

DAVID Y. IGE
GOVERNOR OF HAWAII



VIRGINIA PRESSLER, M.D.
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
STATE LABORATORIES DIVISION (SLD)
2725 WAIMANO HOME ROAD
PEARL CITY, HAWAII 96782-1496

A. Christian Whelen
SLD Administrator

In reply, please refer to:
File: SLD/ADMIN

Medical Marijuana Testing Facility Application

Legal Name of Laboratory or Facility	
Facility Address (physical location of testing)	
Mailing Address if different from physical location	
Name of Director or Manager (person responsible for laboratory results)	Telephone:
	Fax Number:
	E-mail address:
Contact Person	Telephone:
	Fax Number:
	E-mail address:
Quality Assurance Officer	Telephone:
	Fax Number:
	E-mail address:

1. Area(s) of Interest: Check all that apply

Area	Minimum Required Analytes
Chemistry – Potency	(Delta 9)-Tetrahydrocannabinol (THC) Tetrahydrocannabinol Acid (THCA)

	<p>Cannabidiol (CBD)</p> <p>Cannabidiolic Acid (CBDA)</p> <p>Cannabigerol (CBG)</p> <p>Cannabinol (CBN)</p>
Chemistry – Heavy Metals	<p>Arsenic</p> <p>Lead</p> <p>Cadmium</p> <p>Mercury</p>
Chemistry - Pesticides	<p>Pesticides that are regulated by EPA (the U.S. Environmental Protection Agency)</p>
Chemistry – Solvents	<p>Butanes</p> <p>Heptanes</p> <p>Benzene</p> <p>Toluene</p> <p>Hexane</p> <p>Total Xylenes (m, o, p-xylene)</p> <p>Alcohols (e.g., methanol, ethanol, etc.)</p> <p>Ketones (e.g., acetone)</p>
Chemistry – Moisture Content	<p>Moisture content of plant material</p>
Microbiology	<p>Total viable Aerobic Bacteria Count</p> <p>Total Yeast and Mold</p> <p>Total Coliform Bacteria</p> <p>Bile-tolerant Gram Negative Bacteria</p> <p><i>E. coli</i> (pathogenic strains)</p> <p><i>Salmonella</i> species</p> <p><i>Aspergillus fumigatus</i></p> <p><i>Aspergillus flavus</i></p> <p><i>Aspergillus niger</i></p> <p>Mycotoxins</p>

2. Current International Standards for Organization (ISO) 17025 Status for the laboratory:
 - ISO 17025 Accredited
 - Parent company ISO 17025 Accredited
 - Applied for ISO 17025 Accreditation (minimum requirement)
3. Submit electronic versions of the following documents with this application: (e.g., on a USB thumb drive):
 - A. Management Systems

Management System documentation including, but not limited to: a laboratory organization chart including the identification of key personnel by name, lines of authority and responsibilities of personnel, Organizational plans, mission, goals, and objectives, Management objective and the laboratory's administrative policies and procedures, continuous improvement strategy and methods; including systematic monitoring and change management and Management controls to ensure consistent performance.

If this laboratory is part of a larger organization, a chart indicating this laboratory's position within the larger organization and the reporting relationships within the organization.
 - B. Security

A written security policy that describes the methods and devices that will be used to provide security for the medical marijuana samples in the laboratory.
 - C. Facilities

A description of the facilities and equipment that shall be used in the operation of the testing laboratory.

Equipment information including the type of equipment used in medical marijuana testing, performance checks and function verification, testing and calibration schedules, maintenance, and representative records. Include the identification of external maintenance and calibration services if applicable.
 - D. Employees

A list of employees of the laboratory including their education, qualifications and experience.

Training documentation for each employee of the laboratory performing technical and / or administrative procedures. Documentation must include subjects, acknowledgements by trainers And analyst, and the date, time, and place of training.

Documentation that analysts are proficient in the analytical / administrative procedures (initial, 6 months, and annual thereafter). Documentation must include subjects, acknowledgements by trainers and analyst, and the date, time, and place of assessment.

E. Procedures

A list of the method(s) and products used for each medical marijuana analyte. Include the reference and performance characteristics of each method.

Documentation demonstrating that the analytical methods used by the laboratory are appropriate for their intended purpose.

Standard Operating Procedures used by the facility, including but not limited to: statistically representative sampling, sample preparation, reagent and reference standard preparation; the instrument operation; technical procedures and quality control criteria to be used in performing the analysis for each analyte; data recording and calculation of results; data review, storage and reporting.

Sample management including chain of custody, receipt, rejection, handling, storage and disposition of samples of usable medical marijuana.

F. Quality Systems

Quality Assurance (QA) Manual that includes but is not limited to the QA Plan, QA Policies and QA Procedures to be followed by the laboratory.

Most recent Proficiency Test (PT) studies for each analyte, including the date of the PT, the score and any corrective action(s) taken, if required.

The laboratory's most recent inspection(s) by their accreditation body (ideally to ISO 17025 standard) and the laboratory's responses to any findings of non-compliance with standards or recommendations.

The laboratory's accreditation in Hawaii or another jurisdiction, accompanied by the scope of accreditation.

G. Mailing / Delivery Address

Deliver or send all required materials by certified mail to State Laboratories Division, 2725 Waimano Home Road, Pearl City, Hawaii, 96782.

Name of person completing application:		
Please print legibly	Signature	Date

NOTE: Upon notification by DOH of meeting the requirements for certification, applicants must submit a certification fee of \$3000.00 (certified check, cashier's check, or money order only; please no personal or company check) payable to State of Hawaii Department of Health **before** DOH will issue the certificate.