

* This information is subject to change

Clinical Laboratory & Physician Office Laboratory

A clinical laboratory is defined in state and federal law as any place where testing is done on human specimens for diagnostic purposes.

A physicians office labroatory (POL) is considered a clinical laboratory if any patient testing is done on-site. (e.g., fingerstick blood tests)

Licensure

Facility must: Be approved as a Clinical Laboratory in California.

1. Apply for CLIA Certificate of Waiver or higher
2. Apply for CA Clinical Laboratory Registration with the state of CA, Laboratory Field Services
<https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/lab155.pdf>
 - a. Annual application fee applies
 - b. Complete LAB 155 and send form and payment to:
CDPH Laboratory Field Services
Facility Registration
850 Marina Bay Parkway, Bldg P, 1st floor
Richmond, CA 94804-6403

For more information about CA Laboratory Licensing and Registration:
<https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/Home.aspx>

Patient Testing

Training Tools: www.LeadCare2.com/training

Facility must: Confirm capillary blood lead test results greater than or equal to 10 µg/dL with a venous sample by a reference lab.

Quality Control

Facility must: Run two levels of Quality Control samples according to the manufacturer's instructions, which are:

1. With each new lot of test kits.
2. With each new shipment of materials, even if it's the same lot previously received.
3. With each new operator (i.e. operator who has not performed the test recently).
4. Monthly, as a check on continued storage conditions.
5. When problems (storage, operator, instrument, or other) are suspected or identified.
6. If otherwise required by your laboratory's standard QC procedures.

Result Reporting

Reporting Solutions by State: www.LeadCare2.com/reporting

Facility must:

1. Report results greater than or equal to 10 µg/dL within 3 working days of analysis.
2. Report results less than 10 µg/dL within 30 calendar days of analysis.
3. Report **all** patient blood lead results electronically to the California Department of Public Health (CDPH) using the California Electronic Blood Lead Reporting System per CA Health and Safety Code, Section 124130.
 - a. Requires access to a computer with Internet connection
 - b. Review the California Electronic Blood Lead Reporting System: Requirements and Procedures Manual
 - c. Contact CLPPB: (510) 620-5683 or email EBLRSupport@cdph.ca.gov to get started with electronic blood lead reporting.

For more information, see Section 124130 of the California Health and Safety Code:
<https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/Home.aspx>

Please refer additional questions to: CDPH Childhood Lead Poisoning Prevention Branch (CLPPB) at(510) 620-5683 .

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Proficiency Testing

NOT REQUIRED, for CLIA-waived labs: Recommended, to monitor the quality of your blood lead testing program.

Contact Wisconsin State Laboratory of Hygiene (WSLH) proficiency program for more information about their program at (800) 462-5261 or go to <http://www.slh.wisc.edu/proficiency/>

REQUIRED for moderately / highly complex labs: To access reimbursement through the California Child Health and Disability grant (CHDP) for blood lead analysis you must:

1. Enroll in and be rated proficient in the California Blood Lead Proficiency Assurance Program (CBLPAP) - see page 2. [http://www.cdph.ca.gov/certlic/labs/Pages/CaliforniaBloodLeadProficiencyAssuranceProgram\(CBLPAP\).aspx](http://www.cdph.ca.gov/certlic/labs/Pages/CaliforniaBloodLeadProficiencyAssuranceProgram(CBLPAP).aspx)
2. Enroll in a Proficiency Testing program approved by CMS. We recommend the Wisconsin State Laboratory of Hygiene (WSLH) proficiency program. For more information about their program call (800) 462-5261 or go to <http://www.slh.wisc.edu/proficiency/>
3. Maintain an average score of at least 80% on proficiency testing for two of the last three consecutive regulatory proficiency events after initial enrollment in CBLPAP.

For more information refer to Centers for Medicare & Medicaid Services in regards to proficiency testing or review the Proficiency Testing and PT referral brochure at <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure8.pdf>

Still Have Questions?

Contact the LeadCare Product Support Team at (800) 275-0102.
Contact CDPH Childhood Lead Poisoning Prevention Branch (CLPPB) at (510) 620-5600.