

**HAWAII DEPARTMENT OF HEALTH
OFFICE OF HEALTH CARE ASSURANCE**

INSTRUCTIONS FOR CLINICAL LABORATORY PERMIT OR LICENSE APPLICATION,
Form OHCA 110.1 App. (Read BOTH SIDES of this page)

Clinical laboratories are defined as sites performing diagnostic tests on human specimens for the purpose of diagnosis, treatment, or evaluation of the health status of patients.

Hawaii Administrative Rules Title 11 Chapter 110.1 “Clinical Laboratories and Laboratory Personnel” regulates all clinical laboratories performing clinical laboratory tests in Hawaii.

Unless exempted, these laboratories must obtain a Class I Clinical Laboratory Permit, Class II Clinical Laboratory Permit, or Clinical Laboratory License from the Hawaii Department of Health to operate in Hawaii. Permits and licenses must be renewed every 2 years. There is a \$100 fee for an initial application, and a \$75 fee to renew the Permit/License every 2 years.

Class I permits are given to sites where only waived and provider performed microscopy tests are performed. Lists of these tests are available on www.cms.hhs.gov/clia.

Class II permits are given to Medicare certified or state licensed facilities that perform waived, provider performed microscopy, and point of care tests only on the facilities’ patients. Point of care tests are performed by portable instruments or systems that may be transported to the site of the patient.

Licenses are given to sites where clinical laboratory tests are performed that are not limited to waived, provider performed microscopy tests, and point of care tests.

Section 1. Check the box indicating the type of permit or license.

Section 2. Fill in the name of the laboratory, address of the testing site, phone number, and fax number. If the testing site is mobile and not a permanent site, the address of a “home” office can be entered.

Section 3. Fill in the name of the Laboratory Director, Hawaii License category, Hawaii License #, and expiration date.

Section 4. For Class I and II Permits only. Laboratories are required to have a Laboratory Consultant who is licensed in Hawaii as a Clinical Laboratory Director or Medical Technologist if the Laboratory Director named in Section 3 does not have one of these licenses. Fill in the name of your Laboratory Consultant and Clinical Laboratory License #. Information on licensure is available on <https://health.hawaii.gov/statelab/licensing/>.

Section 5. Complete the CLIA Application (CMS-116), Laboratory Personnel Form (HCFA-209), Test Menu form, and Disclosure of Ownership and Control Interest Statement (Form 1513). **NOT APPLICABLE FOR LABS ALREADY CLIA CERTIFIED**

Section 6. The laboratory director must sign and date.

**HAWAII DEPARTMENT OF HEALTH
OFFICE OF HEALTH CARE ASSURANCE**

APPLICATION INSTRUCTIONS FOR A CLINICAL LABORATORY PERMIT OR
LICENSE (Page 2 of 2)

Clinical laboratories in Hawaii are exempted from obtaining a permit or license if they are:

- a) Operated by the U.S. government;
- b) Operated exclusively as a research or teaching laboratory involving no patient services;
- c) Operated by a licensed physician who is serving as the laboratory director and performing diagnostic laboratory tests solely for the physician's own patients;
- d) Operated by a police department of any county performing breath alcohol analysis; or
- e) Conducting a study of public health importance with the written approval of the director of health.

Request for variance or waiver from Chapter 110.1

The Department of Health, upon application, may grant variances or waivers to specific requirements of Chapter 110.1 if the intended protections afforded by the rules are met; and

- 1) The rule would impede experimentation or demonstration of new and innovative approaches to delivery of services, where the approach has the potential to improve service delivery; or
- 2) Strict application would cause undue hardship to the laboratory and equivalent standards affording protection of patient health, safety, and care exist and will be met in lieu of the exact rule requirements.

Clinical laboratories requesting an exemption, variance, or waiver should contact the Office of Health Care Assurance CLIA program at 692-7420 for more information.