

# 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 regions 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 this element	Yes	No	Not Applicable	Comments
	<b>Subpart A</b>				
§ 1604.101	Laboratories participating must all have completed by July 1 laboratory level accreditation for compliance for addition to this list of laboratories				
	All third parties must have appropriate documentation of accreditation or equivalent by July 1, 2019, or proof of accreditation				
	<b>Subpart B – Laboratory Testing</b>				
§ 1604.101	Environment for each sample				

# Example Clia Procedure Manual Checklist

**Shasha Hu**

A red circular graphic with a gradient, appearing as a partial circle or a stylized arrow pointing to the right, located to the right of the name bar.

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

## Decoding **Example Clia Procedure Manual Checklist**: Revealing the Captivating Potential of Verbal Expression

In a time characterized by interconnectedness and an insatiable thirst for knowledge, the captivating potential of verbal expression has emerged as a formidable force. Its capability to evoke sentiments, stimulate introspection, and incite profound transformations is genuinely awe-inspiring. Within the pages of "**Example Clia Procedure Manual Checklist**," a mesmerizing literary creation penned by a celebrated wordsmith, readers set about an enlightening odyssey, unraveling the intricate significance of language and its enduring impact on our lives. In this appraisal, we shall explore the book's central themes, evaluate its distinctive writing style, and gauge its pervasive influence on the hearts and minds of its readership.

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