

Point of service blood lead analyzers, such as the LeadCare® II, allow for onsite lead screening by health care providers. Users of blood lead analyzers designated by the United States Food and Drug Administration to be a Clinical Laboratory Improvement Amendments (CLIA) waived device are considered a “laboratory.” As a laboratory, you must comply with specific reporting, state licensing, and registration requirements. This brochure provides an overview of these requirements and includes information about electronic reporting of blood lead results.

Contact Information

Questions about federal CLIA certification, state registration or licensing:

www.cdph.ca.gov/programs/lfs
or Laboratory Field Services (LFS) at
(510) 620-3800

Electronic blood lead reporting information:

www.cdph.ca.gov/programs/clppb
or Childhood Lead Poisoning Prevention
Branch at (510) 620-5653 or (510) 620-5600,
or email EBLRSupport@cdph.ca.gov

Occupational lead testing information:

www.cdph.ca.gov/programs/olppp
or Occupational Lead Poisoning Prevention
Program (OLPPP) at (510) 620-5733 or
(510) 620-5757

OSHA list information:

www.osha.gov/SLTC/bloodlead/index.html
or OSHA Blood Lead Program at (801) 233-5000

CHDP Reimbursement:

DHCS — Children’s Medical Services (CMS) at
(916) 327-1767

Information on the California Blood Lead Proficiency Assurance Program:

[http://www.cdph.ca.gov/programs/biochem/
Pages/default.aspx](http://www.cdph.ca.gov/programs/biochem/Pages/default.aspx)
or Environmental Health Laboratory Branch
(EHLB) at (510) 620-2892 or (510) 620-2801

Childhood Lead Poisoning Prevention Branch
California Department of Public Health
850 Marina Bay Parkway, Building P, Third Floor
Richmond, CA 94804-6403
Phone: (510) 620-5600
Fax: (510) 620-5656



An Overview of Requirements for Point of Service Blood Lead Testing Devices in California

All information contained in this document is a summarization and is not intended to be fully representational of the law. For complete details, please contact the appropriate department representative listed on the back panel.

What must I report?

You must report **all blood lead results electronically** to the California Department of Public Health (CDPH). In addition to reporting the blood lead analysis results and the date it was performed, you must also report:

- Patient name; address or phone number; and date of birth or age
- The name, address, and phone number of the provider that ordered the test

You may also be required to report additional information. For exact requirements, please see Section 124130 of the California Health and Safety Code found at:

www.cdph.ca.gov/programs/CLPPB/Pages/AboutCLPPB.aspx

How do I report?

To electronically report results to the state, you will use the Online Blood Lead Reporting Form. Contact the Childhood Lead Poisoning Prevention Branch (CLPPB) at (510) 620-5653 or (510) 620-5600, or email EBLRsupport@cdph.ca.gov to get started with electronic blood lead reporting.

How soon do I have to report?

- Results **greater than or equal to 10 µg/dL*** must be reported **within 3 working days** of analysis.
- Results **less than 10 µg/dL*** must be reported **within 30 calendar days** of analysis.

What are the licensing, registration, and certification requirements?

To use a point of service blood lead analyzing device, you must be registered or licensed with the State of California Laboratory Field Services and have a federal CLIA Certificate of Waiver, Provider Performed Microscopy Procedures, Compliance, or Accreditation.

To perform blood lead testing to monitor occupational exposure, you must appear on the Occupational Safety and Health Administration (OSHA) List of Laboratories Approved for Blood Lead Analysis.

Can I get reimbursed for blood lead analysis?

The California Child Health and Disability Program (CHDP) offers reimbursement for blood lead analysis. You may qualify for CHDP reimbursement if your clinic is:

- enrolled and rated as proficient in the California Blood Lead Proficiency Assurance Program administered by CDPH Environmental Health Laboratory Branch (EHLB).
- enrolled in the CHDP program as outlined in the CHDP Provider Manual found at: www.medi-cal.ca.gov
- able to submit claims and documentation on the Confidential Screening/Billing Report form.

You must comply with the federal certification, state licensing or registration, and reporting requirements whether or not you are pursuing CHDP reimbursement.

How do I get started?

In order to begin electronic blood lead reporting, you must complete Online Blood Lead Reporting Form training, provided by the Childhood Lead Poisoning Prevention Branch (CLPPB). Training sessions take about 20 minutes and are conducted by phone.

You will need:

- access to a computer with an Internet connection
- the California Electronic Blood Lead Reporting System: Requirements and Procedures manual

To get a copy of the manual and to schedule a training session, call (510) 620-5653 or email EBLRsupport@cdph.ca.gov.

Once you've completed the telephone training, you can immediately begin electronic blood lead reporting.

Can I get training for fingerstick testing technique?

Blood samples can be contaminated by lead present in the environment. Correct fingerstick technique procedures must be followed to obtain accurate blood lead test results. To learn more about proper fingerstick technique for blood lead testing, call your local Childhood Lead Poisoning Prevention Program. Contact information for local lead poisoning prevention programs as well as the State Branch can be found at: www.cdph.ca.gov/programs/clppb.