IOWA | Health and Human Services
Division of Compliance and Administration

Medical Cannabis Independent Laboratory Application

Form Instructions

This document collects the necessary information that is required as part of your Iowa Independent Medical Cannabis Laboratory license application.

In addition to the forms included in this packet, you are also required to provide the following supporting documentation:

- Proof of standard ISO/IEC 17025 accreditation by an international organization for standards-approved accrediting body
- Controlled substance registration certificate from the United States Drug Enforcement Administration
- Certificate of registration from the Iowa Board of Pharmacy
- Business Ownership Disclosure Questionnaire with attached business ownership chart
- Premises map or sketch

Read each section carefully and review the attached appendices.

Once completed, send this application along with the supporting documentation to:

cann.compliance@hhs.iowa.gov OR

Iowa Health and Human Services
Bureau of Cannabis Regulation
321 East 12th Street
Des Moines, Iowa 50319

Once received, the Iowa Department of Health and Human Services – Bureau of Cannabis Regulation (HHS) will provide email receipt confirmation of your application. All communications will be by email and/or telephone unless specifically denoted otherwise by the licensee.

Questions regarding the application process or requirements may be sent to cann.compliance@hhs.iowa.gov or you may call (877) 214-9313.

Medical Cannabis Independent Laboratory Application

1 – Business Information

Laboratory Name (DBA):

Business Legal Entity Name:

Premises Address:

Mailing Address:

Primary Contact Name:

Primary Contact Email Address:

Primary Contact Phone Number:

2 - Premises Information

Yes	No	
☐	☐	Is the proposed premises on federal or public land?
☐	☐	Is the proposed premises on any reservation of tribal trust land of a federally recognized Indian tribe?
☐	☐	Is the proposed premises fully enclosed by permanent walls and doors?
☐	☐	Is the proposed premises at the same address as a licensed medical cannabis manufacturer?
☐	☐	Is the proposed premises at the same address as a licensed medical cannabis dispensary?
☐	☐	Is the proposed premises at the same location as a business with a liquor license or food license?

I attest that provided with this application is a map or sketch of the premises proposed for licensure, including the defined boundaries of the premises, the location of any primary residence located on the same tax lot as the licensed premises, and a scaled floor or plot plan sketch of all enclosed areas.

3 - Interest Disclosures

I attest that provided with this application is a Business Ownership Disclosure Questionnaire with an attached business ownership chart. I further attest that this laboratory has no equity ownership interest in a medical cannabis manufacturer.

4 - Attestations

By signing this form, I attest each of the following statements are true. I understand HHS, may require proof and/or inspection of any of the below information and referenced documents at any time.

4.1 Laboratory Requirements

I attest that the laboratory holds the following accreditations and/or certifications and verification of each is provided with this application:

- Standard ISO/IEC 17025 accreditation by an international organization for standards-approved accrediting body
- Controlled substance registration certificate from the United States Drug Enforcement Administration
- Certificate of registration from the Iowa Board of Pharmacy

I understand the licensee is responsible for maintaining these accreditations and certifications and providing updated proof of good standing to HHS.

4.2 Proficiency Testing

I understand that the licensee is required to comply with proficiency testing to evaluate the licensee's performance and capabilities in conformance with proficiency testing requirements established by HHS. (See Appendix A)

I understand that the licensee is required to perform proficiency testing and/or verification and validation for all methods related to medical cannabis testing.

4.3 Laboratory Acceptance and Criteria Document

I understand that licensee requirements and best practices for testing and analysis of medical cannabis are contained within v4.3 Laboratory Acceptance and Criteria Document. The document is published by HHS with content collaboration with medical cannabis manufacturers and laboratories.

4.4 Data Maintenance, Transmission and Reporting

I understand that the licensee is responsible for data tracking, maintenance, recordkeeping and reporting according to IAC 641-154 and the Laboratory Acceptance and Criteria Document. All data and records related to medical cannabis are subject HHS review and inspection.

4.5 Security and Personnel

I understand that the licensee shall maintain a security policy to prevent the diversion of medical cannabis samples, develop and maintain a controlled access system to limit and track access to restricted areas, implement a video monitoring and surveillance system, and

maintain a personnel identification system to control and monitor employee access and restricted access areas.

4.6 Inspections and Audits

I understand that the licensee is responsible for establishing and implementing the requirements set forth in Iowa Code chapter 124E and Iowa Administrative Code 641-154. The licensee premises is subject to reasonable inspection by the Department or its designee. I further understand that licensee requirements are subject to Department inspection and audit at any time.

4.7 Compliance and Enforcement

I understand that the licensee is governed by Iowa Code chapter 124E and Iowa Administrative Code 641-154. I have reviewed the requirements of the licensee as required by Iowa Code chapter 124E and 641 IAC 154. The licensee is responsible for compliance with applicable state and federal law. I acknowledge that failure to maintain compliance may result in denial, suspension or revocation of a medical cannabis laboratory license.

4.8 Communications

I understand that any communications with the reference lab, related and including but not limited to, methodologies, validation or proficiency testing, must include HHS. Concerns and issues will all be routed through HHS.

5 – Testing Services

Comprehensive compliance testing includes four services. An independent lab is not required to provide all testing services. Requirements for each service are provided in the table below. Comprehensive compliance testing requirements can be found in v4.3 Laboratory and Acceptance Criteria Document and Testing Overview Process hosted on the program's website:

Testing Service	Testing Service Description	Matrix, Form	Analyte(s) Screened	Method, Instrumentation Required
1. Vaporizer Cartridge Metals Validation	Validation of cartridges or metals leaching, prior to use	Conducted on non-regulated reference material	Heavy metals	Acid digestion, ICP-MS
2. 3rd Party Hemp-Derived Cannabinoids	3rd party cannabinoids screened for process lot analytes	Isolate or crystalline	Solvents	HS-GC-FID, HS-GC-MS
			Heavy Metals	Acid digestion, ICP-MS
			Pesticides	LC-MS/MS, GC-MS/MS
			Solvents	HS-GC-FID, HS-GC-MS

3. Medical Cannabis "Process Lots"	Screening concentrates used in final products	Cannabis concentrates of various consistencies	Heavy Metals	Acid digestion, ICP-MS
			Pesticides	LC-MS/MS, GC-MS/MS
4. Medical Cannabis "Package Lots"	Screening final packaged products	Vaporizers, concentrates, tinctures, capsules, topicals, etc.	Cannabinoid Content	HPLC
			TAMC	Culture-based methods
			TYMC	Culture-based methods
			Salm., STEC, *Asp.*	Molecular Screening, Culture confirmation

Please indicate the testing services the independent lab intends to provide below.

These attestations will be used to determine which methods an independent lab must verify in Stage 2 proficiency tests. Simplified methods that correlate to the indicated testing services will be provided to prospective labs by the reference laboratory before Stage 2 proficiency tests to guide the development of their own methods.

A prospective lab is responsible for all costs associated with conducting the proficiency tests required to receive approval to analyze go-to-market samples, including procurement of the reference materials necessary for verifications. Stage 1 and Stage 2 proficiency tests must be satisfied before a prospective lab may analyze go-to-market samples:

Testing Service	Intent to Offer Service
1. Vaporizer Cartridge Metals Validation ▪ Heavy metals screening on vaporizer cartridges procured by manufacturers, prior to being filled with regulated material	☐ **Yes** ☐ **No**
2. 3rd Party Hemp-Derived Cannabinoids ▪ Solvent, pesticide, and heavy metals screening on 3rd party hemp concentrates incorporated into final products	☐ **Yes** ☐ **No**
3. Medical Cannabis "Process Lots" ▪ Solvents, pesticide, and heavy metals screening on cannabis concentrates incorporated into final products	☐ **Yes** ☐ **No**
4. Medical Cannabis "Package Lots" ▪ Cannabinoids content and microbiological screening of final packaged products prior to delivery to dispensaries	☐ **Yes** ☐ **No**

6 – Acknowledgment

I hereby acknowledge that I have carefully reviewed the contents of this application and supporting documentation and understand that

I confirm that to the best of my knowledge and belief, the information contained herein is true, accurate, and complete. I understand that any misrepresentation or omission may have legal or administrative consequences.

Each applicant whose name will appear on the license certificate must sign this acknowledgment.

Applicant Name(s)	Signature	Date
	_____	
	_____	
	_____	
	_____	

Appendix A - Independent Laboratory Proficiency Testing (PT) Program Overview

Introduction

This document provides guidance to prospective independent laboratories on the required PTs prior to receiving approval to test medical cannabis products in Iowa, as well as ongoing PTs as a function of annual review and renewal.

PT Program Overview

A prospective independent laboratory must have submitted a complete Independent Laboratory Application and satisfied the basic requirements of laboratories to enter Stage 1. Required PTs and Verification Studies for independent labs are conducted in three stages:

Stage 1: Inter-Laboratory Potency Proficiency Test
- Performance Criteria of Stage 1 must be satisfied to enter Stage 2

Stage 2: Method-Specific Verification Studies
- Performance Criteria of Stage 2 must be satisfied to receive approval to analyze go-to-market samples

Stage 3: Ongoing, Annual Inter-Laboratory Potency Proficiency Test
- Annual repeat of Stage 1 establishes inter-lab comparability and satisfies annual review requirements for independent laboratories.

Stage 1: Inter-laboratory Potency Proficiency Test

Purpose

The purpose of the initial inter-laboratory potency PT is to establish comparability between a prospective independent lab and the reference lab, the State Hygienic Lab at the University of Iowa (SHL). This PT demonstrates a core competency for analysis of a priority analyte by a prospective laboratory. It will also serve as the baseline PT for the annual renewal process for independent laboratories. This inter-laboratory PT will be conducted using an accredited PT Provider (PTP).

PT Sample Composition and Analysis

The reference or sample material for this PT will be an "*oil-matrix with >0.3% THC content*," and the performance criteria is quantifying the cannabinoid content for THC.

PT Provider Accreditation and Procurement

HHS will collaborate with an independent lab candidate to procure a PTP. PTPs must be a not-for-profit organization that is accredited to ISO/IEC 17043 and authorized to provide PTs to ISO 17025 laboratories and be able to ship cannabis across state lines. Prospective laboratories are responsible for all costs associated with conducting the PT.

Required Notice and PT Scheduling

Upon procuring a PTP, the prospective independent laboratory must notify HHS on their proposed PTP and date of PT study. This is to accommodate scheduling and procurement for SHL's participation in the PT.

Test Instruction and Reporting

This potency PT must be an oil-matrix reference material with >0.3% THC content and be administered by an ISO/IEC 17043 PTP. The required mechanisms for reporting will be determined by the PTP, with the ability to provide PT results to HHS.

Performance Evaluation Criteria

The performance and acceptance criteria for the potency PT will be determined by the PTP. If the prospective lab's results are within the acceptance criteria of the PT, they are cleared to begin planning for Stage 2 Verification Studies.

Retesting

The ability to contest or retest nonconforming results will be determined by specific PT and PTP. Failure to pass acceptance of a PT does not prohibit a prospective independent lab from engaging additional Stage 1 PTs.

Stage 2: Method and Matrix-Specific Verification Studies

Purpose

Following acceptance of Stage 1 PTs, the purpose of method-specific verification studies are to verify that a prospective independent laboratory can conduct the testing services as indicated in their Independent Laboratory Application, for all of the respective analytes and action levels pursuant the most recent version of the Laboratory Acceptance & Criteria Document.

Use of Existing, Validated Methods

The specific methodology for conducting the testing for services as indicated by prospective laboratory in their application will be provided by SHL in a manner SHL determines. Methods are not required to be followed verbatim by the prospective lab, but core methodological requirements will be specified in this guidance.

Reference Sample Procurement

Prospective laboratories are responsible for working with licensed manufacturers for the procurement of the necessary process or package lot reference samples to conduct method and matrix verification studies. A prospective laboratory is responsible for all costs associated with reference materials and verification studies. HHS will work with manufacturers on compliant transfer of sample materials.

Required Notice and Verification Study Scheduling

The prospective independent laboratory must notify HHS no later than three weeks prior to the planned date of the verification study. This is to accommodate scheduling for review of the verification study results.

Test Instruction and Reporting

Upon securing reference materials from manufacturers and scheduling their verification studies, a prospective independent laboratory will use the validated methods provided to them to conduct the verification studies. At a minimum, the following performance criteria must be addressed for each method and matrix: Selectivity, Limit of Detection and Limit of Quantification, Working Range,

Analytical Sensitivity, Trueness, Precision, Measurement Uncertainty, and Ruggedness. Study reports will be provided to the HHS and SHL immediately upon completion and QA.

Performance Evaluation Criteria

Performance criteria will be established by the action levels and tolerances pursuant to the most recent version of Laboratory Acceptance and Criteria Document. Laboratories must be capable of meeting quantification, accuracy, and precision requirements laid out in this document for each method and matrix it intends to perform. SHL will support HHS in interpreting verification study results. If an independent lab satisfies verification of their methods for the services they intend to provide, they will receive written approval from HHS to conduct go-to-market testing.

Retesting

If a prospective laboratory does not provide acceptable results for any product form or analyte pursuant to the Laboratory Acceptance and Criteria Document, they are not prohibited from reengaging Stage 2 Verification Studies.

Stage 3: Ongoing, Annual Inter-Laboratory Potency Proficiency Test

Purpose

The purpose of Stage 3 PTs is to establish ongoing inter-comparability between any independent labs and the reference lab (SHL) on the same priority analyte. In addition to confirming required certifications, it also serves as an annual review for independent laboratories.

Test Instruction and Reporting

Please see Stage 1 Inter-Laboratory Potency PT. This is a repeat of the Stage 1 process for initial onboarding.