



## Resource Guide

Subject:	Laboratory Test Procedures (According to Current Site-Specific CLIA Certificate)
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review  California Department of Public Health (CDPH) / Department of Health Care Services (DHCS)
Relevant Law/Standard:	All sites that perform laboratory testing for human health assessment, diagnosis, prevention, or treatment of disease, have a current, unrevoked, unsuspended site-specific Clinical Laboratory Improvement Amendment (CLIA) certificate, or evidence of renewal
Agency//Organization Source:	CDPH
Agency/Organization URL	<a href="https://www.cdph.ca.gov/">https://www.cdph.ca.gov/</a>

**Background:**

All sites that perform laboratory testing for human health assessment, diagnosis, prevention, or treatment of disease has a current, unrevoked, unsuspended site-specific Clinical Laboratory Improvement Amendment (CLIA) certificate, or evidence of renewal and State Clinical Acceptable documentation such as the original certificate, copy of the original certificate, renewal receipt or other evidence of renewal submission is present on site or readily available upon request. The CLIA certificate or evidence of renewal should include the current site/clinic address (see Links)

**Purpose:**

The site will operate in compliance with Clinical Laboratory Improvement Amendment (CLIA) regulations. Therefore, the site shall meet all quality standards to ensure accuracy, reliability and timeliness of patient test results. All lab results are to be communicated to the provider and member in a timely manner.

**Guidelines:**

1. Prior to testing biological specimens, personnel are appropriately trained for the type and complexity of the laboratory services performed. Personnel have demonstrated the ability to perform all testing operations reliably and to report results accurately.
2. Site personnel that perform CLIA waived tests have access to and are able to follow test manufacturer's instructions.
3. When requested, site personnel are able to provide a step-by-step verbal explanation or demonstration of test procedure and how to determine test results.

**The CLIA Certificate on site includes one of the following:**

1. Certificate of Waiver: Site is able to perform only exempt waived tests.
2. Certificate for Provider-Performed Microscopy (PPM): Physicians, dentists, or mid-level practitioners are able to perform PPM procedures and waived tests.

3. Certificate of Registration: Allows moderate and/or high complexity lab testing to be conducted until compliance with CLIA regulations are determined by survey.
4. Certificate of Compliance: Lab has been surveyed and found in compliance with all applicable CLIA requirements.
5. Certificate of Accreditation: Lab is accredited by an accreditation organization approved by the Centers for Medicare & Medicaid Services (CMS).

**Links:**

Department of Health and Human Services Center for Medicare & Medicaid Services  
CLIA Certification Application

<https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf>

California Department of Public Health Laboratory Services  
Clinical Laboratory Registration Application

<https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/lab155.pdf>

About CLIA for Family Practice

AAFP <https://www.aafp.org/practice-management/regulatory/clia.html>

The material in this document is a knowledge-sharing tool provided by the FSR team to enhance compliance with Facility Site Review requirements. All content is for informational purposes and may be used and/or modified according to site-specific practices. Ensure appropriate review and approval by site management prior to adoption.