



STATE OF FLORIDA
DEPARTMENT OF HEALTH

Application for Marijuana Testing Laboratory Certification

This application for Marijuana Testing Certification (Application) is designed to allow the Florida Department of Health, Office of Medical Marijuana Use (OMMU) to certify Marijuana Testing Laboratories (MTLs) to operate within the state.

This application is divided into three parts:

- I. Part I requires the applicant to provide basic information about the applicant and Application.
- II. Part II requires the applicant to provide the OMMU with detailed items to demonstrate the ability to operate as a MTL as set forth below in Sections 1-13.

<u>Section</u>	<u>Title</u>	<u>Page Limit</u>
1	Technical Ability: Accreditations and/or Certifications	#
2	Technical Ability: Microbial Analysis	#
3	Technical Ability: Chemical Analysis	#
4	Technical Ability: Physical Analysis	#
5	Technical Ability: On-site Inspections	#
6	Technical Ability: On-site Auditing	#
7	Accountability: Premises	#
8	Accountability: Operations	#
9	Personnel: Laboratory Director	#
10	Personnel: Staff	#
11	Financials: Certified Financial Documents	No limit
12	Financials: Business Structure	#
13	Infrastructure: Facilities	#

- III. Part III provides information on Application submittal, the required application fee, and includes the applicant signature page.

Application Instructions

APPLICATIONS MUST BE SAVED AS OPTICAL CHARACTER RECOGNITION PORTABLE DOCUMENT FORMAT (OCR PDF) FILES AND BE SUBMITTED ON A USB FLASH DRIVE.

1. Organization: When submitting an Application for certification as an MTL, applicants must organize the Application so that each document submitted with the Application is labeled accurately with the section number of the Application to which it corresponds.

Blind Grading

With the exception of Sections 9, 11, and 12, Part II of the Application will be evaluated using a blind grading method and must be de-identified. Each Application will be assigned a random application number. Part II will be separated from Parts I and III and will be distributed to the evaluators electronically, identified only by the random application number.

It is important that Part II, Sections 1-8, 10, and 13 are prepared without reference to proper nouns or other identifying information for individuals and business entities.

The only sections that should include identifying information are Section 9 – Personnel: Laboratory Director, Section 11 – Financials: Certified Financial Documents, and Section 12 – Financials: Business Structure.

An Application that includes information that identifies the organization, consultants, entities, or people in Sections 1-8, 10, and 13 will be redacted prior to forwarding to the evaluators for grading.

Each section must be saved as a separate file on the USB flash drive. Files must be named using the following format: Section Number – Section Title

Examples: Section 1 – Technical Ability: Accreditations and/or Certifications
 Section 2 – Technical Ability: Microbial Analysis

Applications not submitted on USB flash drives or in the required format will be denied.

2. Page Limit: Narrative responses must be double-spaced and written in Times New Roman, 12 point font with 1-inch margins. Applicants are required to abide by the page limits for each section. ***Pages in excess of the page limit will be removed from the Application prior to evaluation.***

3. Addendums: Sections 1-7, 9, and 13 allow for the submission of specific documentation such as leases or property sketches, or other information that would be difficult to express in a narrative response, such as photographs, maps, diagrams, or blueprints. Such documents may be submitted as addendums, as indicated in those sections. Addendums must be included with the section that they support and do not count against that section's page limit.

Addendums are not an opportunity for applicants to provide additional narrative responses in excess of a section's page limit. Additional narrative responses provided in addendums will be removed prior to evaluation and will not be considered.

4. Application Evaluation: All Applications must be compliant with the minimum statutory mandates of section 381.988, Florida Statutes, and with the requirements of Rule 64-4.016, F.A.C. Applications that do not comply with this section and rule shall not be approved for certification as an MTL.

Evaluators shall determine whether an applicant has adequately met the minimum acceptable criteria for certification as an MTL. Only applicants that have been found to adequately meet the minimum acceptable criteria of each section of this Application shall be certified as an MTL. Evaluators shall assess a section's adequacy according to the rubric below:

The applicant satisfactorily addressed all items and provided all necessary documentation. The provided responses and documentation demonstrated competency and accountability. Most items had multiple, specific examples of experience and knowledge. Most plans are clear, detailed, well documented, and thorough. Most supplemental information is clear and legible. When necessary the applicant provided documentation for most representations of future performance. Responses related to financials reflect that the applicant is not owned or controlled by a medical marijuana treatment center, and there are clear lines of authority within the applicant's organization.

5. Redactions and Public Records Law: Applications are public records. Any exemptions to public records laws must be identified at the time the Application is submitted. In order to claim a public records exemption, the applicant must provide a redacted copy of the Application with the statutory basis for each exemption clearly identified.

UNLESS INFORMATION FALLS UNDER ANOTHER PUBLIC RECORDS EXEMPTION, FAILURE TO SPECIFICALLY AND CLEARLY IDENTIFY INFORMATION CLAIMED AS EXEMPT AS A TRADE SECRET OR FAILURE TO PROVIDE A REDACTED COPY OF THE APPLICATION AT THE TIME OF SUBMISSION WILL RESULT IN THE RELEASE OF THE FULL APPLICATION IN RESPONSE TO PUBLIC RECORDS REQUESTS.

Part I

Applicant:

Name: _____
(Name must be the same as the name registered with the state)

Mailing Address (if different):

Street Address City ZIP Code

Contact Name: _____

Phone Number: _____ Email Address: _____

Laboratory Director:

Name of Medical Director Employed by the MTL: _____

Mailing Address: _____
Street Address City ZIP Code

Phone Number: _____ Email Address: _____

Provide a list of all owners, managers, officers, and board members indicating the date of each individual's most recent level 2 background screening. With each name, include their position or proposed position in the proposed MTL.

Part II

Responses to this part must be in accordance with the instructions set forth on pages 2 – 3.

Section 1 – Technical Ability: Accreditations and/or Certifications (# page limit)

1. Proof of a current, valid ISO/IEC 17025:2017, or a current, valid ISO/IEC 17025:2005, accreditation or certification:
 - a. All material submitted for initial ISO/IEC 17025:2017 or ISO/IEC 17025:2005 accreditation or certification;
 - b. All material submitted for the most recent ISO/IEC 17025 audit, to include either 2005 or 2017 standards, if applicable;
 - c. A certificate or other document showing that the MTL applicant has met the requirements of Rule 64-4.016(3), F.A.C.;
 - d. Materials showing the qualifications of the entity or person that awarded the ISO/IEC 17025:2017 or ISO/IEC 17025:2005 accreditation or certification; and
 - e. An initial certification report or most recent audit report from an independent, third-party auditing body.
2. Proof of a current valid AOAC International, Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals – An Aid to the Interpretation of ISO/IEC 17025:2005 (2015) (AOAC International ISO/IEC 17025:2005), or the ability to meet these requirements.
 - a. All material submitted for initial AOAC International ISO/IEC 17025:2005 accreditation or certification;
 - b. All material submitted for the most recent AOAC International ISO/IEC 17025:2005, if applicable;
 - c. A certificate or other document showing that the MTL applicant had met the requirements of Rule 64-4.016(3), F.A.C.;
 - d. Materials showing the qualifications of the entity or person that awarded the AOAC International ISO/IEC 17025:2005 accreditation or certification; and
 - e. An initial certification report or most recent audit report from an independent, third-party auditing body.
3. Results from most recent proficiency testing, if applicable.

Section 2 – Technical Ability: Microbial Analysis (# page limit)

1. Provide standard operating procedures that will ensure a consistent analysis of dry marijuana, derivative products, and edibles for the following microbial analyses:
 - a. Any *Escherichia coli*;
 - b. Any *Salmonella* species;
 - c. Total fungus, yeast, mold;
 - d. Aflatoxins (B1, B2, G1, G2); and
 - e. Ochratoxin A.
2. Provide standard operating procedures for the following laboratory procedures:
 - a. Proper aseptic technique;
 - b. Disposal of biological waste;
 - c. Autoclave procedures; and

- d. Other standard operating procedures the applicant finds pertinent to microbial analysis.

Section 3 – Technical Ability: Chemical Analysis (# page limit)

1. Provide standard operating procedures that will ensure a consistent analysis of dry marijuana, derivative products, and edibles for the following chemical analyses:
 - a. Residual solvents;
 - b. Metals;
 - c. Pesticides, herbicides, and fungicides; and
 - d. Cannabinoids.
2. Provide standard operating procedures for the following laboratory procedures:
 - a. Pesticide, herbicide, and fungicide extraction;
 - b. Metals digestion;
 - c. Dilutions;
 - d. Instrument calibration;
 - e. Instrument maintenance;
 - f. Laboratory glassware cleaning;
 - g. Hazardous waste disposal; and
 - h. Other standard operating procedures the applicant finds pertinent to chemical analysis.

Section 4 – Technical Ability: Physical Analysis (# page limit)

1. Provide standard operating procedures that will ensure a consistent analysis of dry marijuana, derivative product, and edibles for the following physical analyses:
 - a. Water activity;
 - b. Moisture content; and
 - c. Filth and foreign material.
2. Provide standard operating procedures for the following laboratory procedures:
 - a. Instrument calibration;
 - b. Instrument maintenance; and
 - c. Other standard operating procedures the applicant finds pertinent to physical analysis.

Section 5 – Technical Ability: Inspections (# page limit)

1. Provide a description of the applicant's planned inspection protocol, including the following:
 - a. Frequency of inspections;
 - b. Systems, equipment, and procedures of interest, including:
 - i. Equipment used in the preparation and analysis of marijuana testing;
 - ii. Computer systems and software;
 - iii. Ventilation and exhaust systems;
 - iv. Safety equipment, facilities, and location;
 - v. Standard operating procedures; and
 - vi. Maintenance contracts for any of the above equipment, systems, or software.

Section 6 – Technical Ability: Auditing (# page limit)

1. Provide a description of the applicant's planned audit protocol, to include the following:
 - a. Frequency of audits;

- b. Systems, equipment, and procedures of interest, including:
 - i. Any laboratory inventory management system;
 - ii. Analytical report generation;
 - iii. Raw analytical data storage;
 - iv. Hard copy analytical report archiving;
 - v. Equipment and instrument maintenance logs;
 - vi. Staff training and competency reports;
 - vii. Accreditation or certification reports; and
 - viii. Proficiency testing reports

Section 7 – Accountability: Premises (# page limit)

1. A floor plan of the laboratory facility, to include secure storage areas, or proposed floor plans for proposed facilities demonstrating security measures, including the following:
 - a. Locking options for each means of ingress and egress;
 - b. Alarm systems that:
 - i. Secure all entry points and perimeter windows and
 - ii. Are equipped with motion detectors, pressure switches and duress, panic, and hold-up alarms.
 - c. Video surveillance system that:
 - i. Records continuously 24 hours per day;
 - ii. Has cameras in fixed places that allow for the clear identification of persons and activities in the controlled areas of the premises, including secure storage, sample preparation, and sample analysis areas;
 - iii. Has cameras fixed in all entrances and exits to the premises which record both indoor and outdoor and ingress and egress vantage points;
 - iv. Has the capability of recording clear images and displays the time and date of the recording;
 - v. Demonstrates a plan for retention of video surveillance recordings for at least 45 days.
 - d. Outdoor lighting;
 - e. Name and function of each room; and
 - f. Layout and dimensions of each room.
2. Security and storage plans for each facility, to include:
 - a. Plans to ensure all marijuana is stored in a secured locked room or vault; and
 - b. Plans to ensure at least two employees, or security contractors, are on the premises when marijuana is being received and during any phase of testing.
3. A plan to ensure compliance with federal, state, and local regulations regarding sanitation and waste disposal, including procedures for the storage, handling, transportation, and management of solid and liquid waste generated during marijuana testing

Applicants may provide floor plans to demonstrate the security measures required by this section as addendums. Floor plans submitted as addendums are limited to # pages.

Section 8 – Accountability: Operations (# page limit)

1. Diversion and trafficking prevention procedures, including:

- a. A plan for tracking and securing marijuana throughout an applicant's inventory process, which includes a laboratory inventory management system;
 - b. Description of the laboratory inventory management system to be used by the applicant;
 - c. A description of personnel qualifications and experience with chain of custody, laboratory inventory management systems, and/or other tracking mechanisms;
 - d. A description of personnel reserved solely for security purposes; and
 - e. A marijuana waste disposal plan.
2. A transportation plan, including:
- a. The use of transportation manifests that:
 - i. Are generated from the seed-to-sale tracking system or a laboratory inventory management system;
 - ii. That include the:
 1. Departure date;
 2. Name and address of the originating medical marijuana treatment center (MMTC) or MTL;
 3. Quantity and form of product to be delivered;
 4. The marijuana's unique identifier;
 5. Arrival date and estimated time of arrival;
 6. Delivery vehicle make and model, and license plate number; and
 7. Name and signature of the employees delivering the product.
 - iii. Are retained for at least three (3) years.
 - b. Requirement that at least two (2) persons are on site to receive marijuana for testing.
3. Methods of screening and monitoring employees, including a plan to ensure all owners, managers, board members, officers and employees are in compliance with the statutory requirement to clear the background screening requirement of section 381.986, Florida Statutes.
4. Policies and procedures for recordkeeping.
5. An emergency management plan.
6. Example of document used to report testing results.

Section 9 – Personnel: Laboratory Director (# page limit)

PLEASE NOTE THAT APPLICANTS ARE PERMITTED TO DESIGNATE ONLY ONE LABORATORY DIRECTOR. RESPONSES TO THIS SECTION SHOULD BE RELATED TO THE LABORATORY DIRECTOR LISTED IN PART I OF THIS APPLICATION ONLY. INFORMATION REGARDING ADDITIONAL SCIENTISTS INVOLVED WITH THE MTL CAN BE INCLUDED IN SECTION 12 OF THE APPLICATION.

1. Specialty area, if any.
2. Experience or knowledge of the following:
 - a. Good manufacturing practices;
 - b. Analytical and organic chemistry;
 - c. Analytical laboratory methods; and
 - d. Analytical laboratory quality control, including a laboratory inventory management system.
3. Experience or knowledge related to the following:
 - a. Extraction techniques;
 - b. The manufacture of medical marijuana products, and

- c. Botanical medicines.
4. Description of how the laboratory director employed by the applicant will supervise the activities of the laboratory, including marijuana handling, secure storage, sample preparation, sample analysis, hazardous waste disposal, marijuana waste disposal, instrument maintenance, quality assurance and quality control procedures, and chain of custody.
5. Description of how the applicant will ensure it has a laboratory director at all times.
6. Description of how the applicant will ensure that its laboratory director, and other owners, managers, and employees will refrain from engaging in any conflict of interests with any MMTCs, including falsifying results or entering into other inappropriate relationships.
7. A copy of the proposed laboratory director's CV or resume.

Section 10 – Personnel: Staff (# page limit)

1. Provide an organizational chart illustrating the supervisory structure of the applicant, including all owners, officers, board members, managers, and employees. Supervisory positions on the organizational chart should match the positions, or proposed positions.
2. Provide a list of current and proposed staffing, including positions, duties, and responsibilities. Applicants may note positions that have been filled, but may not include the individual's name. Please include the following information for filled positions:
 - a. Professional licensure disciplinary action in all jurisdictions; and
 - b. Any awards, recognition, or relevant experience.
3. Provide plans and procedures for loss of key personnel.
4. Provide plans for alcohol and drug-free work place.

Section 11 – Financials: Certified Financial Documents (no page limit)

1. Provide audited, certified financials of the applicant issued within the immediately preceding 12 months.
 - a. Certified financials must be the applicant's. Certified financials for parent companies, subsidiaries, or other entities that are not the applicant itself will not be accepted.
 - b. There is no page limit for this section. However, only the certified financial statements may be submitted. Any additional materials that are not part of the certified financials will be removed and not considered in scoring.

Section 12 – Financials: Business Structure (# page limit)

1. Provide an explanation of the applicant's corporate structure, including:
 - a. The applicant's business form;
 - b. All owners of the applicant;
 - c. All individuals and entities that can exercise control of the applicant;
 - d. All individuals and entities that share in the profits and losses of the applicant;
 - e. All subsidiaries of the applicant;
 - f. Any other individuals or entities for which the applicant is financially responsible;
 - g. A description of the assets and liabilities of the applicant and the applicant's subsidiaries; and
 - h. Any pending lawsuits to which the applicant is a party.
2. Any lawsuits within the past seven (7) years to which the applicant was a party.

3. All financial obligations of the applicant that are not listed as a “liability” in the certified financials; including loans, notes, or any other debt that could be converted to ownership in the applicant.
4. A description of the ability or plan to expand any testing of marijuana.
5. A statement that a person or entity seeking to be certified as an MTL is not owned or controlled by an MMTC.

Documentation regarding the applicant’s business structure must support the response to this section and may not be used to supply additional narrative response.

Section 13 – Infrastructure: Facilities (# page limit)

1. Provide a list including the locations of all properties the applicant plans to utilize to test marijuana, if selected. Designate whether properties are owned or leased.
NOTE: Successful applicants will be required to provide documentation that they have moved forward with securing the properties identified in their Application. Failure to meet the representations made in the Application for certification as an MTL is grounds for revocation.
2. Provide a sketch or other illustration approximating the property boundaries, land topography, vegetation, proposed and/or existing structures, easements, wells, and roadways for each property proposed that will be utilized in testing marijuana.

Applicants may provide sketches of land that will be utilized for testing and proof of zoning as addendums to this section, not to exceed # pages. Ownership documentation, sketches, and proof of zoning submitted as addendums do not count against the page limit for this section. Information in any addendum to this section must support the response to this section and may not be used to supply additional narrative response.

Part III

Completed Applications must be delivered to the Department of Health at 4052 Bald Cypress Way, Tallahassee, Bin M-01, Florida 32399.

The Application MUST include:

1. A non-refundable \$##### application fee in the form of a money order or cashier's check made payable to the Florida Department of Health;
2. A list of ALL materials for which the applicant claims ANY public records exemption, including a specific legal citation to the exemption; and
3. A full proposed redacted version of the Application, if applicable.

The completed Application, along with supporting documents must be submitted on a USB flash drive. Applications submitted in hard copy form will be denied.

The undersigned applicant/representative hereby agrees to operate the MTL described in this Application in accordance with the requirements of sections 381.986 and 381.988, Florida Statutes, and all Department of Health rules and regulations.

The information contained in this Application and the attached addendums required, which serves as a basis for licensure, is true and correct. I understand that any misrepresentation of the facts in this Application, or failure to comply with the requirements of statutes, regulations, and rules, is grounds for denial or revocation of MTL certification approval.

Approved MTLs with an active certification must comply with all rules or regulations as they are adopted regardless of the representations made in their initial Application.

I understand that knowingly making a false statement in writing with the intent to mislead a public servant in the performance of his or her official duty is guilty of a misdemeanor of the second degree, punishable as provided in sections 775.082 or 775.083, Florida Statutes.

Signature of Applicant/Representative

Date

Name of Applicant/Representative (print or type): _____