

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.	Items Laboratories must be in compliance with regulations with regard to their license	Yes	No	Not Applicable	Comments
	Subpart A				
§ 163.101	Laboratories carrying out high complexity or				
	low or medium complexity tests must be certified for				
	competency for each test or group of tests.				
	Low and medium complexity laboratories must have				
	competency for each test or group of tests.				
	and if applicable				
	Subpart B - Subpart B Testing				
§ 163.102	Environment for each sample				

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M Mark



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