THE MARYLAND CANNABIS ADMINISTRATION'S TECHNICAL AUTHORITY FOR CANNABIS TESTING

Effective February 2025

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

Revision 6.0

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Introduction

Analytical testing of 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 cannabis tested.

The Maryland Cannabis Administration (MCA), 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 cannabis. This technical authority has the force and effect of law and must be followed by ITLs and licensees pursuant to the Code of Maryland Regulations (COMAR) 14.17.06.02.

Cannabis purity 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. This technical authority provides the lists of contaminants and the acceptable tolerances that the ITL is required to report. 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 for analysis 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 MCA and in good standing and accredited to ISO/IEC 17025 by an International Laboratory Accreditation Cooperation (ILAC) recognized third party.

The MCA 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 cannabis industry.

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. The amount of sample required for cannabinoid or contaminant testing may vary due to sample matrix, analytical method, and laboratory-specific procedures.

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 – Cannabis Testing Requirements for information regarding required testing for each sample matrix)

Collection Procedure for Laboratory Compliance and Retention Samples

Equipment:

1. PPE-Disposable Gloves/Facemask/Shield;
2. Calibrated Balance;
3. Sterile Sample Collection Vessel;
4. Isopropyl Alcohol; and
5. Required METRC tags.

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 balance are clean and decontaminated.
3) Label an aseptic collection vessel with the appropriate METRC tag 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.

Table 1: Sample size requirements for usable cannabis

Max Batch Mass	Minimum Compliance Sample Size	Retention Sample Size
<10lbs (<4536 grams)	10 sample increments totaling 0.5% batch mass	23 grams
10-20lbs (4536-9072 grams)	12 sample increments totaling 0.5% batch mass	23 grams

6) For usable cannabis products: Each sample must be taken in final product form from randomly chosen positions in the lot/batch. The sample volume collected must meet or exceed minimum volume requirements for all compliance testing performed. A lot/batch is defined as far as is practicable, consisting of items of a single type, grade, class, size and composition, manufactured under uniform conditions at essentially the same time.

Table 2: Sample size requirements for infused edibles, infused non-edibles, concentrates, tinctures for oral administration testing batches

Cannabis Product Category	Minimum Compliance Sample Size	Retention Sample Size
Infused edibles	125g	125g
Infused non-edibles	16g	16g
Tinctures for oral administration	16g	16g
Concentrates	8g	8g

Table 3: Sample size requirements for vape cartridges

Vape Carts Bulk Concentrate*	Vape Cartridge Submitted for testing**	Retention Sample Size
8g	4 cartridges	8g bulk/ 4 cartridges

*This refers to the amount of concentrate that must be collected for compliance testing. This concentrate is collected by the licensee during the process to fill the lot of cartridges.
**This refers to the items of vape cartridges that must be collected for heavy metals testing. These cartridges are collected by the laboratory from the filled lot.

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

The above sample collection procedure is based on U.S. Pharmacopeia Convention Chemical Tests / 561 Articles of Botanical Origin. 2014 July.

Potency

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

- ∆9-Tetrahydrocannabinol (∆9-THC);
- ∆8-Tetrahydrocannabinol (∆8-THC);
- Total THC (raw plant material only)
- 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);
- Cannabigerolic acid (CBGA);
- Cannabichromene (CBC);
- Tetrahydrocannabivarin (THCV);
- Tetrahydrocannabivarinic acid (THCVA);
- Cannabidivarin (CBDV);
- Cannabinol (CBN); and
- Any additional cannabinoids if labeled on a usable cannabis product.

To minimize the variability that exists with cannabis testing all laboratory methods should contain the following controls listed in Appendix I which are based on AOAC standard method performance requirements (SMPRs) and the American Council of Independent Laboratories (ACIL)"Guide to Harmonizing Cannabis Laboratory Quality and Testing Practices". MCA accepts a potency variance of +/- 10% due to the heterogeneity of the cannabis plant and in cannabis infused products. Cannabis infused products failing to meet the allotted 10% variance in potency will need to have the labels updated to reflect actual cannabinoid concentration if the product does not exceed requirements to meet adult-use or medical exempt products. The total THC calculation is as follows: THC + (0.877*THCA). All cannabinoids should be reported "as is" and not adjusted by moisture content.

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 and/or verification. Elevated potency levels will be routinely monitored and confirmed by the MCA. Enforcement action will be taken for laboratories falsely reporting elevated potency levels in METRC and on Certificate of Analysis.

Pesticides

Pesticide applicators and applications shall follow State and federal pesticide requirements for any crop protection agent applied. The Maryland Department of Agriculture (MDA) approves crop protection agents available for use on cannabis. For more information on MDA approved crop protection agents, visit the MCA website. MCA's current list of pesticide targets and action limits are documented in Table 4. To minimize the variability that exists with cannabis testing all laboratory methods should contain the following controls listed in Appendix I which are based on AOAC standard method performance requirements (SMPRs) and the American Council of Independent Laboratories (ACIL)"Guide to Harmonizing Cannabis Laboratory Quality and Testing Practices". Cannabis samples with pesticide active ingredients detected above the action level listed below fail, and the product must be destroyed. The ITL is required to contact MCA within 24 hours of the failed result. At the request of a licensee, the MCA may, on a case-by-case basis, authorize a retest to validate the results of a failed test. Refer to Appendix J for further information.

Table 4: List of Target Pesticides and Plant Growth Regulators action limits and limit of quantitation (LOQ).

Pesticide/PGR	USE	Action Limit (PPM)	LOQ (PPM)
Acetamiprid	Insecticide	0.2	0.1
Abamectin	Insecticide	0.5	0.25
Aldicarb	Insecticide	0.4	0.2
Ancymidol	PGR	0.2	0.1
Azoxystrobin	Fungicide	0.2	0.1
Bifenazate	Insecticide	0.2	0.1
Bifenthrin	Fungicide	0.2	0.1
Boscalid	Fungicide	0.4	0.2
Carbaryl	PGR	0.2	0.1
Carbofuran	Insecticide	0.2	0.1
Chlorantraniliprole	Insecticide	0.2	0.1
Chlorpyrifos	Insecticide	0.2	0.1
Clofentezine	Acaricide	0.2	0.1
Cyfluthrin	Insecticide	1.0	0.5
Daminozide (Alar)	PGR	1.0	0.5
DDVP (Dichlorvos)	Insecticide	0.1	0.075
Diazinon	Insecticide	0.2	0.1
Dimethoate	Insecticide	0.2	0.1
Ethephon	PGR	1.0	0.5
Etoxazole	Acaricide	0.2	0.1
Fenpyroximate	Insecticide	0.5	0.25
Fipronil	Insecticide	0.4	0.2
Flonicamid	Insecticide	1.0	0.5
Fludioxonil	Fungicide	0.4	0.2

Pesticide/PGR	USE	Action Limit (PPM)	LOQ (PPM)
Flurprimidol	PGR	0.2	0.1
Hexythiazox	Ovicide	1.0	0.5
Imazalil	Fungicide	0.2	0.1
Imidacloprid	Insecticide	0.4	0.2
Kresoxim-methyl	Fungicide	0.4	0.2
Malathion	Insecticide	0.2	0.2
Metalaxyl	Fungicide	0.2	0.1
Methiocarb	Insecticide	0.2	0.1
Methomyl	Insecticide	0.4	0.2
Myclobutanil	Fungicide	0.2	0.1
Naled	Insecticide	0.5	0.25
Oxamyl	Insecticide	1.0	0.5
Paclobutrazol	PGR	0.4	0.2
Permethrin	Insecticide	0.5	0.25
Phosmet	Insecticide	0.2	0.1
Piperonyl butoxide	Insecticide	1.0	0.5
Propiconazole	Fungicide	0.4	0.2
Pyrethrins	Insecticide	1.0	0.5
Spinosad	Insecticide	0.2	0.1
Spiromesifen	Insecticide	0.2	0.1
Spirotetramat	Insecticide	0.2	0.1
Thiacloprid	Insecticide	0.2	0.1
Thiamethoxam	Insecticide	0.2	0.1
Trifloxystrobin	Fungicide	0.2	0.1

Residual Solvents

Some producers of cannabis products use solvents to extract and/or concentrate the active ingredients from cannabis. The MCA 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 the variability that exists with cannabis testing all laboratory methods should contain the following controls listed in Appendix I which are based on AOAC standard method performance requirements (SMPRs) and the American Council of Independent Laboratories (ACIL)"Guide to Harmonizing Cannabis Laboratory Quality and Testing Practices". Products failing for residual solvents are allowed to be remediated. Refer to Appendix J for further information.

No health-based residual solvent 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 5: Concentration Limits for Residual Solvents and Limit of Quantitation (LOQ)

Solvent	Action Limit (PPM)	LOQ (PPM)
Heptanes	<5000	2500
Hexanes	<290	200
Butanes	<5000	2500
Benzene	<2	1
Toluene	<890	450
Total Xylenes	<2170	1000
Propanes	<5000	2500
Ethanol*	<5000; Tinctures only <100000	2500

*Ethanol testing is required for infused non-edibles, but there is no action limit applied for these products.

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 MCA has established acceptable limits of detection based on the literature available. The criteria for acceptability in Table 3a and Table 3b (below) list 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 MCA.

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;
3. Another method approved by MCA.

The laboratory’s selected method will require quality controls (positive and negative) performed with each sample set-up. See Appendix F for quality control information and templates. All peel plate methods require an automatic reader and time stamp. Standard method performance requirements and testing methods available are listed in Appendix I to use as guidance for validation and verification of methods. Products failing due to TAMC and TYMC may be remediated refer to Appendix H for more details. Products failing for any other listed microbiological impurity must be destroyed. The ITL is required to contact the MCA within 24 hours of the failed result. For presumptive positive pathogen failures follow the protocol listed in Appendix G.

Table 6: Microbiological Impurities and accepted detection limits in flower and processed products

Microbiological Impurity	Detection Limit (CFU/g)
TAMC	<100,000
TYMC	<100,000
E. coli	<1
Salmonella spp.	Not Detected

Table 7: Action limits and Limit of Quantification (LOQ) for Mycotoxins

Mycotoxin	Action Limit (PPB)	LOQ (PPB)
Aflatoxin B1	<20	10
Aflatoxin B2	<20	10
Aflatoxin G1	<20	10
Aflatoxin G2	<20	10
Ochratoxin A	<20	10

Table 8: Microbiological Impurities and Detection Limits for Edible Products

Microbiology Impurity	Detection Limit (CFU/g)
Total Coliforms	<100
Shiga Toxin producing E. coli (STEC)	Not Detected
Salmonella, spp	Not Detected
L. monocytogenes	Not Detected
E.coli	<1

Water activity (A_w) is a measure of the available water that can be utilized for microbiological growth. A_w ranges from 0 to 1 with microbial growth unlikely below A_w 0.6. Most cannabis is dried and cured to a final water activity level of A_w 0.3-0.6, and most pathogens cannot grow below A_w 0.9 (Holmes et al. 2015). Water activity, or the moisture of the cannabis flower in items, measured below A_w 0.65 will safeguard cannabis products against microbial growth during storage and before sale. To minimize variability that exist with cannabis testing all laboratory methods should contain the following controls listed in Appendix G based on AOAC standard method performance requirements and the American Council of Independent Laboratories (ACIL)"Guide to Harmonizing Cannabis Laboratory Quality and Testing Practices". Flower products failing for water activity may be remediated. Edible products failing for water activity must be destroyed. The ITL is required to contact the MCA within 24 hours of the failed result. Refer to Appendix J for further information. Liquid edible products are excluded from water activity testing.

Table 9: Water activity limits for cannabis flower and edible cannabis products

Water Activity	Action Limit (Aw)
Usable Cannabis and Usable Cannabis Products	<0.65
Edible Cannabis Products	<0.85

Heavy Metals

Elemental impurities do not provide any therapeutic benefit to the cannabis patient or consumer. 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 MCA requires an ITL to test for heavy metal presence in cannabis. Table 10 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 11 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 exist with cannabis testing all laboratory methods should contain the following controls listed in Appendix G based on AOAC standard method performance requirements and the American Council of Independent Laboratories (ACIL) "Guide to Harmonizing Cannabis Laboratory Quality and Testing Practices". Products failing for heavy metals may be remediated see Appendix J for further information.

The permitted daily exposure (PDE) for heavy metals is based on the Q3D Elemental Impurities Guidance for Industry and USP Chapter <232> Elemental Impurities-Limits**.**

Table 10: Action Limits and LOQ concentrations for heavy metals in usable cannabis and cannabis products (except edible products)

Element	Route of Administration Action Limit			LOQ (PPM)
	Inhalation (PPM)	Oral (PPM)	Cutaneous (PPM)	
Lead (Pb)	<1.0	<0.5	<5	0.25
Arsenic (Ar)	<0.4	<1.5	<3	0.2
Mercury (Hg)	<0.2	<3.0	<3	0.1
Cadmium (Cd)	<0.4	<0.5	<2	0.2
Chromium (Cr)	<0.6	<1100	<1100	0.3

Table 11: Action Limits and LOQ concentrations for heavy metals in edible cannabis products

Element	Action Limit (PPM)	LOQ (PPM)
Lead (Pb)	<0.5	0.25
Arsenic (Ar)	<1.5	0.2
Mercury (Hg)	<3.0	0.1
Cadmium (Cd)	<0.5	0.2

Excipients

The presence of any processing chemical shall not exceed the levels provided in this document. Excipient is defined as a non-cannabis inactive ingredient designated for analysis. Vitamin E Acetate has been identified as a target analyte by the MCA. All vape cartridges must be tested for Vitamin E Acetate. The limit of quantitation for Vitamin E Acetate is 100ppm. VEA detection in vape samples that exceed the limit of quantitation will require the product to be destroyed. The ITL is required to contact the MCA within 24 hours of the failed result. At the request of a licensee, the MCA may, on a case-by-case basis, authorize a retest to validate the results of a failed test. Refer to Appendix J for further information.

COMAR 14.17.13.08 (C) states cannabis vaporizing devices may not include any solvent, solution, or other substance deemed to be a risk to public health or safety by the Administration according to COMAR 14.17.02.04. In the event additional solvents, solutions, or other substances are identified as prohibited excipients, MCA will notify licensees and registrants to immediately discontinue use in production.

Stability Testing

Stability testing is to be performed at 6-month intervals up to 18 months for usable cannabis and cannabis products except edible products. Stability testing for edibles products is performed at 4-week intervals up to 12 weeks. 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 MCA through the METRC tracking system to ensure cannabis purity and potency are maintained throughout the storage process without significant change. Significant change for 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 MCA licensed growers is available in Appendix C – Stability Testing Protocol – MCA Licensed Grower.

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

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

Appendix A- Cannabis Compliance Testing Requirements

Table 1: Testing Requirements by Lab Test Batches

	Raw Plant Material (Buds,Shake/ Trim, Prerolls)	Concentrate (Solvent/Non-Solvent Based)	Infused Non-Edible	Inhalable/ Vape Concentrate	Infused Edible and Exempt	Infused Edible (Capsule)	Infused Liquid Edible and Exempt	Tincture for Oral Administration	External Hemp
Moisture Content	√								
Potency Analysis	√	√	√	√	√	√	√	√	√
Terpene Analysis	√	√	√	√				√	
Foreign Matter Inspection	√	√	√	√	√	√	√	√	
Microbial Screen (TYMC, TAMC)	√	√	√	√				√	
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					√	√	√		

Table 2: Product Categories and COA Reporting Requirements

METRC Product Category	COA Reporting Requirement	
	Analyte Group Tested	**Unit to report**
Raw Plant Material (Buds, Shake/trim, prerolls)	Cannabinoids/Terpenes-	%
	Moisture Content	%
	Water Activity	A_w
	Foreign Matter Inspection	%
	Mycotoxin Screen	ppm
	Microbial Screen (TYMC, TAMC)	cfu/g
	Salmonella	Pass/Fail
	E. coli	cfu/g
	Pesticides	ppb
	Heavy Metals Screen	ppm
Concentrates	Cannabinoids/Terpenes-	%
	Foreign Matter Inspection	%
	Microbial Screen (TYMC, TAMC)	cfu/g
	Salmonella	Pass/Fail
	E. coli	cfu/g
	Mycotoxin Screen	ppb
	Pesticides	ppm
	Heavy Metals Screen	ppm
	Residual Solvents Screen	ppm
Infused Non-edible	Cannabinoids/Terpenes-	mg/g
	Foreign Matter Inspection	%
	Microbial Screen (TYMC, TAMC)	cfu/g
	Salmonella	Pass/Fail
	E. coli	cfu/g
	Mycotoxin Screen	ppb
	Pesticides	ppm
	Heavy Metals Screen	ppm
	Residual Solvents Screen	ppm
Vape Cart	Cannabinoids/Terpenes-	%
	Foreign Matter Inspection	%
	Microbial Screen (TYMC, TAMC)	cfu/g
	Salmonella	Pass/Fail
	E. coli	cfu/g
	Mycotoxin Screen	ppb
	Pesticides	ppm
	Heavy Metals Screen	ppm
	Residual Solvents Screen	ppm
	Vitamin E Acetate	ppm
(1) Infused Edible, (2) Exempt Edible Product, and (3) Infused Edible (Capsule)	Cannabinoids	mg/g
	Foreign Matter Inspection	%
	Water Activity	A_w
	Total Coliforms	cfu/g
	Salmonella	Pass/Fail
	E. coli	cfu/g
	Shiga toxin producing E. coli	Pass/Fail

METRC Product Category	COA Reporting Requirement	
	Analyte Group Tested	**Unit to report**
	L.monocytogenes	Pass/Fail
	Mycotoxin Screen	ppb
	Heavy Metals Screen	ppm
(1) Infused Liquid Edible, and (2) Exempt Liquid Edible	Cannabinoids	mg/g
	Foreign Matter Inspection	%
	Total Coliforms	cfu/g
	Salmonella	Pass/Fail
	E. coli	cfu/g
	Shiga toxin producing E. coli	Pass/Fail
	L.monocytogenes	Pass/Fail
	Mycotoxin Screen	ppb
	Heavy Metals Screen	ppm
Tincture for Oral Administration	Cannabinoids/Terpenes-	%
	Foreign Matter Inspection	%
	Microbial Screen (TYMC, TAMC)	cfu/g
	Salmonella	Pass/Fail
	E. coli	cfu/g
	Mycotoxin Screen	ppb
	Pesticides	ppm
	Heavy Metals Screen	ppm
	Residual Solvents Screen	ppm

All quantitative chemistry analysis should have values reported the following way: 1) reported value >LOQ should be the value, 2) reported value>LOD should be reported as <LOQ, 3) reported value <LOD should be reported as ND (Not Detected).

All quantitative microbiology analysis should have values <LOQ reported as ND (Not Detected).

Appendix B- Definitions

Administration- The Maryland Cannabis Administration established under Alcoholic Beverages and Cannabis Article, 36-201, Annotated Code of Maryland.

Batch -

(a) All of the plants of the same variety of 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.

Cannabis-

(a) The plant cannabis sativa l. and any part of the plant, including all non-synthetically derived, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol concentration greater than 0.3 percent on a dry weight basis.

(b) includes cannabis products, seeds, seedlings, immature plants, and clones.

(c) Does not include hemp or hemp products, as defined in the Agriculture Article, 14-101, Annotated Code of Maryland.

Cannabis Product-

(a) A product that is composed of cannabis, cannabis concentrate, cannabis extract, or any other ingredient and is intended for use or consumption.
(b) Includes any product produced and regulated under subtitle 14.17, including:
    (1) Cannabis vaporizing devices;
    (2) Concentrated cannabis products;
    (3) Edible cannabis products; and
    (4) Usable cannabis products.
(c) Does not include a home cultivation product.

Cannabis Vaporizing Device-

(a) a device that can be used to deliver aerosolized or vaporized cannabis or cannabis products to an individual inhaling from the device.
(b) Includes:

    (1) A vape pen;
    (2) Vaping liquid; and
    (3) Any component, part, or accessory of such a device regardless of whether it is sold separately, including a concentrated or infused cannabis liquid, for the purposes of heating and producing a vapor.

Capsule- A solid preparation containing a single serving of tetrahydrocannabinol or other cannabinoid that:

(a) Is intended to be swallowed whole;
(b) Not formulated to be chewable, dispersible, effervescent, orally disintegrating, used as a suspension, or consumed in a manner other than swallowed whole; and
(c) Does not contain any added natural or artificial flavor or sweetener.

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

Concentrated Cannabis Product-

(a) A product derived from cannabis that has undergone a process to concentrate one or more active cannabinoids.
(b) Concentrated cannabis products include:
    (1) Kief;
    (2) Hashish;
    (3) Bubble hash;
    (4) Oil;
    (5) Wax;
    (6) Shatter;
    (7) Resin; or
    (8) Any other product produced by extracting cannabinoids from the plant using solvents, carbon dioxide, heat, screens, presses, or steam distillation.
(c) Does not include any cannabis vaporizing device as defined in 14.17.

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

Edible Cannabis Product-

(a) Means a cannabis product intended for human consumption by oral ingestion, in whole or in part.
(b) Includes a cannabis product that dissolves or disintegrates in the mouth.
(c) Does not include any concentrated cannabis products, infused non-edible cannabis products, or capsules or tinctures that do not contain any food or food ingredients.

Green Waste-unauthorized misbranded, contaminated, unused, surplus, returned, or out of date cannabis or product containing cannabis.

Independent Testing Laboratory - A facility, entity, or site that is:

(a) Registered with the Administration to perform tests on cannabis or cannabis products;
(b) Independent of any entity licensed under Alcoholic Beverages and Cannabis Article, 36-401 to grow, process or dispense cannabis; and
(c) Accredited as operating to International Organization for Standardization (ISO) standard 17025 by and accreditation body:
    (1) Operating in accordance with ISO standard ISO/IEC 17011; and
    (2) That is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).

Infused Non-edible cannabis product- means ointment, salve, suppository, dermal patch, cartridge, or any other product containing cannabis that has been processed so that the dried leaves and flowers are integrated into other material that is not intended for human consumption by inhalation or oral ingestion.

Liquid edible product-

(a) An edible cannabis product that is a liquid beverage or liquid food-based product for which the intended use is oral consumption.
(b) Excludes a tincture as defined in 14.17.

Lot - All of a 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.

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 cannabis collected by laboratory personnel from a licensee and provided to an independent testing laboratory for testing.

Seed-to-sale tracking system-A software system procured by the Administration that tracks cannabis from either the seed or immature plant stage, until the cannabis is sold to a patient, caregiver, or consumer.

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 cannabis.

Tetrahydrocannabinol or "THC"-unless otherwise specified means any:

(a) Tetrahydrocannabinol, including delta-8-tetrahydrocannabinol, delta-9-tetrahydrocannabinol, and delta-10-tetrahydrocannabinol, regardless of how derived;
(b) Other cannabinoid, other than cannabidiol that the Administration determines to cause intoxication; and
(c) Other chemically similar compound, substance, derivative, or isomer of tetrahydrocannabinol, as identified by the Administration.

Tincture-a solution that is:

(a) Dissolved in alcohol, glycerin, or vegetable oil; and
(b) Distributed in a dropper bottle of four ounces or less.

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 or the weight of any noncannabis ingredients combined with cannabis, such as ingredients added to prepare a topical administration.

Usable Cannabis Product-

(a) A prepackaged product containing usable cannabis.
(b) Includes:
    (1) A pre-rolled amount of usable cannabis;
    (2) Securely stored, sealed, and labeled amount of usable cannabis; and
    (3) Any other type or amount of usable cannabis that has been wrapped, rolled, or otherwise encased for the purposes of smoking.

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

Appendix C- Grower Stability Testing Protocol

Stability testing shall be performed for each released batch of usable cannabis. This document outlines the required protocol to be followed by MCA licensed growers and MCA registered ITLs performing stability studies.

Definitions:

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 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 Panel - Each stability sample is to be tested for a) Micro-organisms; and b) Potency to ensure product potency and purity and provide support for expiration dates.

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 (0, 6, 12 and 18 months).

Stability Testing Goals:

The design will assess:

- Degradation of cannabinoids in usable 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 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 MCA.
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 products 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 to the laboratory’s standard operating procedures.
11. Laboratory methodology shall be consistent throughout the study. Changes to technology or protocols throughout the study require approval from MCA.

Appendix D- Processor Stability Testing Protocol

Stability testing shall be performed for each released lot of processed cannabis. This document outlines the required protocol to be followed by MCA licensed processors and MCA registered ITLs performing stability studies.

Definitions:

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

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

Lot – All of a 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).

Stability Testing Goals:

The design must assess:

- Degradation of cannabinoids in 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 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 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 products 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.
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 MCA.
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.

Appendix E- Edibles Uniformity and Stability Testing Protocol

Shelf-life testing shall be performed for each unique edible cannabis product available for patient and adult-use consumption. This document outlines the required protocol to be followed by MCA licensed processors and the MCA registered ITLs performing testing. The protocol consists of 10 individual product samples being analyzed for content uniformity as well as a 12-week time 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.

Stability Requirements (Time points 1-3):

Following the initial content uniformity testing and product compliance 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.

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).

Table 1: Quantitative Analysis Control Chart- Broth-based QC Example

+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	X	
EC Control Results						
BGB Control Results						

Temp Incubated_____ °C Time/Date_____ Initials_____

Table 2: Quantitative Petri film/charm controls QC Example

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_____

Table 3: Quantitative Aerobic Bacterial Count QC Example

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_____

Table 4: Certified Reference Material Table Example

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

Quality Control (QC) performed for qualitative analysis must include a Sterility Control, Negative Control, and a Positive Control at a MINIMUM every time you set up samples for that day using the same lot of reagents. 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.

Table 5: Qualitative Analysis Control Chart Example

+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_____

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 MCA via phone and email (mca.labs@maryland.gov) of the confirmed pathogen positive.
3. Enter all failed test results into Metrc.
4. Notify the licensee and coordinate sample pickup with the MCA.
    a. Refrigerate selective agar plates, the original enrichment broth, and the blood plates at 2-8º Celsius until pickup by MCA.
5. Perform environmental swab testing of the licensee's facility after a presumptive positive is detected.
6. Perform environmental swab testing of the licensee's facility after it has been decontaminated.
7. Notify the MCA of the environmental swab testing results.

Table 1: Confirmation steps required for pathogen detection

Pathogen Detected	**Confirmation steps required**
E. coli	API 20E
STEC	API 20E; if confirmed proceed with Latex agglutination and/or qPCR for O157 or non-O157
L. monocytogenes	API Listeria and/or latex agglutination
Salmonella spp.	API 20E, and/or qPCR

Appendix H- Green Waste Disposal Procedure For Independent Testing Laboratories

This standard operating procedure provides a standardized method of disposal for cannabis green waste at MCA registered independent testing laboratories. The procedure ensures accountability for cannabis green waste by establishing appropriate documentation and destruction processes. MCA requires registered independent testing laboratories to implement the Green Waste Disposal Procedure upon adoption of Revision 5.0 of this technical authority.

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 MCA 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 items (i.e. grams, each);
    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);.
    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.

Appendix I- Method Performance Requirements Performance Test Methods Available for Use, and Quality Control Requirements

*SMPR's and PTM's will be revised annually. PTM's published in the interim must be approved for use by the MCA. Method validations are required when an independent testing laboratory is developing its own method for use. The following criteria must be provided and approved by MCA in advance of the method being utilized as well +as demonstrated by the ITL:

- Sensitivity
- Selectivity
- Repeatability
- Reproducibility
- Robustness
- Accuracy
- Linearity
- LOD
- LOQ

Method verifications are required to verify that an independent testing laboratory can meet the quality control requirements of a reference or validated method. Quality control requirements of the method include but are not limited to the following:

- Limit of detection and quantitation studies
- Initial and continuing calibration verification, as defined by the method
- Control spikes and/or fortified blanks
- Passing proficiency testing samples in the appropriate matrix (if commercially available)

The LOD and LOQ required for analytical chemistry methods should be established using the Environmental Protection Agency "Definition and Procedure for the Determination of the Method Detection Limit". The LOD should be re-evaluated at least annually.

Quality control requirements for each assay are based on recommendations from the American Council of Independent Laboratories (ACIL)"Guide to Harmonizing Cannabis Laboratory Quality and Testing Practices.

POTENCY:

For method validations, should use the Standard Method Performance Requirements (SMPRs) as guidance listed below:

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

- **Edible Chocolate: AOAC SMPR 2017.019**

Sample Analysis:

- **Quantitation of Cannabinoids in Cannabis Dried Plant Materials, Concentrates, and Oils AOAC 2018.11 or an MCA approved method**

Table 1: Required Quality Controls for Potency/Terpene Analysis

Control	Potency Requirements	Terpene Requirements
Reagent or Solvent Blank	Not to exceed LOD	Not to exceed LOD
Method Blank	Not to exceed LOD	Not to exceed LOD
Laboratory Control Sample (LCS)	Recovery 85-115%	Recovery 70-130%
Sample Duplicate	RPD ≤ 30% for all analytes with concentrations greater than LOQ	RPD ≤ 30%
Initial Calibration Verification (ICV)	Recovery 85-115%	Recovery 70-130%
Continued Calibration Verification (CCV)	Recovery 90-110%, same source of standards used in calibration curve Recovery 85-115% if using ICV	Recovery 70-130%

PESTICIDES/MYCOTOXINS:

Method validations should use the Standard Method Performance Requirements (SMPRs) as guidance listed below:

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

Table 2: Required Controls for pesticide/mycotoxin analysis

Control	Requirements
Reagent or Solvent Blank	Not to exceed LOD
Continuing Calibration Verification (CCV)	Recovery 70-130%
Initial Calibration Verification (ICV) Midpoint of the calibration curve from a second source	Recovery 70-130%
Method Blank	Not to exceed LOD
Laboratory Control Sample (LCS)	Recovery 60-120%
Sample Duplicate	RPD ≤ 30%

RESIDUAL SOLVENTS:

For method validations, should use the Standard Method Performance Requirements (SMPRs) as guidance listed below:

- **Identification and Quantitation of Selected Residual Solvents in Cannabis-Derived Materials: AOAC 2019.002**

Table 3: Required Controls for Residual Solvents

Control	Requirements
Method Blank	Not to exceed LOQ
Laboratory Control Sample (LCS)	Recovery 70-130% except for analytes with boiling point <0C
Sample Duplicate	RPD ≤ 30%
Initial Calibration Verification (ICV)	Recovery 70-130%
Continued Calibration Verification (CCV)	Recovery 70-130%

MICROBIOLOGICAL IMPURITIES:

For method validations, should use the Standard Method Performance Requirements (SMPRs) as guidance 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**

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 Gene Screen (stx and eae)**
- **3M Molecular Detection Assay 2-STEC Gene Screen (stx)**
- **GENE-UP PRO STEC/Salmonella Assay**
- **BAX System Real-Time PCR Assay for E.coli 0157:H7 Extract**

WATER ACTIVITY:

Sample Analysis:

- **Standard Practice for Determination of Water Activity in Cannabis Flower: ASTM D8196 or MCA approved method**

Table 4: Required controls for Water Activity

Control	Water Analysis Method	Frequency	Requirements
Continued Calibration Verification (CCV)	Water Activity Standards	Two CCVs, bracketing the limits	Should meet manufacturers specifications
Duplicate Sample	Run one duplicate per batch	RPD < 5%	

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 or MCA approved method**

Table 5: Required controls for Heavy Metal Testing

Control	Requirements
Method blank	Does not exceed LOQ
Reagent blank	Does not exceed LOD
Laboratory Control Sample (LCS)	Recovery 85-115%
Continuing Calibration Verification (CCV)	Recovery 80-115%
Initial Calibration Verification (ICV) Mid-point on the calibration curve. Run immediately after setting up calibration.	Recovery 80-115%
Sample Duplicate	RPD ≤ 30%

Appendix J- Product Remediation and Testing Requirements

The MCA authorizes the remediation of products after certain test failures. The MCA does not provide guidance for methods to remediate failed products. The following table defines failure criteria for each area of testing, and indicates which tests are allowed remediation.

Table 1: Remediation Guidelines based on compliance test category

Test Category	Test value resulting in failed test	Remediation allowed
Foreign Matter Inspection	Present	No
Microbial Screen (TYMC, TAMC)	>100,000 CFU/g	Yes
Mycotoxin Screen	>20 ppb	No
Water Activity	Raw Flower >0.65 Aw Infused edible products (excluding infused liquid edible products) >0.85 Aw	Raw Flower- yes Infused edible products- no
Heavy Metal Screen	Cannot exceed Action Limits.	Yes
Residual Solvent Test	Cannot exceed Action Limits.	Yes
Pesticide Residue Analysis	Cannot exceed Action Limits.	No
Vitamin E Acetate	>100 ppm	No
Pathogens: Shiga Toxin Producing E. coli, Salmonella, spp., and L. monocytogenes	Detected	No
Total Coliform	>100 CFU/g	No
E. coli	>10 CFU/g	No

A failed test result that is eligible for remediation will require the product to be remediated, then retested prior to transfer for retail sale. The remediation must be documented in the seed-to-sale system. To retest a failed item, two new lab samples must be created and manifested to the testing facility. The first sample is required to be tested for the full compliance testing panel. The second sample only requires retesting of the failed result. A certificate of analysis must be uploaded for each retest sample. For microbial screening failures, the retest results from both samples should be averaged and reported on the new certificate of analysis. For chemistry screening failures, the

result from the full compliance retest should be reported. The new certificate of analysis to be associated with the final product must have: 1) retest stated across the top 2) include a statement indicating that the results are a retest of the parent package, and 3) indicate which results have been updated after the remediation and retesting.

A failed test result that does not allow for remediation needs to be reported to MCA via email to mca.labs@maryland.gov within 24 hours of the failed test by the ITL. All failed products that do not allow remediation are required to be destroyed.

At the request of a licensee, the MCA may, on a case-by-case basis, authorize a retest to validate the results of a failed test. All microbiology testing, except microbial screening tests TYMC and TAMC, are not permitted to submit a request for retest and the product must be destroyed. The request to retest a product must be submitted to MCA within three days of the test failure through the Product Retest Request Form. The retest must be performed by a secondary independent testing laboratory or the MCA reference laboratory. The retest must be done from the retention sample and the testing should be performed twice. All retesting costs are the responsibility of the licensee. If the sample passes both tests upon retesting the product may be released for sale. If the sample does not pass both tests the product must be destroyed.

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