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DEPARTMENT OF HEALTH

OFFICE OF MEDICAL MARIJUANA

GUIDANCE FOR QUALITY TESTING AND SAMPLING BY APPROVED LABORATORIES

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Introduction.

The Pennsylvania Department of Health's vision is to have a high quality, efficient and compliant medical marijuana program for commonwealth residents with serious medical conditions. When fully implemented, the Medical Marijuana Program will provide access to medical marijuana for patients with a serious medical condition through a safe and effective method of delivery that balances a patient's need for access to the latest treatments with patient care and safety. A large part of patient safety and care is making sure that each medical marijuana product sold to a dispensary is tested for harmful contaminants and that labels accurately reflect the content and potency of medical marijuana being dispensed.

Scope.

The Department of Health, Office of Medical Marijuana, is issuing this guidance as part of regulatory requirements for testing and sampling of medical marijuana by an approved laboratory accredited to International Organization for Standardization (ISO) 17025 under 28 Pa. Code §1171. This guidance will be updated by the Department as needed to reflect the current practices within the medical marijuana industry and current thinking of the Department based on changes in best practices, advances in science and technology, and other relevant information available to the Department.

Applicability.

This guidance represents the current testing methods and sampling standards that will be accepted by the Department in the testing of medical marijuana and medical marijuana products under 28 Pa. Code § 1171.27, § 1171.29 and § 1171.30. This guidance also allows an approved laboratory to maintain standards of testing within the scope of their certificate of accreditation as required under 28 Pa. Code § 1171.30. The Department will maintain oversight of testing methods and sampling standards by conducting onsite visits and the review of certificates of analysis submitted by an approved laboratory in the Department's electronic tracking system and provided to the grower/processor requesting the testing of medical marijuana.

Nothing in this guidance will prevent a grower/processor from requesting from the Department that an approved laboratory test medical marijuana during any phase of production before the medical marijuana is tested as part of a process lot.

Definitions.

The following terms used throughout this guidance are those defined in 28 Pa. Code § 1141.21 and 28 Pa. Code § 1171.21.

Certificate of analysis—A document that confirms that the test performed by an approved laboratory on a harvest batch, harvest lot or process lot meets the testing requirements set forth by the Department.

Chain of custody—The written procedures used by employees of an approved laboratory to record the possession and transfer of samples and test samples from the time the samples and test samples are collected until the test of the sample or test sample is completed.

Form of medical marijuana—The characteristics of the medical marijuana recommended or limited for a particular patient, including the method of consumption and any particular dosage, strain, variety and quantity or percentage of medical marijuana or particular active ingredient.

Harvest batch—A specifically identified quantity of medical marijuana plant that is uniform in strain, cultivated utilizing the same growing practices, harvested at the same time and at the same location, and cured under uniform conditions.

Harvest lot—A specifically identified quantity of medical marijuana plant taken from a harvest batch.

Medical marijuana—Marijuana for certified medical use as set forth in the regulations.

Medical marijuana container—A sealed, traceable, food compliant, tamper resistant, tamper evident container used for the purpose of containment of packaged medical marijuana being transported from a grower/processor to a medical marijuana organization or a laboratory.

Medical marijuana product—The final form and dosage of medical marijuana that is grown, processed, produced, sealed, labeled and tested by a grower/processor and sold to a dispensary.

Process lot—Any amount of a medical marijuana product of the same type and processed using the same medical marijuana extract, standard operating procedures and the same or combination of different harvest lots.

Sample—Medical marijuana collected by an employee of an approved laboratory from a grower/processor for testing by the laboratory.

Test sample—An amount of medical marijuana or an amount of soil, growing medium, water or solvents used to grow or process medical marijuana, dust or other particles obtained from the swab of a counter or equipment used in the growing or processing of medical marijuana, or other item used in the growing or processing of medical marijuana in a facility taken by an employee of an approved laboratory or an agent of the Department at the request of the Department from a grower/processor and provided to an approved laboratory for testing.

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Sample Transportation

The samples must be transported as defined in 28 Pa. Code § 1171.33.

Sampling Plan.

Sampling is a regulatory requirement defined in 28 Pa. Code § 1171.27. A sample taken for testing by an approved laboratory should be representative of the harvest batch, harvest lot or process lot being tested and the amount removed should be based on appropriate statistical criteria such as those adopted by the American National Standards Institute/American Society for Quality Z1.4-2008.

1. Test Sampling.

The sampling and testing processes process shall begin with a grower/processor designating a harvest batch or harvest lot for either processing into extract or flower. Sampling size based upon the criteria below will be acceptable by the Department.

Test Sampling for Extract Based Product	
Applies to Harvest Batch or Harvest Lot **This test sampling applies to any harvest batch or harvest lot that a grower/processor designates will be used for processing medical marijuana.**	
Final Yield for Testing	**Composite Sample**
Less than 5 pounds	No more than 8 grams or a quantity the approved laboratory and grower/processor determines is sufficient to perform all the required tests.
5 to 25 pounds	8-15 grams or a quantity the approved laboratory and grower/processor determines is sufficient to perform all the required tests. A grower/processor **may not** change the designation of the harvest batch or harvest lot from an extract-based product to a flower product after a passing test is determined by an approved laboratory.
10 pounds equivalent (fresh frozen)	12-20 grams or a quantity the approved laboratory and grower/processor determines is sufficient to perform all the required tests, but no more than 20 grams. The harvest batch or harvest lot of fresh frozen may not exceed 60 lbs. in size. A grower/processor may request a waiver from the Department that a harvest batch or harvest lot greater than 60 lbs. in weight be tested if the weight does not exceed 75 lbs. in weight. A sampling plan must also be included in the waiver request.

Test Sampling for Extract Based Product Cont.	
Applies to a Process Lot	
Final Yield for Testing	**Composite Sample**
Final Product (Process Lot)	3-7 grams or a quantity the approved laboratory and grower/processor determines is sufficient to perform all the required tests. Sampling should be taken from a random selection of final packaged product that represents the dosage and form of medical marijuana processed and produced at the same time.

Test Sampling for Flower Product	
Applies to Harvest Batch or Harvest Lot This test sampling applies to any harvest batch or harvest lot that a grower/processor designates will be used for flower.	
Final Yield for Testing	**Composite Sample**
10 pounds or less.	8-10 grams or a quantity the approved laboratory and grower/processor determines is sufficient to perform all the required tests. A grower/processor **may** change the designation of the harvest batch or harvest lot from a flower product to an extract-based product after a passing test is determined by an approved laboratory.
Applies to a Process Lot	
Final Yield for Testing	**Composite Sample**
Final Product (Process Lot)	3-14 grams or a quantity the approved laboratory and grower/processor determines is sufficient to perform all the required tests. Sampling should be taken from a random selection of final packaged product that represents the form and dosage of medical marijuana produced at the same time.

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Test Methods and Validation.

All testing methods that are developed and used by an approved laboratory should meet or exceed the minimum standard as stated in the American Herbal Pharmacopeia's "*Cannabis Inflorescence* Standards of Identity, Analysis and Quality Control", 2014 Revision Edition. All testing methods must be fully validated to address the accuracy, precision, specificity, linearity, range, and sensitivity of the testing method.

Chemical Profile	Suggested Testing Methodologies
Cannabinoids which require quantitation	Tested using a chromatographic method such as High-Performance Liquid Chromatography or Ultra High- Performance Liquid Chromatography.
Terpenes	Using a chromatographic method such as Gas Chromatography or Gas Chromatography/ Mass Spectroscopy, or Liquid Chromatography.
Pesticide residue analysis	Using Liquid Chromatography, Gas Chromatography/ Mass Spectroscopy, or Electron Capture Detection.
Residual solvents (processed products which use organic solvents for extraction)	Using Gas Chromatography, or Gas Chromatography/ Mass Spectroscopy technology.
Heavy metal	Using Inductively Coupled Plasma or Inductively Coupled Plasma-Mass Spectroscopy technology.
Microbiological testing	Appropriate methods for performing include plating & culture. See reference in U.S. Food and Drug Administration Laboratory Methods.
Moisture content & water activity	Using methodology described in Dutch Office of Medical Cannabis 2014. Alternative methods such as the use of moisture balances may also be acceptable.

Required Contaminant Analyses and Acceptance Criteria.

Testing required under 28 Pa. Code § 1171.29 (relating to testing requirements): approved laboratories should refer to the following chart and guidelines for testing and acceptance criteria. Please note that PCR testing is not acceptable and is not approved by the Department. Samples must be plated and measured in CFUs.

Medical Marijuana Harvest and Final Product Acceptance Criteria			
Analyte	Maximum level	Comment	Guideline
Metals			
Arsenic	0.4 ppm	Metals testing is required for every harvest lot and process lot.	FDA Q3D, Elemental Impurities Guidance. Limits are at or below the recommended guidelines.
Cadmium	0.30 ppm		
Lead	1.0 ppm		
Mercury	0.2 ppm		

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Medical Marijuana Harvest and Final Product Acceptance Criteria			
Analyte	Maximum level	Comment	Guideline
Mycotoxins			
Aflatoxin B1 Aflatoxin B2 Aflatoxin G1 Aflatoxin G2 Ochratoxin A	5 ppb 20 ppb total	Consistently test for all five mycotoxins. B1 has a limit of 5 ppb and there is a 20ppb total limit for all five mycotoxins combined.	American Herbal Pharmacopoeia Recommended Standards
Analyte	Maximum level	Comment	Guideline
Microbials			
Water Activity	A_w 0.65	Not required for fresh frozen samples.	Dutch Office of Medical Cannabis
Moisture Content	Between 5-15%		
Salmonella	Absence in 1g	Microbial testing required for every harvest and process lot. A result higher than 1000 CFU/g will prompt an alert and review by the Department. A result higher than 100 CFU/g will prompt an alert and review by the Department.	American Herbal Pharmacopeia Cannabis Inflorescence
E. Coli	Absence in 1g		
Mold and Yeast	• 10,000 CFU/g Harvest Lot • 1000 CFU/g Process Lot • 10,000 CFU/g Final processed flower at product testing		
Total Viable Aerobic Bacteria Microbial Count	• 10,000 CFU/g Harvest Lot • 10,000 CFU/g Process Lot (including flower at product testing)		
Bile tolerant gram-negative bacteria	• 1000 CFU/g Harvest Lot • 100 CFU/g Process Lot • 1000 CFU/g Final flower at product testing		
Analyte	Maximum level	Comment	Guideline
Pesticides			
Those listed in Appendix A of 28 Pa. Code § 1151 or any pesticide suspected or known to be used on the crop.	Appendix A includes a positive list of what is allowed. Other pesticides are not permitted, but will be tested.	Testing for pesticides will be randomly done by an approved laboratory on harvest batches or harvest lots. Consistent testing of stock solutions will occur if a medical marijuana organization has notified the OMM that they intend to use a particular pesticide.	Appendix A of 28 Pa. Code § 1151 & APHL "Guidance for State Medical Cannabis Testing Programs" (2016)

Analyte	Maximum level	Comment	Guideline
Solvents			
Butane	5000 ppm	Residual solvent testing required for every process lot.	US Pharmacopeia 467
Ethanol	5000 ppm		

Testing Requirements Summary Table

Test	Harvest Lot (before processing)	Process Lot (extraction-based final product)	Process Lot (final flower)	Process Lot (vape pen empty) *	Stability Testing
Moisture Content & Water Activity	X		X		X (flower only)
Microbiological	X	X	X	X	X
Mycotoxins	X	X	X		X
Heavy Metals	X	X	X	X	X
Solvents		X			
Pesticides	X				
Potency	X	X	X		X
Terpenes	X	X	X		X

* For vape pens that cannot be opened once filled and heat sealed (primarily disposable), the empty vape pens would be sent to the lab for testing. The lab would test 7 vape pens for the equivalent of 3.5 grams of finished product (using the median size of a 500 mg vape pen). The lab may make one composite sample from the 7 vape pens to be tested. Please refer to the "Process Lot (extraction-based final product) column above for testing requirements for the product.
* For vape pens that can be opened, the cartridge would be removed and the product would be tested as usual. Please refer to the "Process Lot (extraction-based final product) column above.

Pesticide Usage Guidelines

The Department suggests two approaches be considered by a grower/processor:

1) Pesticide free production. The entire process from acquisition of seeds or cuttings through harvest would take place under clean, controlled conditions that would be absent of any pesticides, chemical agents, or plant growth regulators.

2) Use of permitted pesticides under 28 Pa. Code § 1151.43 (relating to pesticides) that meet the growing requirements under 28 Pa. Code § 1151.27 (relating to requirements for growing and processing medical marijuana).

Please note the list of pesticides in 28 Pa. Code § 1151.43, Appendix A are the only pesticides allowed to be used on crops in Pennsylvania. If a laboratory detects an amount of a pesticide from Appendix A that exceeds normal or acceptable limits, the laboratory will notify the Department.

A list of other pesticides known to be used by cannabis growers (see Table 1 below), represents compounds that are not permitted, and that the Department will monitor through laboratory testing. If an approved laboratory detects a pesticide on the list below or another pesticide within the National Institute of Standards and Technology (NIST) library during the testing process, the approved laboratory will notify the Department. The Department will work in cooperation with the Department of Agriculture to investigate and take appropriate action against the grower/processor. The Department may also obtain test samples from a grower/processor to conduct pesticide residue testing.

Table 1 - Additional Pesticide Testing Information

Other Known Pesticides

Abamectin	Cyfluthrin	Hexythiazox	Piperonyl Butoxide
Acephate	Cypermethrin	Imazalil	Prallethrin
Acequinocyl	Daminozide	Imidacloprid	Propiconazole
Acetamiprid	DDVP	Kresoxim-methyl	Propoxur
Aldicarb	Diazinon	Malathion	Pyridaben
Azoxystrobin	Dimethoate	Metalaxyl	Spinetoram
Bifenazate	Dimethomorph	Methiocarb	Spinosad
Bifenthrin	Ethoprophos	Methomyl	Spriromesifen
Boscalid	Etofenprox	Methyl parathion	Spirotetramat
Carbaryl	Etoxazole	Mgk-264	Spiroxamine
Carbofuran	Fenhaxamid	Myclobutanil	Tebuconazole
Captan	Fenoxycarb	Naled	Thiacloprid
Chlorantraniliprole	Fenpyroximate	Oxamyl	Thiamethoxam
Chlorfenapyr	Fipronil	Paclobutrazol	Trifloxystrobin
Chlorpyrifos	Flonicamid	Permethrins	
Clofentezine	Fludioxonil	Phosmet	

- The laboratory will report any pesticides that are detected above the limit of detection (LOD).
- The laboratory shall establish a limit of quantification of 0.1 μg/g or lower for all pesticides.
- The laboratory shall analyze at minimum 0.5 grams of the representative sample of cannabis to determine whether residual pesticides are present.
- The laboratory shall report whether any residual pesticides are detected above the limit of detection (LOD) and shall report the result of the residual pesticides testing in unit micrograms per gram (μg/g) on the Certificate of Analysis.

Stability Testing.

In accordance with 28 Pa. Code § 1171.26 (relating to stability testing and retention of samples), a grower/processor shall provide samples from each process lot (final sample) to an approved laboratory for testing at 6-month and 1-year intervals for extraction-based products. The sample shall be taken from the reserved sample portion provided to the approved laboratory that is collected from each process lot being tested. Any reserve samples remaining after testing at the end of the 1-year period shall be destroyed in accordance to the approved laboratory's disposal process.

A grower/processor shall provide samples from each process lot (final sample) to an approved laboratory for testing at 1-month and 3-month intervals for finished flower products.

The stability tests of final products will include testing for potency, terpenes, microbials, mycotoxins, and heavy metals. Moisture content is only required for stability testing when the final product is flower.

The approved laboratory shall also provide a storage system, including appropriate containers that will maintain the products over the intended shelf life of the medical marijuana product.

Test results shall be reported by the approved laboratory in the electronic tracking system and will only be available to the grower/processor from which the sample was taken and the Department.

Any medical marijuana being held by an approved laboratory for stability shall be stored per grower/processor requirements for that medical marijuana product.

Please note that as of June 1, 2018, the Department has suspended the requirement of stability testing on harvest batches or harvest lots. However, samples collected for stability testing prior to June 1, 2018, as required, are being tested as previously indicated and reviewed by the Department.