

* This information is subject to change

Licensure

Facility must: Hold a CLIA Certificate of Waiver or higher and a State Clinical Laboratory License or Permit.

Federal CLIA Certification:

1. The form can be downloaded at: <http://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf>
2. CLIA applications should be mailed to:
Hawaii Dept. of Health
CLIA Program
601 Kamokila Blvd #395
Kapolei HI 96707

State Licensure Process:

1. Laboratories must obtain a Class I, Class II permit or License from the state.
2. Forms and info are obtained from:
Susan Naka, MT (ASCP), MS
Clinical Laboratory Surveyor
Hawaii Dept. of Health Office of Health Care Assurance
601 Kamokila Boulevard, Room 395
Kapolei, Hawaii 96707
Susan.Naka@doh.hawaii.gov
Ph: (808) 692-7420 Fax: (808) 692-747

Patient Testing

Training Tools: www.LeadCare2.com/training

Facility must: Confirm capillary blood lead test results greater than or equal to 5 µg/dL with a venous sample by a reference lab according to pages 31-32 of the Childhood Lead Poisoning Prevention Guidelines at: <https://health.hawaii.gov/cshcn/files/2019/01/Updated-Health-Care-Provider-Packet-HI-CLPPP.pdf>

For questions, please contact:

Derek Priddy, Program Coordinator
Hawaii Childhood Lead Poisoning Prevention Program (HI-CLPPP)
741 Sunset Avenue
Honolulu, HI 96816
Phone: (808) 733-9066 FAX: (808) 733-9068
E-Mail: DOH.LEAD@doh.hawaii.gov

For more information, please visit: lead.hawaii.gov

Quality Control

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

1. Each new lot of test kits.
2. Each new shipment of materials even if it's the same lot previously received.
3. 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

Mandatory:

- Point of Care users are required to send all blood lead test results to the Department of Health Hazard Evaluation and Emergency Response Office (HEER) according to Hawaii Administrative Rule 11-5. HEER uses an electronic surveillance database to track blood lead results. Point of Care users should fill out a confidential, validated spreadsheet with their blood lead test results and email it to HEER each month or contact HI-CLPPP to set up electronic laboratory reporting (ELR) if their system is compatible.

To receive the validated spreadsheet template or to set up ELR, please contact:

Derek Priddy, Program Coordinator
Hawaii Childhood Lead Poisoning Prevention Program (HI-CLPPP)

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Proficiency Testing

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/>

Still Have Questions?

- Contact the LeadCare Product Support Team at (800) 275-0102