Medical Cannabis Laboratory Approval Program

APPLICATION PROCESS AND REQUIRED DOCUMENTATION

The Medical Cannabis Laboratory Application consists of three-steps to thoroughly assess applying laboratories.

1. The laboratory must submit the application and all required documentation
2. Laboratories that meet the requirements will be contacted for a site visit
3. Minnesota Department of Health Approval

Once a laboratory has received MDH approval, the Minnesota medical cannabis manufacturers are free to establish contract relationships.

*It is required that all approved laboratories achieve ISO 17025 certification.

Step 1: Application and Documentation

In compliance with the Medical Cannabis Registry Program under Minnesota Statutes, sections 152.22 through 152.37, a laboratory requesting approval to provide testing services to the state’s medical cannabis manufacturers must supply the following information:

1. Completed application form supplied by the Commissioner
2. Signed and Notarized attestation form stating operational and financial independence from all Minnesota medical cannabis manufacturers
3. Quality Assurance Manual (see Appendix A for requirements)
4. Standard Operating Procedure (see Appendix B for requirements)
5. Sample handling, receipt and acceptance procedures and policies (or reference if located in SOP or QM)
6. Demonstration of laboratory capability and acceptable performance through existing certificates/approvals, documented demonstrations of analytical capabilities and documented and acceptable proficiency testing samples from an approved provider
7. Method validation procedures for testing methods
8. The name and educational qualifications of at least one technical manager responsible for achieving and maintaining the quality and analytical standards of practice
Step 2. Onsite Visit

The purpose of the onsite visit is to determine the ability of the laboratory to conduct testing for medical cannabis product for the scope of accreditation requested. The following records may be reviewed at the onsite visit. Other records may be requested, if deemed necessary.

1. Detection Limits
2. Training Records
3. Temperature Logs and Calibration Records
4. Balance Logs and Calibration Records
5. Equipment Maintenance Logs
6. Analytical Run Logs/Bench Sheets
7. Microbiology Logs (media, autoclave, sterility checks)
8. Proficiency Results
9. Glassware calibration logs
10. Analytical Test Reports

Step 3. MDH Approval

Once site visits are completed and documented, MDH will make a determination of whether the laboratory is approved. If approved MDH will indicate with analytes and methods the laboratory is approved to perform for Minnesota medical cannabis manufacturers.

Manufacturer Agreements

Once approval has been communicated, manufacturers will contract with one or more of the approved independent laboratories to test medical cannabis.
Appendix A

Quality Manual Requirements:

The quality manual is a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users.

The laboratories quality manual must include or reference at a minimum the following sections:

1. Title page with name, address and phone number of laboratory contact person
2. Effective date of revision
3. Approval signatures (technical director, quality manager, and lab director)
4. Organizational chart
5. Document control procedures
   a. Procedure for document approval, issuance, and change. The laboratory must ensure that obsolete documents are suitably marked.
6. Job descriptions
7. Procedures for traceability of measurements
   a. Procedure to provide documented historical reconstruction of all laboratory activities that produced the analytical data
8. List of accredited methods
9. Contract review
   a. Procedure to ensure that the client requirements, including the method to be used, are defined, the laboratory has the resources to perform the work, and the appropriate test method is selected to meet the clients’ needs
10. Test procedures (SOP references)
11. Sample handling
12. Major equipment
13. Reference standards
   a. Procedure for the calibration of all reference standards (e.g. standards, weights, thermometers, balances)
14. Calibration, verification and maintenance of equipment
15. Verification procedures (e.g. PT samples, split samples, use of reference materials)
16. Corrective action procedures
   a. Procedure to investigate and resolve all instances of non-conformance with policies and/or test methods
17. Handling complaints
   a. Procedure for the resolution of complaints received from customers.
18. Protecting confidentiality
19. Internal audit
   a. Procedure and frequency of internal audits.
20. Data review
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a. Procedure for data review prior to release of results
21. Training personnel including data integrity and ethics
22. Reporting analytical results
   a. Include sample test report template
   b. Include list of qualifiers
23. Table of contents, lists of references, glossaries and appendices
Appendix B

Standard Operating Procedure Manual Requirements

A standard operating procedure is a written document that details the method for an operation, analysis, or action, with thoroughly prescribed techniques and steps. SOPs are officially approved as the methods for performing certain routine or repetitive tasks.

The laboratory's standard operating procedure manuals must include at a minimum the following sections for each method:

1. Identification of the method/technology (e.g. GC/MS)
2. Applicable matrix or matrices
3. Limits of detection and quantitation
4. Scope and application, including parameters to be analyzed;
5. Summary of the method
   a. List sample volume, extraction, digestion, concentration, other preparation steps employed, the analytical instrumentation and detector system(s), and the techniques used for quantitative determinations.
6. Definitions;
7. Interferences;
   a. This section should discuss any known interferences specific to the method employed
8. Safety;
9. Equipment and supplies;
10. Reagents and standards
   a. Provide sufficient details on the concentration and preparation of reagents and standards to allow the work to be duplicated, but avoid lengthy discussions of common procedures.
11. Sample collection, preservation, shipment and storage
   a. Provide information on sample collection, preservation, shipment, and storage conditions
12. Quality control
   a. Describe specific quality control steps and frequencies for each QC operation and acceptance criteria (see Essential Quality Control Checks)
13. Calibration and standardization
14. Describe initial calibration procedures, continuing calibration procedures, frequency and acceptance criteria
15. Data analysis and calculations
   a. Describe qualitative and quantitative aspects of the method. Provide equations used to derive final sample result.
16. Method performance
17. Pollution prevention
18. Data assessment and review of data
19. Corrective actions for out-of-control data
20. Contingencies for handling out-of-control or unacceptable data
21. Waste management
22. References
23. Any tables, diagrams, flowcharts and validation data

Essential Quality Control Checks

The following twelve quality control checks are to be considered essential and must be incorporated into the laboratory's documented quality system, unless a written rationale is provided that indicates why these controls are inappropriate for a specific analytical method.

These essential QC checks are:

1. Demonstration of Capability (DOC),
2. Method Detection Limit (MDL),
3. Reagent blank (also referred to as method blank),
4. Laboratory fortified blank (LFB, also referred to as a spiked blank, or laboratory control sample (LCS)),
5. Matrix spike (MS), matrix spike duplicate (MSD), or laboratory fortified blank duplicate (LFBD) for suspected difficult matrices,
6. Internal standard/s, surrogate standard/s (for organic analysis) or tracer (for radiochemistry),
7. Calibration (initial and continuing),
8. Control charts (or other trend analyses of quality control results),
9. Corrective action (root cause analyses),
10. Specific frequency of QC checks,
11. QC acceptance criteria, and
12. Definitions of a batch (preparation and analytical)