

**California Department of Public Health
Environmental Health Laboratory Branch**

Waived Lead Testing (e.g. LeadCare II®)

Laboratories using a waived device for blood lead testing in California must:

- Have a CLIA certificate of waiver, PPMP, compliance or accreditation as appropriate to the level of testing offered by the laboratory.
- Be registered or licensed with the State of California, Laboratory Field Services (LFS).
- Report electronically all blood lead level results, for both adults and children, to the CDPH Childhood Lead Poisoning Prevention Branch (CLPPB).
- Appear on the OSHA List of Laboratories Approved for Blood Lead Analysis, if doing blood level testing for monitoring of occupational exposure.
- Appear on the California Blood Lead Proficiency Assurance Program (CBLPAP) list of proficient laboratories in order to be reimbursed for the analytic phase of blood lead testing through the CDHS Child Health and Disability Prevention (CHDP) program.

Registration or licensure:

For information about obtaining a California registration or license, contact the State of California Department of Public Health (CDPH) Laboratory Field Services (LFS) web site <http://www.cdph.ca.gov/programs/lfs/Pages/default.aspx> and select “Certificates and Licensing” and “Clinical Laboratory Facilities Information”.

Note: For a waived device, the laboratory must follow the manufacturer's recommendations. For users of the ESA LeadCare® II, this means that all blood lead results of 10 µg Pb/dL or greater must be confirmed by sending a venous specimen to a reference laboratory for confirmation by a non-waived method.

Reporting blood lead results:

All blood lead results, for both adults and children, and regardless of level, must be electronically reported to the CDPH Childhood Lead Poisoning Prevention Branch (CLPPB) (California Health and Safety Code, Section 124130). Contact CLPPB at (510) 620-5653 for instructions on electronic reporting of blood lead results.

Occupational Monitoring:

Laboratories that perform blood lead analyses for occupational monitoring of adults must meet federal OSHA accuracy requirements, as demonstrated by successful participation in a blood lead proficiency testing (PT) program, per the OSHA lead standards. To be in compliance with federal OSHA regulations for occupational blood lead testing, a laboratory must participate in the OSHA Blood Lead Laboratories program and must appear on the current OSHA List of Laboratories Approved for Blood Lead Analysis. The use of new, direct read-out portable instruments that are waived from PT requirements under CLIA is still subject to the specific OSHA proficiency requirements. Venous blood should always be used for monitoring adult lead exposures, except where prohibited by medical or other reasons. For a current list of approved laboratories or more information, contact the U.S. Department of Labor's OSHA Salt Lake City Technical Center, Division of Quality Control, Salt Lake City, Utah, at (801) 233-4925 or on the web at <http://www.osha.gov/SLTC/bloodlead/index.html>.

CHDP Reimbursement:

To be eligible for reimbursement for the analytic phase of blood lead testing through the California Department of Health Care Services (DHCS) Child Health and Disability Prevention (CHDP) program, a laboratory must:

- Have their CHDP contract updated to include blood lead testing. Please contact your county CHDP program.
- Be enrolled in proficiency testing (PT) for blood lead and be rated as proficient in the California Blood Lead Proficiency Assurance Program (CBLPAP) administered by the CDPH Environmental Health Laboratory Branch (EHLB). Contact EHLB at (510) 620-2879 or at (510) 620-2876. Programs that provide blood lead proficiency testing materials are:
 - American Academy of Family Physicians, <http://www.aafp.org/online/en/home/practicemgt/pt.html>
 - College of American Pathologists, <http://www.cap.org/apps/cap.portal>
 - State of New York, Wadsworth Center, <http://www.wadsworth.org/testing/lead/ptprogram.htm>
 - Wisconsin State Laboratory of Hygiene, <http://www.slh.wisc.edu/wps/wcm/connect/extranet/pt/>