and signed.

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Table of Contents Johns Hopkins Laboratory Procedure Manual

1. Understanding the eBook Johns Hopkins Laboratory Procedure Manual
 - The Rise of Digital Reading Johns Hopkins Laboratory Procedure Manual
 - Advantages of eBooks Over Traditional Books
2. Identifying Johns Hopkins Laboratory Procedure Manual
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Johns Hopkins Laboratory Procedure Manual
 - User-Friendly Interface
4. Exploring eBook Recommendations from Johns Hopkins Laboratory Procedure Manual
 - Personalized Recommendations
 - Johns Hopkins Laboratory Procedure Manual User Reviews and Ratings
 - Johns Hopkins Laboratory Procedure Manual and Bestseller Lists
5. Accessing Johns Hopkins Laboratory Procedure Manual Free and Paid eBooks

- Johns Hopkins Laboratory Procedure Manual Public Domain eBooks
- Johns Hopkins Laboratory Procedure Manual eBook Subscription Services
- Johns Hopkins Laboratory Procedure Manual Budget-Friendly Options
- 6. Navigating Johns Hopkins Laboratory Procedure Manual eBook Formats
 - ePub, PDF, MOBI, and More
 - Johns Hopkins Laboratory Procedure Manual Compatibility with Devices
 - Johns Hopkins Laboratory Procedure Manual Enhanced eBook Features
- 7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Johns Hopkins Laboratory Procedure Manual
 - Highlighting and Note-Taking Johns Hopkins Laboratory Procedure Manual
 - Interactive Elements Johns Hopkins Laboratory Procedure Manual
- 8. Staying Engaged with Johns Hopkins Laboratory Procedure Manual
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Johns Hopkins Laboratory Procedure Manual
- 9. Balancing eBooks and Physical Books Johns Hopkins Laboratory Procedure Manual
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Johns Hopkins Laboratory Procedure Manual
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine Johns Hopkins Laboratory Procedure Manual
 - Setting Reading Goals Johns Hopkins Laboratory Procedure Manual
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Johns Hopkins Laboratory Procedure Manual
 - Fact-Checking eBook Content of Johns Hopkins Laboratory Procedure Manual
 - Distinguishing Credible Sources
- 13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development

- Exploring Educational eBooks

14. Embracing eBook Trends

- Integration of Multimedia Elements
- Interactive and Gamified eBooks

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