



Resource Guide

Subject:	Laboratory Test Procedures
Facility Site Review Source:	Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL
Relevant Law/Standard:	42 CFR, 493.35(b)(1-3) 493.43(b)(1-3) 493.55(b)(1-3) BPC 1200-1213
Agency/Organization Source:	Centers for Medicare & Medicaid Services
Agency/Organization URL	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA

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.
- 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.

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.

Personnel Training Standards:

- Prior to testing biological specimens, personnel have been 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.
- Site personnel that perform CLIA waived tests have access to and can follow test manufacturer’s instructions.
- When requested, site personnel can provide a step-by-step verbal explanation or demonstration of test procedure and how to determine test results.

- The required training and certification are established by legislation for personnel performing moderate and high complexity tests.

The CLIA Certificate on site includes one of the following:

1. Certificate of Waiver: Site can 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).

Exceptions

1. Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.
2. Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application, or
3. Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for laboratory sites within same physical location or street address.
4. A multi-site CLIA waiver can be used at all affiliated locations. A copy of the CLIA waiver must be at each individual location with the address of the main location on the waiver. A copy of the CLIA application must be reviewed by the CSR to verify the locations included for old and new locations.

Links:

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

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

Clinical Laboratory Registration Application, California Department of Public Health Laboratory Services

<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>

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