

# CLIA Inspection Checklist for

## LRN-C, RADIOBIOASSAY AND BIOMONITORING LABORATORIES

### INTRODUCTION

In 2009, the Centers for Medicare & Medicaid Services (CMS) released a memorandum stating chemical (organic) CT laboratories will be added to the CLIA certified under the umbrella of the main laboratory. In order to help members prepare for CLIA inspection of their LRN-C program, APHL, with guidance from CMS, created this Checklist for LRN-C, Radioassay and Biomonitoring laboratories.

While this Checklist intends to provide guidance to CT laboratories preparing for a CLIA inspection, the document is NOT all-inclusive. Laboratories should be aware some topics or states may have slightly different or additional requirements. Also, some items listed in the document may not be applicable in all situations. If laboratories have any questions or are unclear about specific requirements, the EHC advises laboratories to contact their [regional CMS office](#).

For further explanation on the contents and acronym listed in the Checklist, please refer to the CLIA Inspection Guidance for LRN-C, Radioassay & Biomonitoring Laboratories document. The EHC strongly advises users of this Checklist to first read the Guidance Document before completing the Checklist. Also, CMS's Information Guidelines on CLIA provide more detail for compliance. <https://www.cms.gov/Regulatory-and-Compliance/Legislative-Calendar/Inspection-Guidance-for-Laboratories>.

### THE CHECKLIST FOR LABORATORIES

CLIA Req.	What Laboratories must be in compliance with regulations with regard to this element	Yes	No	Not Applicable	Comments
	<b>Subpart A</b>				
§ 91.103 (a)	Laboratories carrying out high complexity or any of laboratory must submit a certificate for recognition for addition to this list of laboratories				
	Has this result meet the appropriate requirements of subpart C or subpart D, as appropriate to the CLIA test, and if applicable				
	<b>Subpart B – Laboratory Testing</b>				
§ 91.103 (b)(1)	Environment for each sample				

# Example Clia Procedure Manual Checklist

**William B. Coleman, Gregory J.  
Tsongalis**



### **Example Clia Procedure Manual Checklist:**

*Henry's Clinical Diagnosis and Management by Laboratory Methods E-Book* Richard A. McPherson, Matthew R. Pincus, 2011-09-06 Recognized as the definitive book in laboratory medicine since 1908 Henry's Clinical Diagnosis and Management by Laboratory Methods edited by Richard A. McPherson MD and Matthew R. Pincus MD PhD is a comprehensive multidisciplinary pathology reference that gives you state of the art guidance on lab test selection and interpretation of results. Revisions throughout keep you current on the latest topics in the field such as biochemical markers of bone metabolism, clinical enzymology, pharmacogenomics and more. A user friendly full color layout puts all the latest most essential knowledge at your fingertips. Update your understanding of the scientific foundation and clinical application of today's complete range of laboratory tests. Get optimal test results with guidance on error detection, correction and prevention as well as cost effective test selection. Reference the information you need quickly and easily thanks to a full color layout, many new color illustrations and visual aids and an organization by organ system. Master all the latest approaches in clinical laboratory medicine with new and updated coverage of the chemical basis for analyte assays and common interferences, lipids and dyslipoproteinemia, markers in the blood for cardiac injury evaluation and related stroke disorders, coagulation testing for antiplatelet drugs such as aspirin and clopidogrel, biochemical markers of bone metabolism, clinical enzymology, hematology and transfusion medicine, medical microbiology, body fluid analysis and many other rapidly evolving frontiers in the field. Effectively monitor the pace of drug clearing in patients undergoing pharmacogenomic treatments with a new chapter on this groundbreaking new area. Apply the latest best practices in clinical laboratory management with special chapters on organization, work flow, quality control, interpretation of results, informatics, financial management and establishing a molecular diagnostics laboratory. Confidently prepare for the upcoming recertification exams for clinical pathologists set to begin in 2016.

*Manual of Molecular and Clinical Laboratory Immunology* Barbara Detrick, John L. Schmitz, Robert G. Hamilton, 2020-07-16 THE authoritative guide for clinical laboratory immunology. For over 40 years the Manual of Molecular and Clinical Laboratory Immunology has served as the premier guide for the clinical immunology laboratory. From basic serology testing to the present wide range of molecular analyses the Manual has reflected the exponential growth in the field of immunology over the past decades. This eighth edition reflects the latest advances and developments in the diagnosis and treatment of patients with infectious and immune mediated disorders. The Manual features detailed descriptions of general and specific methodologies placing special focus on the interpretation of laboratory findings and covers the immunology of infectious diseases including specific pathogens as well as the full range of autoimmune and immunodeficiency diseases, cancer and transplantation. Written to guide the laboratory director the Manual will also appeal to other laboratory scientists especially those working in clinical immunology laboratories and pathologists. It is also a useful reference for physicians, mid level providers, medical students and allied health students with an interest in the role that

immunology plays in the clinical laboratory      **Quality Point-of-care Testing** ,2004      **Quality Improvement Manual in Anatomic Pathology** Raouf E. Nakhleh,Patrick L. Fitzgibbons,2002      **Labmedicine** ,2006      **Molecular Pathology in Clinical Practice** Debra G.B. Leonard,2007-11-25 Molecular Pathology In Clinical Medicine is an authoritative comprehensive textbook that provides the general pathologist in clinical practice as well as residents and fellows during their training with the current standard in molecular testing The text is divided into 8 sections as defined by the molecular pathology specialty board genetics inherited cancers infectious disease neoplastic hematopathology solid tumors HLA typing identity testing and laboratory management The book integrates the latest advancements in the field with the basic principles and practical applications Each chapter discusses the clinical significance of each diagnostic test available assays quality control and lab issues interpretation and reasons for testing Chapters cover such topics as HIV herpes hepatitis deafness developmental disorders bioterrorism warfare organisms lymphomas breast cancer and melanoma forensics parentage and much more 189 illustrations 45 of them in full color illustrate the principles outlined in the text This textbook is a classic in the making and a must have reference to meet the needs of every pathologist resident and fellow      **Henry's Clinical Diagnosis and Management by Laboratory Methods: First South Asia Edition\_E-book** Richard A. McPherson,2016-08-31 To interpret the laboratory results To distinguish the normal from the abnormal and to understand the merits and demerits of the assays under study The book attempts to train a laboratory medicine student to achievesound knowledge of analytical methods and quality control practices to interpret the laboratory results to distinguish the normal from the abnormal and to understand the merits and demerits of the assays under study      Clinical Laboratory Instrumentation and Automation Kory M. Ward,Craig A. Lehmann,Alan M. Leiken,1994 Contains the core chapters stressing basic theory and application and also examines trouble shooting specimen processing and quality assurance It addresses the economic topics of efficiency and cost It covers all of these varied topics analytical theories and applications the use of lab computers basic electronics instrument reliability the small lab physician s office laboratory and more      **Archives of Pathology & Laboratory Medicine** ,2005      **Molecular Diagnostics** William B. Coleman,Gregory J. Tsongalis,2007-10-28 Accompanying CD ROM contains a companion eBook version of Molecular diagnostics for the clinical laboratorian Second edition for downloading and use in the reader s PC or PDA Page 4 of cover      *Transfusion Service Manual of Standard Operating Procedures, Training Guides, and Competence Assessment Tools* ,1996      Clinical Virology Manual Steven Specter,Richard L. Hodinka,Stephen A. Young,2000 This comprehensive manual serves as a source of basic and clinical information for the physician regarding viruses and viral diseases and as a reference source for laboratorians to aid in the diagnosis of virus infection by providing detailed information on individual techniques Section one of the manual describes laboratory procedures to detect viruses including quality control in the laboratory and specimen handling Individual chapters provide information or a detailed protocol on how to set up and test samples for viral diagnosis The second section focuses on

the viral agents and the third is a reference of the various federal state and local laboratories that diagnose virus infections  
*Community and Nurse-Managed Health Centers* Donna L. Torrissi, Tine Hansen-Turton, 2005-06-03 Print CourseSmart  
**Health Devices**, 1994      **Colorado Laboratory Bulletin**, 1992      *Medicare and Medicaid Guide*, 1969  
**Administrative Manual** American Association of Blood Banks, 1985      **Clinical Immunology and Serology** Christine Dorresteyn Stevens, 2009-08-24 Western Carolina University Cullowhee North Carolina Introduction to clinical immunology for second and fourth year level clinical laboratory science students Combines essential theoretical principles with commonly used serological techniques Chapters include objectives outlines and glossary      **Critical Issues in Cytopathology** Tilde S. Kline, Gia-Khanh Nguyen, 1996      *Medical Laboratory Management and Supervision* Lionel A. Varnadoe, 1996 A textbook for college students intending to enter leadership positions in medical laboratories a study guide for laboratory workers preparing for a management certification examination or a self study tutorial for those familiar with the technical and medical aspects of the laboratory who would like to know more about its management Includes sample exam questions for each section Annotation copyright by Book News Inc Portland OR

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