THE MARYLAND MEDICAL CANNABIS COMMISSION'S TECHNICAL AUTHORITY FOR MEDICAL CANNABIS TESTING

REVISION 4.0

The Maryland Medical Cannabis Commission (MMCC) has developed this technical authority document to define contaminants and corresponding action limits associated with those contaminants in medical cannabis. This information is intended for use by the independent testing laboratories registered with the MMCC.

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INTRODUCTION

Analytical testing of medical cannabis for safety and potency is increasingly recognized as a critical and necessary component of the industry for several reasons (Freeman et al. 2016):

- Laboratory testing minimizes the risk of pesticides, microbes, heavy metals, toxins, and residual solvents from being consumed by an immunocompromised population;
- Quantification of cannabinoid profiles and potency becomes available for the consumer and aids in determining appropriate dosing for individual use; and
- Laboratory testing provides a sense of public safety and product quality for the medical cannabis tested.

The Maryland Medical Cannabis Commission (MMCC), with the assistance of a scientific work group, has established this technical authority to serve as a reference guide for the independent testing laboratories (ITL) to follow when analyzing medical cannabis. This technical authority has the force and effect of law and must be followed by ITLs pursuant to the Code of Maryland Regulations (COMAR) 10.62.15.05 and 10.62.23.04. The contaminants in medical cannabis identified in COMAR 10.62.15.05 and 10.62.23.04 may not exceed the levels specified in this guidance.

Medical cannabis safety and potency is to be analyzed based on the most current version of the cannabis inflorescence monograph published by the American Herbal Pharmacopeia (AHP), or a scientifically valid methodology that is equal or superior to that of the AHP monograph. COMAR 10.62.15.05 and 10.62.23.04 list the quality control testing requirements for medical cannabis. This technical authority provides the lists of contaminants and the acceptable tolerances that the ITL is required to report as stated in COMAR 10.62.15.05 and 10.62.23.04. The tolerances were established following a review of available literature in the cannabis industry as well as references from the International Conference for Harmonisation (ICH) Guideline Q3C on Impurities and the ICH Guideline Q3D on Elemental Impurities Guidance for Industry.

The four categories of contaminants identified in COMAR 10.62.15.05 and 10.62.23.04 include:

- Pesticides;
- Residual Solvents;
- Microbiological Impurities; and
- Heavy Metals.

In an effective testing program, standardized sampling procedures are an integral component to quality laboratory testing. The data generated from all analytical methods must be consistently reliable and legally defensible. To achieve this, method precision and accuracy measurements should be performed during the sample testing process. This guidance will provide best practices for sample collection by the ITL.

All sampling and analysis described in this guidance shall be conducted by an ITL registered with the MMCC and in good standing and accredited to ISO/IEC 17025 by an International Laboratory Accreditation Cooperation (ILAC) recognized third party.

The MMCC is committed to evidence-based decision-making when implementing technical guidance for the registered ITL. As research into cannabis use and safety advances, this technical authority will be revised and updated to reflect the state of science as it pertains to the medical cannabis industry.

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SAMPLING

The objective of a sampling procedure is to ensure the proper collection, clear labeling, proper preservation, careful transportation, and storage of samples by trained personnel for laboratory analyses. Collection of the sample is critical as it must be truly representative of the material being analyzed or the results will not be meaningful. ITLs are required to develop a statistically valid sampling method and collect a representative sample from each batch or lot of final product that is adequate to perform the required testing (COMAR 10.62.15.04B and 10.62.23.03B). The amount of sample required for cannabinoid or contaminant testing may vary due to sample matrix, analytical method, and laboratory-specific procedures.

Medical cannabis sampling procedures play an important role in identifying and/or confirming the integrity of a sample, as well as the completeness of request and chain of custody forms.

To reliably provide the laboratory with a representative sample, standard sampling methods with descriptive steps must be applied with quality and consistency. All sampling must be consistently performed using accepted methodologies. It is the responsibility of the ITL to define a standard operating procedure that minimizes both imprecision and bias and lists chronological steps that ensure a consistent and repeatable method.

When sampling for compliance, all ITLs are required to follow the sampling protocol listed on page 5 of this document, "Collection Procedure for Laboratory Compliance and Retention Samples." In addition, the following sampling guidelines shall be demonstrated by the laboratory when performing sampling at a licensed grower or licensed processor:

- The use of appropriate sampling equipment to avoid contamination;
- The documentation of observations and procedures used during sample collection;
- The use of an aseptic collection technique is required for antimicrobial testing;
- The importance of personal hygiene and use of personal protective equipment; and
- The method used by personnel to consistently obtain samples throughout the batch.

(See Appendix A – Medical Cannabis Testing Requirements for information regarding required testing for each sample matrix).

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COLLECTION PROCEDURE FOR LABORATORY COMPLIANCE AND RETENTION SAMPLES

Equipment:

1. PPE-Disposable Gloves/Facemask/Shield;
2. Calibrated Scale;
3. Appropriate Sample Collection Vessel; and
4. Isopropyl Alcohol.

Procedure:

1) Put on disposable gloves to mitigate the risk for contamination of the sample during the collection process.
2) Ensure the work surface and scale are clean and decontaminated.
3) Label a collection vessel with the appropriate METRC identifier and confirm the batch or lot mass. Do not sample if pertinent information is not available.
4) Retrieve the container you will be collecting the sample from and wipe off the lid of the container if applicable.
5) For usable cannabis: The minimum sample volume to be collected from each batch is 0.5% of the batch mass. The minimum number of sample increments listed below must be collected for the gross sample (this includes both compliance and retain sample). Withdraw samples from the upper, middle, and lower sections of each container, with the upper section sample being taken from a depth of not less than 10 centimeters. In circumstances where there are 1-10 containers in a batch, collect a sample from all containers. Record the time the sample was collected, any inconsistencies with the sampling plan, and any other remarks that may be relevant to data analysis or quality assurance.

Max Batch Mass	Minimum Sample Size
10lbs	10 sample increments totaling 0.5% batch mass

For processed products (excluding edible cannabis products): Each sample must be taken in final product form from randomly chosen positions in the lot. The sample volume collected must meet or exceed minimum volume requirements for all compliance testing performed.

6) Place the sample in the appropriate collection vessel, seal and place to the side.
7) Wipe down the scale and work surface using isopropyl alcohol.
8) Dispose of gloves.
9) Document the appropriate chain of custody information (i.e. sample volume) to be recorded in METRC.

**The following sample collection procedure is based U.S. Pharmacopeia Convention Chemical Tests / 561 Articles of Botanical Origin 2021 July*

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POTENCY

Every batch and/or lot of cannabis cultivated and/or processed for transfer to a licensed dispensary must pass the required compliance testing listed in COMAR 10.62.15 and 10.62.23. Potency is analyzed by quantitating the following compounds:

- ∆9-Tetrahydrocannabinol (THC);
- Tetrahydrocannabinolic Acid (THCA);
- Cannabidiol (CBD);
- Cannabidiolic Acid (CBDA);
- The terpenes described in the most current version of the cannabis inflorescence monograph published by the American Herbal Pharmacopeia (AHP);
- Cannabigerol (CBG); and
- Cannabinol (CBN)

To minimize the variability that exists with potency testing of cannabis flower, all method validations must meet the standard method performance requirements (SMPRs) listed in Appendix I. For matrices not listed, the method performance requirements must be as close to the published SMPRs as possible. Additionally, to maintain consistency, the MMCC requires that ITLs use the sample preparation and the sample analysis methods listed in Appendix I.

**Note: Test samples for potency will consist of a random selection of buds/flower from the analytical sample of cannabis flower collected from a licensee. The laboratory is to maintain procedures for homogenization which are supported through method validation. Elevated potency levels will routinely be monitored and confirmed by the MMCC. Enforcement action will be taken for laboratories falsely reporting elevated potency levels in METRC and on Certificates of Analysis.*

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PESTICIDES

COMAR 10.62.11.03G states pesticide applicators and applications shall follow State and federal pesticide requirements for any pesticide applied. The Maryland Department of Agriculture (MDA) approves crop protection agents available for use on medical cannabis. For more information visit the MMCC website (https://mmcc.maryland.gov/Pages/Pesticide-Application.aspx). MMCC's current list of pesticide targets are documented in Table 1. To minimize the variability that exists with testing of cannabis flower, all method validations must meet the standard method performance requirements (SMPRs) listed in Appendix I. Cannabis samples with pesticide active ingredients detected above the action level listed below fail, and the product must be destroyed.

Table 1: List of Target Pesticides and Plant Growth Regulators in Parts Per Million (PPM)

Pesticide/PGR	USE	LOQ
Acetamiprid	Insecticide	0.2
Abamectin	Insecticide	0.5
Aldicarb	Insecticide	0.4
Ancymidol	PGR	0.2
Azoxystrobin	Fungicide	0.2
Bifenazate	Insecticide	0.2
Bifenthrin	Fungicide	0.2
Boscalid	Fungicide	0.4
Carbaryl	PGR	0.2
Carbofuran	Insecticide	0.2
Chlorantraniliprole	Insecticide	0.2
Chlorpyrifos	Insecticide	0.2
Clofentezine	Acaricide	0.2
Cyfluthrin	Insecticide	1.0
Daminozide (Alar)	PGR	1.0
DDVP (Dichlorvos)	Insecticide	0.1
Diazinon	Insecticide	0.2
Dimethoate	Insecticide	0.2
Ethephon	PGR	1.0
Etoxazole	Acaricide	0.2
Fenpyroximate	Insecticide	0.5
Fipronil	Insecticide	0.4
Flonicamid	Insecticide	1.0
Fludioxonil	Fungicide	0.4

Pesticide/PGR	USE	LOQ
Flurprimidol	PGR	0.2
Hexythiazox	Ovicide	1.0
Imazalil	Fungicide	0.2
Imidacloprid	Insecticide	0.4
Kresoxim-methyl	Fungicide	0.4
Malathion	Insecticide	0.2
Metalaxyl	Fungicide	0.2
Methiocarb	Insecticide	0.2
Methomyl	Insecticide	0.4
Myclobutanil	Fungicide	0.2
Naled	Insecticide	0.5
Oxamyl	Insecticide	1.0
Paclobutrazol	PGR	0.4
Permethrin	Insecticide	0.5
Phosmet	Insecticide	0.2
Piperonyl butoxide	Insecticide	1.0
Propiconazole	Fungicide	0.4
Pyrethrins	Insecticide	1.0
Spinosad	Insecticide	0.2
Spiromesifen	Insecticide	0.2
Spirotetramat	Insecticide	0.2
Thiacloprid	Insecticide	0.2
Thiamethoxam	Insecticide	0.2
Trifloxystrobin	Fungicide	0.2

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RESIDUAL SOLVENTS

Some producers of cannabis products use solvents to extract and/or concentrate the active ingredients from cannabis. The MMCC has adopted a list of target residual solvents based on common extraction and concentration techniques in the industry. Concentration limits are based on the "International Conference for Harmonisation (ICH) Guideline Q3C (R5) on Impurities: Guidelines for residual solvents." The concentration limits listed in ICH Q3C are based on the toxicity of the individual solvent and on the magnitude of exposure to occur from consuming 10 grams of the pharmaceutical. To minimize variability that exists with testing of cannabis flower, all method validations shall include the standard method performance requirements (SMPRs) listed in Appendix I.

Note: No health-based solvent residual limits have been established specifically for cannabis extract or concentrate products. We are uncertain whether the selected action levels for solvents in cannabis products sufficiently protect persons who smoke cannabis. However, the ICH Q3C does assume 100% absorption by any exposure route.

Table 2: Concentration Limits for Residual Solvents in Parts Per Million (PPM)

Solvent	PPM
Heptanes	<5000
Hexanes	<290
Butanes	<5000
Benzene	<2
Toluene	<890
Total Xylenes	<2170
Propanes	<5000
Ethanol	<5000

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MICROBIOLOGICAL IMPURITIES

The presence of microbes is common in natural products. It is important to distinguish between organisms ubiquitous in nature and those that are known pathogens. "Indicator tests" don't directly test for pathogens, but instead serve as quality tests or indications that follow-up pathogen testing should be performed (Holmes et al. 2015). Additionally, while microbial and fungal limits are not typically reported as "pass/fail," the MMCC has established acceptable limits of detection based on the literature available. The criteria for acceptability in Table 3a and Table 3b (below) lists the microbiological impurities and the associated detection limits.

Total Aerobic Microbial Count (TAMC), Total Yeast and Mold Count (TYMC) and Coliform Testing

A registered independent laboratory shall use:

1. An approved AOAC, FDA, or USP validated culture based method; or
2. Another method approved by MMCC.

Pathogen Testing

A registered independent laboratory shall use:

1. An approved AOAC, FDA, or USP validated agar plating method; or
2. (i) Another approved AOAC, FDA, or USP validated method and (ii) agar plating of pathogens.

The laboratory's selected method will require quality controls (positive and negative) performed with each sample set-up, as well as additional criteria identified by each method (e.g., peel plate requires an automatic reader and time stamp). Standard method performance requirements and testing methods available are listed in Appendix I and must be followed by the ITL. See Appendix F - Microbiological Quality Control for additional quality control information and templates. Quality control worksheets for qualitative analysis, quantitative analysis, and specific organism detection are available on the MMCC website (https://mmcc.maryland.gov/Pages/testinglabs.aspx). If a pathogen is detected during compliance testing, the ITL should follow protocol listed in Appendix-G-Presumptive Positive Pathogen Detection.

Table 3a: Microbiological Impurities and Accepted Detection Limits in Colony Forming Units (CFU/g) and Parts per Billion (PPB) for flower and processed products.

Microbiological Impurity	***CFU/g***
Total Aerobic Microbial Count (TAMC)	*<100,000*
Total Yeast and Mold Count (TYMC)	*<100,000*
E. coli	*<1*
Salmonella spp.	*"Not Detected"*

Mycotoxin	**PPB**
Aflatoxin B1	<20
Aflatoxin B2	<20
Aflatoxin G1	<20
Aflatoxin G2	<20
Ochratoxin A	<20

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Table 3b: Microbiological Impurities and Accepted Detection Limits in Colony Forming Units (CFU/g) and Parts per Billion (PPB) for Edibles Products.

Microbiological Impurity	***CFU/g***
Total Coliforms	*<10*
Shiga Toxin producing E.coli (STEC)	"Not Detected"
Salmonella, spp	"Not Detected"
L. monocytogenes	"Not Detected"
E. coli*	<1 or "Not Detected"

**E.coli should be recorded as <1 CFU/g for quantitative analysis and "Not Detected" for qualitative analysis.*

Water activity (Aw) is a measure of the available water that can be utilized for microbiological growth. Aw ranges from 0 to 1 with microbial growth unlikely below Aw 0.6. Most cannabis is dried and cured to a final water activity level of Aw 0.3-0.6, and most pathogens cannot grow below Aw 0.9 (Holmes et al., 2015). Water activity, or the moisture of the cannabis flower in units, measured below Aw 0.65 will safeguard cannabis products against microbial growth during storage and before sale. In order to maintain consistency, the MMCC requires that ITLs use the sample analysis method listed in Appendix I for water activity.

Table 3c. Acceptable water activity limits for cannabis flower and edible cannabis products.

Water Activity	**(AW)**
Flower products	<.65
Edible cannabis products	<.85

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HEAVY METALS

Elemental impurities do not provide any therapeutic benefit to the medical cannabis patient. Because of their high degree of toxicity, arsenic, cadmium, chromium, lead, and mercury rank among the priority metals that are of public health significance (Tchounwou P et al. 2012). The MMCC requires an ITL to test for heavy metal presence in medical cannabis (COMAR 10.62.15.05 and COMAR 10.62.23.04). Table 4a lists the five heavy metals required in compliance testing and their associated action limits based on a 5 gram/day consumption for inhalation limits and a 10 gram/day consumption for oral limits. Table 4b lists the four heavy metals required in contaminant testing for edible cannabis products and their associated concentration limits based on a 10 gram/day consumption. To minimize variability that exists with testing of cannabis flower, all method validations shall meet the standard method performance requirements (SMPRs) listed in Appendix I. For consistency, the MMCC requires that ITLs use the sample analysis method listed in Appendix I for detection and quantification of heavy metals in cannabis flower and processed products.

Note: The permitted daily exposure (PDE) for heavy metals is based on the Q3D Elemental Impurities Guidance for Industry.

Table 4a: Heavy Metals and Associated Concentration Limits in Parts Per Million (PPM) for Flower and Processed Products.

Heavy Metal	PPM (Inhalation)	PPM (Oral)
Lead	*<1.0*	*<0.5*
Arsenic	*<0.4*	*<1.5*
Mercury	*<0.2*	*<3.0*
Cadmium	*<0.4*	*<0.5*
Chromium	*<0.6*	*<1070.0*

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Table 4b: Heavy Metals and Associated Concentration Limits in Parts Per Million (PPM) for Edible Cannabis Products.

Heavy Metal	PPM (Oral)
Lead	*<0.5*
Arsenic	*<1.5*
Mercury	*<3.0*
Cadmium	*<0.5*

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EXCIPIENTS

COMAR (10.62.23) states that the presence of any residual solvent or processing chemical not exceed the levels provided in this document. On November 15, 2019, the Commission issued Bulletin 2019-013 banning the use of Vitamin E Acetate (VEA) as a processing chemical in the production of cannabis vaping products and requiring VEA screening be performed on all vaping products (see Appendix 1). VEA detection in vape samples that exceeds 0.7% by weight will be cause for product destruction.

STABILITY TESTING

COMAR (10.62.15.07 and 10.62.23.06) states that stability testing is to be performed at 6-month intervals. The purpose of stability testing is to provide evidence on how the quality of a drug substance varies with time under the influence of a variety of environmental factors (ICH 2003).

The ITL must have policies and procedures established for the collection of stability and retention samples and the analysis of stability testing samples.

The stability testing required will include:

- Cannabinoid content; and
- Microbiological impurities.

Findings of the stability studies must be reported to the MMCC through the METRC tracking system to ensure medical cannabis purity and potency are maintained throughout the storage process without significant change. *Significant change* for medical cannabis is defined as failure to meet the tolerances listed in this technical guidance for purity. Stability studies protocol may change as the industry evolves. Current protocols are listed below.

Stability testing protocol for MMCC licensed growers is available in Appendix C – Stability Testing Protocol – MMCC Licensed Grower.

Stability testing protocol for MMCC licensed processors is available in Appendix D – Stability Testing Protocol – MMCC Licensed Processor.

Stability testing protocol for edibles products is available in Appendix E – Stability Testing Protocol - Edibles.

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APPENDIX A - Medical Cannabis Compliance Testing Requirements

	Raw Plant Material	Concentrate (Solvent/Non-Solvent Based)	Infused Non-Edible	Inhalable/Vape Concentrate	Infused Edible	External Hemp (Extract/Raw Plant Material)
Moisture Content	√					
Potency Analysis	√	√	√	√	√	√
Terpene Analysis	√	√	√	√		
Foreign Matter Inspection	√	√	√	√	√	
Microbial Screen	√	√	√	√		
Mycotoxin Screen	√	√	√	√	√	
Water Activity	√				√	
Heavy Metal Screen	√	√		√	√	
Residual Solvent Test		√	√ *	√		
Pesticide Residue Analysis	√	√	√	√		
Vitamin E Acetate				√		
Shiga Toxin Producing E. Coli					√	
Salmonella, spp.	√	√	√	√	√	
Total Coliform					√	
E.coli	√	√	√	√	√	
L. monocytogenes					√	

** Residual solvent testing should be added where licensee notifies ITL for products categorized as infused non-edibles*

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APPENDIX B - DEFINITIONS

Batch -

(a) All of the plants of the same variety of medical cannabis that have been:
  (1) Grown, harvested, and processed together; and
  (2) Exposed to substantially similar conditions throughout cultivation and processing.
(b) Includes all of the processed materials produced from those plants.

Chain of Custody - The chronological documentation showing the collection, custody, control, transfer, analysis, and disposition of a sample.

Commission - The Maryland Medical Cannabis Commission.

CFU/g - Colony forming units per gram. Refers to a measure of the amount of living bacteria per given amount (1 gram) of a sample.

Independent Testing Laboratory - A facility, entity, or site that offers or performs tests of medical cannabis and products containing medical cannabis:

(a) Accredited as operating to ISO standard 17025 by an accreditation body that:

(i) Operates in accordance with the International Organization for Standardization (ISO) standard ISO/IEC 17011;

(ii) Is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA); and

(iii) Is independent from all other persons involved in the Maryland cannabis industry; and

(b) Registered with the Commission.

Limit of Quantification (LOQ) - The lowest concentration at which the analyte cannot only be reliably detected but at which some predefined goals for bias and imprecision are met.

Lot - All of a medical cannabis finished product that is uniform, that is intended to meet specifications, and that is manufactured, packaged, or labeled together during a specified time period according to a single lot record.

METRC –Marijuana Enforcement Tracking Regulation and Compliance system.

Medical Cannabis - Any product containing usable cannabis or medical cannabis finished product.

Medical Cannabis Concentrate - A product derived from medical cannabis that is kief, hashish, bubble hash, oil, wax, or other product, produced by extracting cannabinoids from the plant through the use of:

(a) Solvents
(b) Carbon dioxide; or
(c) Heat, screens, presses or steam distillation.

Medical Cannabis-Infused Product -

(a) Any oil, wax, ointment, salve, tincture, capsule, suppository, dermal patch, cartridge or other product containing a medical cannabis concentrate or usable cannabis that has been processed so that the dried leaves and flowers are integrated into other material.
(b) Does not include an edible cannabis product as that term is defined in COMAR 10.62.01.01.

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Qualitative - Relating to, measuring, or measured by the quality of something rather than its quantity.

Quantitative - Relating to, measuring, or measured by the quantity of something rather than its quality.

Representative Sample - A sample obtained according to a sampling procedure designed to ensure that the different parts of a batch or lot or the different properties of a batch or lot are proportionally represented.

Sample - An amount of medical cannabis collected by laboratory personnel from a licensee and provided to an independent testing laboratory for testing.

Solvent - A substance that can dissolve another substance, or in which another substance is dissolved, forming a solution.

Target Analyte - A chemical the laboratory must test for to see if it is present in medical cannabis.

Usable Cannabis -

(a) The dried leaves and flowers of the cannabis plant.
(b) Does not include seedlings, seeds, stems, stalks or roots of the plant.

Water Activity - The partial vapor pressure of water in a substance divided by the standard state partial vapor pressure of water.

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APPENDIX C - STABILITY TESTING PROTOCOL (GROWER)

COMAR 10.62.15.07 requires stability testing to be performed for each released batch of usable medical cannabis. This document outlines the required protocol to be followed by MMCC licensed growers and MMCC registered ITLs performing the stability studies.

Definitions:

Batch – All of the plants of the same variety of medical cannabis that have been: a) Grown, harvested, and processed together; and b) Exposed to substantially similar conditions throughout cultivation and processing. This includes all of the processed materials produced from those plants (flower, trim, kief, etc).

Testing Panel - Each sample is to be tested for a) Micro-organisms; and b) Potency to ensure product potency and purity and provide support for expiration dating per COMAR 10.62.15.07.

Stability Sample – 12 grams of material stored in routine conditions by the licensed grower to allow for collection of testing samples at all time points.

Testing Sample – 3 grams collected from the stability sample to be collected by, homogenized and analyzed by the ITL for each time point.

Time Point – The 6-month interval when testing should occur per COMAR 10.62.15.07 (0, 6, 12 and 18 months).

Homogenization – Manipulation of a product by mixing, and/or grinding, to obtain equal distribution of all components or ingredients with the goal of reducing variability.

Stability Testing Goals:

The design will assess:

- Degradation of cannabinoids in usable medical cannabis products over an 18-month period when held at routine storage conditions at a licensed cultivation facility.
- Levels of bacterial/fungal growth in usable medical cannabis products over an 18-month period when held at routine storage conditions at a licensed cultivation facility.

Stability Testing Protocol Requirements:

1. Stability testing shall be performed for each unique strain of cannabis. If material produced is to be distributed/sold as unique products (flower, trim, kief) each of these products shall constitute a batch and must be tested individually as potency, microbiological activity and environmental impact on stability may vary between product forms.
2. The licensed grower shall be responsible for stability sample storage, and selection of the ITL to perform stability testing
3. The ITL shall be responsible for the collection of the stability and testing samples, analysis and submission of stability testing data into METRC.
4. Each stability sample shall contain 12 grams of material to allow the ITL to collect a 3-gram testing sample at each of the four time points. Failure to generate sufficient data for analysis may require repeating the missing time point/testing and potentially the full protocol. In cases where insufficient material to complete full testing is available (kief, trim) from a single batch a modified protocol to assess the stability of these products shall be proposed by the licensed grower for approval by the MMCC.
5. Stability samples shall be uniquely identified, clearly labeled "For Stability Testing Only" and stored in the same environmental conditions as product intended for sale. Care shall be taken to keep the sample segregated from other product to avoid potential contamination of study samples.
6. The ITL shall collect a testing sample of 3 grams from the stability sample at each time point. In cases where the product is packaged in volumes lower than what is required by the laboratory for testing multiple packages of a product from the same batch may be used to produce a single, homogenized sample for testing. These packages shall be collected by the independent testing laboratory and combined into a single sample at the time of testing.
7. Testing samples are to be collected and analyzed by the ITL at 0, 6, 12 and 18 months.
8. Testing performed at T0 is the full compliance panel. Testing performed at T6, T12, and T18 will consist of potency, TYMC, TAMC, E.coli, and Salmonella.
9. Testing results for all time points shall be generated within 14 calendar days of the date of the time point to be measured.
10. Each testing sample must be homogenized consistent with the laboratory's standard operating procedures.

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11. Laboratory methodology shall be consistent throughout the study. Changes to technology or protocols throughout the study require approval from MMCC.
12. The ITL shall provide all data electronically to the MMCC via an electronic reporting portal (https://mmcc.seamlessdocs.com/f/StabilityTestingAndRetentionSampling) within 30 calendar days of the measured time point.

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APPENDIX D - STABILITY TESTING PROTOCOL (PROCESSOR)

Licensed Processor Stability Testing Protocol

COMAR 10.62.23.06 requires stability testing to be performed for each released lot of processed medical cannabis. This document outlines the required protocol to be followed by MMCC licensed processors and MMCC registered ITLs performing the stability studies.

Definitions:

Medical Cannabis-Infused Product – Oil, wax, ointment, salve, tincture, capsule, suppository, dermal patch, cartridge or other product containing medical cannabis concentrate or usable cannabis that has been processed so that the dried leaves and flowers are integrated into other material.

Lot – All of a medical cannabis finished product that is uniform, that is intended to meet specifications, and that is manufactured, packaged or labeled together during a specified time period according to a single lot record.

Testing Panel - Each testing sample is to be tested for a) Micro-organisms; and b) Potency.

Stability Sample – Sufficient material stored in routine conditions by the licensed processor to generate testing samples at all time points.

Testing Sample – Sample to be collected from the stability sample by the ITL sufficient to complete the testing panel for each time point.

Time Point – 6-month interval when testing should occur (0, 6, 12 and 18 months).

Homogenization – Manipulation of a product by mixing, to obtain equal distribution of all components or ingredients with the goal of reducing sample variability.

Stability Testing Goals:

The design must assess:

- Degradation of cannabinoids in medical cannabis processed products over an 18-month period when held at routine storage conditions at a licensed processing facility.
- Levels of bacterial/fungal growth in medical cannabis processed products over an 18-month period when held at routine storage conditions at a licensed processing facility.

Stability Testing Protocol Requirements:

1. Stability testing shall be performed for each unique medical cannabis-infused product. Each product with a unique strain, terpene/cannabinoid profile or delivery method shall be tested independently as potency, microbiological activity and environmental impact on stability may vary between product forms.
2. The licensed processor shall be responsible for stability sample storage and selection of the ITL to perform stability testing.
3. The ITL shall be responsible for the collection of the stability and testing samples, analysis and submission of stability testing data into METRC.
4. Each stability sample shall contain sufficient material to allow the independent testing laboratory to collect a testing sample at each of the four time points sufficient to complete the testing panel. Failure to generate sufficient data for analysis may require repeating the missing time point/testing and potentially the full protocol.
5. Stability samples shall be uniquely identified, clearly labeled "For Stability Testing Only" and stored in the same environmental conditions as product intended for sale. Care shall be taken to keep the sample segregated from other product to avoid potential contamination of study samples.
6. The ITL shall collect a testing sample from the stability sample at each time point sufficient to complete the full testing panel. In cases where the product is packaged in volumes lower than what is required by the laboratory for testing multiple packages of a product from the same batch may be used to produce a single, homogenized sample for testing. These packages shall be collected by the ITL and combined into a single sample at the time of testing.

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7. Testing samples are to be collected and analyzed by the independent testing laboratory at 0, 6, 12 and 18 months. Testing performed at T0 is the full compliance panel. Testing performed at T6, T12, and T18 will consist of potency, TYMC, TAMC, E.coli, and Salmonella.
8. Testing results for all time points shall be generated within 14 calendar days of the date of the time-point to be measured.
9. Laboratory methodology shall be consistent throughout the study. Changes to technology or protocols throughout the study require approval from MMCC.
10. When possible, each sample is to be homogenized at the time of testing by the ITL consistent with the laboratory's standard operating procedure.
11. ITLs shall provide all data electronically (https://mmcc.seamlessdocs.com/f/StabilityTestingAndRetentionSampling) to the MMCC within 30 calendar days of the measured time point.

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APPENDIX E - STABILITY TESTING PROTOCOL (EDIBLES)

Edible Products Shelf Stability Study

COMAR 10.62.37.10E requires shelf life testing be performed for each unique edible cannabis product available for patient consumption. This document outlines the required protocol to be followed by MMCC licensed processors and the MMCC registered ITLs performing testing. The protocol consists of 10 individual product samples being analyzed for content uniformity as well as a 12-week time period monitoring product potency, water activity, and microbiological contaminants.

Content Uniformity Requirements (Time point 0):

1. The licensed processor shall randomly select 10 individual samples of unique edible cannabis products in final form from available production lots, ensuring all production lots available have been represented. These samples must be transferred to an ITL for required testing. Compliance testing performed at T0 will satisfy baseline water activity and microbiological data points. The ITL is responsible for randomly sampling for compliance.
2. The ITL shall visually inspect each sample for foreign matter, odor, and general appearance.
3. Following visual inspection, the samples must each be tested for cannabinoid content. Acceptable content uniformity shall fall within +/- 10%.
4. Following completion of testing, results shall be uploaded directly into METRC by the ITL. Additionally, laboratories should submit testing data to: https://mmcc.maryland.gov/Pages/testinglabs.aspx.

Stability Requirements (Time points 1-3):

Following the initial content uniformity testing there will be three additional time points to test: T(1) at 4 weeks, T(2) at 8 weeks, and T(3) at 12 weeks.

1. The licensed processor should randomly select 3 samples (beginning, middle, and end) from each unique production lot at stated time points.
2. The ITL shall visually inspect each sample for foreign matter, odor, and general appearance. Following the visual inspection, the samples must be homogenized and tested for the following:
   - Microorganisms;
   - Water activity; and
   - Cannabinoid content.
3. Testing results must be uploaded directly into METRC by the ITL. Additionally, laboratories shall submit testing data to https://mmcc.maryland.gov/Pages/testinglabs.aspx.

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APPENDIX F - MICROBIOLOGICAL QUALITY CONTROL

Quantitative quality controls are required to quantitate microbes. ITLs shall run quality controls (QC) each time samples are set up. QC must mimic the sample analysis and needs to run through every incubation period during every run (i.e. a broth base analysis must include a broth-based QC, and a plate- based analysis must include a plate-based QC).

Quality Control (QC) Templates are available on mmcc.maryland.gov.

F(1). Quantitative Analysis Control Chart - Broth-based QC

+Control=E.coli, -Control=S. aureus, Sterility Control=Media blank

Test Controls		*E. coli* ATCC 25922	E. aerogenes ATCC 13048	S. aureus ATCC 25923	Sterility Control	Initial/ Date
LST Control Results		XX	XX	XX	XX	
		X	X	X		
EC Control Results						
BGB Control Results						

Temp Incubated_____ °C Time/Date_____ Initials_____

Quantitative QC Petri film/charm controls

Test Controls charm/petri film plates	*E. coli* ATCC 25922 pos control count	S. aureus ATCC 25923 neg control	Sterility Control	Initial/ Date

Temp Incubated_____ °C Time/Date _____Initials_____

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Aerobic Bacteria Count

Aerobic bacteria plate counts controls

PCA Control Plate	Colony Count	Initial/Date
15 min Air Exposure Plate		
Glass Ware		
PCA		
Butterfield's phosphate-buffered/buffer used		
Positive Quantitative QC value		

Temp Incubated_____ °C Time/Date _____Initials_____

Certified Reference Material/Reference Material Used During Analysis

CRM	Lot Number	ATCC #	Generation	Expiration Date
Escherichia coli				
Enterobacter aerogenes				
Staphylococcus aureus				
Proteus mirabilis				

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BAM Method: Aerobic Plate Count, Total Coliforms & Fecal Coliforms
Result Worksheet

ANALYST(S)

SUB NO.	DILUTION	APC COLONIES PER PLATE	DILUTION	COLIFORM GROUP						Fecal Coliform Count			ESCHERICHIA COLI								
				LST			BG			EC			EMB			E. Coli			LST		
				A	B	C	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C
Positive	-		10																		
Quantitative	-		1.0																		
Control	-		-1																		
	-		-2																		
	-		-3																		
	-		-4																		
	-		-5																		
	-		-6																		
	APC/g:		MPN/g:							MPN/g: FC						E. coli MPN/g:					
	-																				
	-																				
	-																				
	-																				
	-																				
	APC/g:		MPN/g:							MPN/g: FC						E. coli MPN/g:					
	-																				
	-																				
	-																				
	-																				
	-																				
	APC/g:		MPN/g:							MPN/g: FC						E. coli/MPN/g:					
	-																				
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BAM Method: Aerobic Plate Count, Total Coliforms & Fecal Coliforms
Result Worksheet

ANALYST(S)

SUB NO.	DILUTION	APC COLONIES PER PLATE	DILUTION	COLIFORM GROUP						Fecal Coliform Count			ESCHERICHIA COLI								
				LST			BG			EC			EMB			E. Coli			LST		
				A	B	C	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C
	-																				
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	APC/g:		MPN/g:							MPN/g: FC						E. coli MPN/g:					
	-																				
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	-																				
	-																				
	-																				
	APC/g:		MPN/g:							MPN/g: FC						E. coli MPN/g:					
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	-																				
	APC/g:		MPN/g:							MPN/g: FC						E. coli/MPN/g:					
	-																				
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	-																				
	APC/g:		MPN/g:							MPN/g: FC						E. coli MPN/g:					

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F(2). Qualitative Quality Control

Quality Control (QC) performed for qualitative analysis must include a Sterility Control, Negative Control and a Positive Control with each RUN or at a MINIMUM every time you set up samples for that day. The QC must simulate the samples during each phase. If the sample tested is going through an incubation at a specific temperature, then the QC must mirror it on the same medium. Please see the chart below which shows Salmonella as a positive control, E coli as a negative control and Media blank as a sterility control.

Qualitative Analysis Control Chart

+Control=Salmonella, -Control=E.coli, Sterility Control=Media blank

Test Controls	*Salmonella sp.*	*E. coli*	Sterility Control	Initial/ Date
RV Broth				
Tetrathionate Broth				
XLD Agar				
Hektoen Agar				
Wilson Blair Agar				
TSI /LIA/BAP				

Initials/Date: _____ Incubator temperature_____ Water bath temperature_____

Certified Reference Material/Reference Material

CRM	ATCC #	Lot Number	Generation	Expiration Date
Salmonella species				
Escherichia coli				

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APPENDIX G-PRESUMPTIVE POSITIVE PATHOGEN DETECTION

If an ITL identifies a pathogen (E.coli, Salmonella, or Listeria) during routine compliance testing, the following steps should be taken within 24 hours of the presumptive positive:

1. Perform the confirmation steps listed in the chart below for each organism detected.
2. Notify the MMCC via phone and email (scientificsupport.mmcc@maryland) of the confirmed pathogen positive.
3. Enter all failed test results into Metrc.
4. Notify the licensee and coordinate sample pick with the MMCC.
    a. Refrigerate selective agar plates,the original enrichment broth, and blood plates at 2-8º Celsius until pickup by MMCC.
5. Perform environmental swab testing of the licensee's facility after it has been decontaminated.
6. Notify the MMCC with the environmental swab testing results.

PATHOGEN DETECTED (AGAR PLATING ONLY)	CONFIRMATION STEPS REQUIRED
E.COLI	API 20E
STEC	API 20E; IF CONIRMED AS E.COLI LATEX AGGLUTINATION FOR 0157 OR NON-0157, AND/OR QPCR
L.MONOCYTOGENES	API LISTERIA, AND/OR LATEX AGGLUTINATION
SALMONELLA SPP.	API 20E, AND/OR QPCR MAY BE PERFORMED

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APPENDIX H- GREEN WASTE DISPOSAL PROCEDURE FOR INDEPENDENT TESTING LABORATORIES

This standard operating procedure provides a standardized method of disposal for cannabis green waste in MMCC registered independent testing laboratories. The procedure ensures accountability for cannabis green waste by establishing appropriate documentation and destruction processes. MMCC encourages registered independent testing laboratories to implement the Green Waste Disposal Procedure upon adoption of Revision 4.0 of this technical authority. All registered independent testing laboratories will be required to comply with the Green Waste Disposal Procedure following adoption of proposed amendments to COMAR 10.62.16.05B.

Procedure:

1. Following conclusion of the lab's identified retention period, all waste shall be documented on the *Cannabis Green Waste Log* attached to this Standard Operating Procedure. The log shall be available for immediate review upon request by MMCC personnel. The log must include the following information:
    A. Date and time the waste was entered into a waste container;
    B. Product name;
    C. Last 9 digits of metric tag number;
    D. Product weight to be green wasted measured in applicable units (i.e. grams, eaches,etc);
    E. Agent entering into Waste Log;
    F. Date and time of disposal and removal from the facility and into a commercial waste bin for pickup;
    G. Method of disposal (Ex: kitty litter, mulch, bleach, etc);.
    H. Agent or manager disposing of waste; and
    I. Agent verifying disposal of waste.

2. All waste shall immediately be rendered unusable, entered onto the waste log and placed into the waste container. This action must be clearly captured on video.
    A. Flower/dry leaf waste shall be ground to the smallest possible degree and mixed with a non-cannabis product in a 50:50 ratio (minimum).
        - Examples of non-cannabis products include: alcohol, bleach, any other solvent that renders it non-useable, kitty litter, mulch, dirt, or other loose non-consumable material that will render the cannabis non-useable.
    B. Non-flower/non-dry leaf waste shall be emptied into a non-consumable product for disposal.

3. Final destruction shall occur no later than 7 days after the waste is entered onto the *Cannabis Green Waste Log* and placed in a designated commercial waste bin for pick up and physical removal from the lab's inventory. All waste being disposed must be captured on video and will require verification from two laboratory agents documented on the *Cannabis Green Waste Log*.

4. All entries in the *Cannabis Green Waste Log* shall be printed legibly and be consistent with METRC green waste entries. To download a printable copy of the *Cannabis Green Waste Log*. please click here.

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APPENDIX I- METHOD PERFORMANCE REQUIREMENTS AND PERFORMANCE TESTED METHODS AVAILABLE FOR USE

*SMPR's and PTM's will be revised annually. PTM's published in the interim must be approved for use by the MMCC. Methods of analysis validation must meet AOAC SMPR criteria or adopt an available AOAC official method of analysis (OMA)/PTM via method transfer validation.

POTENCY:

For method validations, incorporate the Standard Method Performance Requirements (SMPRs) listed below:

- **Dried Plant Material: AOAC SMPR 2017.002**
- **Concentrates: AOAC SMPR 2017.001**

Sample Analysis:

- **Quantitation of Cannabinoids in Cannabis Dried Plant Materials, Concentrates, and Oils AOAC 2018.11**

PESTICIDES:

For method validations, incorporate the Standard Method Performance Requirements (SMPRs) listed below:

- **Identification and Quantification of Selected Pesticide Residue in Dried Cannabis Flower: AOAC SMPR 2018.011**

RESIDUAL SOLVENTS:

For method validations, incorporate the Standard Method Performance Requirements (SMPRs) listed below:

- **Identification and Quantitation of Selected Residual Solvents in Cannabis-Derived Materials: AOAC 2019.02**

MICROBIOLOGICAL IMPURITIES:

For method validations, incorporate Standard Method Performance Requirements (SMPRs) listed below:

- **Detection of Salmonella species in Cannabis and Cannabis Products: AOAC 2020.002**
- **Detection of Shiga Toxin-Producing Escherichia coli in Cannabis and Cannabis Products: AOAC 2020.012**
- **Viable Yeast and Mold Count Enumeration in Cannabis and Cannabis Products: AOAC 2021:009**
- **Mycotoxin Screening Technique in Cannabis Plant Material and Cannabis Derivatives: AOAC 2020.013**

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Sample Analysis:

- **Yeast and Mold Counts in Foods and Dried Cannabis Flower: AOAC 997.02**
- **3M Petrifilm Rapid Yeast and Mold Plate Count**
- **TEMPO Yeast & Mold**
- **TEMPO AC (Aerobic Count)**
- **TEMPO CC (Coliform Count)**
- **Soleris NF-TVC**
- **Soleris Coliform Test**
- **Soleris Direct Yeast & Mold**
- **CompactDry "Nissui" YMR**
- **Quant X Fungal One Step**
- **DetectX Combined**

Confirmation Testing:

- **GENE-UP® EHEC Series**
- **BAX System Real-Time PCR Assay Suite for STEC**
- **iQ-Check Salmonella II Real-Time PCR**
- **iQ-Check STEC VirX/SerO/SerOII**
- **GENE-UP Salmonella 2 (SLM2)**
- **PathoSEEK Salmonella and STEC E.coli Multiplex Assay with SenSATIVAx Extraction**
- **3M Molecular Detection Assay 2-Salmonella**
- **3M Molecular Detection Assay 2-STEC GeneScreen (stx and eae)**
- **3M Molecular Detection Assay 2-STEC GeneScreen (stx)**
- **GENE-UP PRO STEC/Salmonella Assay**
- **BAX System Real-Time PCR Assay for E.coli 0157:H7 Extract**

Sample Analysis (Water Activity):

- **Standard Practice for Determination of Water Activity in Cannabis Flower: ASTM D8196**

HEAVY METALS

For method validations, please incorporate the Standard Method Performance Requirements (SMPRs) listed below:

- **Determination of Heavy Metals in a Variety of Cannabis and Cannabis Derived Products: AOAC SMPR 2020.001**

Sample Analysis:

- **Heavy Metals in a Variety of Cannabis and Cannabis Derived Products: AOAC 2021.03**

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