Quality Assurance and Testing Protocols

Quality Assurance Sampling Protocols.

(1) To ensure quality assurance samples submitted to certified third-party laboratories (certified labs) are representative from the lot or batch from which they were sampled as required in MCA 37.107.405, certified labs and their employees must adhere to the minimum sampling protocols.

(2) Sampling protocols for all marijuana product lots and batches:

(a) Labs may not use any third-party contracted laboratories to conduct tests.

(b) Lab personnel carrying out the sampling must be trained and certified in the appropriate procedures by the laboratory they are employed by.

(c) Samples must be deducted in a way that is most representative of the lot or batch and maintains the structure of the marijuana sample.

i. Samples for products, including but not limited to, useable marijuana including trim and manicure, extracts (oils or shatters), tinctures, vape pens, kief, hash, edibles, capsules, hash, salves, and ointments must be .5% of the batch size. Example: if the total batch weight is 3.31 pounds, the lab would be required to collect 7.5 grams (3.31 lbs. = 1501 grams x .5% = 7.5 grams). For multiple strain batches, dived the minimum required sample sized by the number of strains. Example: If there are 5 strains that make up the 3.31-pound batch, the lab is required to (at minimum) collect 1.5 grams per strain (7.5g/5strains = 1.5 grams. A minimum of 1 gram per strain is required regardless of batch size and strain count.

ii. Licensees, certified labs, and their employees may not adulterate or change in any way the representative sample from a lot or batch before submitting the sample to certified labs. This includes adulterating or changing the sample in any way as to inflate the level of potency, or to hide any microbiological contaminants from the required microbiological screening such as, but not limited to:

(i) Adulterating the sample with kief, concentrates, or other extracts;

(ii) Treating a sample with solvents to hide the microbial count of the lot or batch from which it was deducted. This subsection does not prohibit the treatment of failed lots or batches with methods approved by DPHHS; or

(iii) Pregrinding a flower lot sample.

(d) All samples must be taken in a sanitary environment using sanitary practices.

(e) Persons collecting samples must wash their hands prior to collecting a sample from a lot or batch, wear appropriate gloves while preparing or deducting the lot or batch for

sample collection, and must use sanitary utensils and storage devices when collecting samples.

(f) Samples must be placed in a sanitary plastic or glass container, and stored in a location that prevents the propagation of pathogens and other contaminants, such as a secure, low- light, cool and dry location.

(g) The licensee must maintain the lot or batch from which the sample was deducted in a secure, low-light, cool, and dry location to prevent the marijuana from becoming contaminated or losing its efficacy.

i. Samples must be accompanied by a transfer manifest.
ii. Samples must be transferred in a locked, climate controlled container.
iii. Samples must be stored in a licensed, climate-controlled facility if the lab requires overnight travel.

(h) Each quality assurance sample must be clearly marked "quality assurance sample" and be labeled with the following information:

(i) The sixteen-digit identification number generated by the traceability system;

(ii) The license number and name of the certified lab receiving the sample;

(iii) The license number and name of the licensee sending the sample;

(iv) The date the sample was collected; and

(v) The weight of the sample.

(i) Licensees or certified labs must collect a minimum of four separate samples from each marijuana flower lot up to five pounds. Licensees or certified labs may collect more samples than this minimum, but must not collect less.

(j) The four separate samples must be taken from different quadrants of the flower lot. A quadrant is the division of a lot into four equal parts. Dividing a lot into quadrants prior to collecting samples must be done in a manner that ensures the samples are collected from four evenly distributed areas of the flower lot and may be done visually or physically.

(k) The four samples may be placed together in one container conforming to the packaging and labeling requirements in subsection (2) of this section for storage and transfer to a certified lab.

(l) Sample must be homogenized to test for pesticides and potency.

(9) Certified labs may retrieve samples from a marijuana licensee's licensed premises and transport the samples to the lab or a lab’s licensed premise within the same day. Certified labs may also return any unused portion of the samples.

(3) Certified labs may reject or fail a sample if the lab has reason to believe the sample was not collected in the manner required by this section, adulterated in any way, contaminated with known or unknown solvents, or manipulated in a manner that violates the sampling protocols, limit tests, or action levels.

(4) DPHHS will take disciplinary action against any licensee or certified lab that fails to comply with the provisions of this section or falsifies records related to this section including, without limitation, revoking the license the licensed producer or processor, or certification of the certified lab.

Quality Assurance Testing

A third-party testing lab must be licensed by the State of Montana, Department of Health and Human Services (DPHHS) as meeting the state requirements MCA 37.107.301 and prior to conducting quality assurance tests required under this section:.

(1) In addition to passing a review of the application and an on-site assessment the laboratory must participate in a proficiency testing (PT) program and participate in two single-blind, single-concentration PT studies, where available, per year for each method it seeks accreditation. For all fields of testing, including those for which PT samples are not available, the laboratory shall ensure the reliability of its testing procedures by maintaining a total quality management system that meets all applicable requirements of V1:M1, Proficiency Testing, of the 2009 TNI Standards.

(2) Certified labs must use industry accepted equipment designed to accurately perform the testing the certified lab is being certified to.

(3) Quality assurance fields of testing. Certified labs must be certified to the following fields of testing by ISO approved auditor and must adhere to the guidelines for each quality assurance field of testing listed below. A lab must become certified or be actively seeking certification in all fields of testing the lab offers regardless of whether the test is required by the Department. Labs are required to gain ISO certification within 360 days, are required to submit proof they are seeking ISO certification and demonstrate proficiency through proficiency testing in each area of testing within 180 days of being issued a license

(a) Potency analysis.

(i) Certified labs must test and report the following cannabinoids when testing for potency:

(A) THCA;

(B) THC;

(C) Total THC;

(D) CBDA;

(E) CBD; and

(F) Total CBD.

(ii) Calculating total THC and total CBD.

(A) Total THC must be calculated as follows, where M is the mass or mass fraction of delta-9 THC or delta-9 THCA: M total delta-9 THC = M delta-9 THC + (0.877 x M delta-9 THCA).

(B) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA: M total CBD = M CBD + (0.877 x M CBDA).

(iii) Regardless of analytical equipment or methodology, certified labs must accurately measure and report the acidic (THCA and CBDA) and neutral (THC and CBD) forms of the cannabinoids.

(iv) Certified labs may combine in equal parts multiple samples from the same flower lot for the purposes of the following tests after the individual samples have been tested for potency analysis.

(a) Moisture analysis. The sample and related lot or batch fails quality assurance testing for moisture analysis if the results exceed the following limits:

(i) Moisture content more than twelve percent.

(b) Filth and Foreign matter screening. A laboratory shall analyze all samples for filth and foreign material present in the sample. "Filth and foreign material" includes but is not limited to hair, insects, feces, packaging contaminants, and manufacturing waste and by-products. The sample and related lot or batch fail quality assurance testing for foreign matter screening if the results exceed the following limits:

(i) Five percent by weight of stems 3mm or more in diameter; and

(ii) Two percent by weight of seeds or other foreign matter, including.

(iii) Mammalian Excreta

(c) Microbiological screening. The sample and related lot or batch fail quality assurance testing for microbiological screening if the results exceed the following limits:

(i) Salmonella: non-detectable in a gram of material;

(ii) E. Coli: non-detectable in a gram of material;

(iii) <10,000 CFU/g of culturable mold

(d) Mycotoxin screening. The sample and related lot or batch fail quality assurance testing for mycotoxin screening if the results exceed the following limits:

(i) Total of Aflatoxin B1, B2, G1, G2: 20 µg/kg of substance; and

(ii) Ochratoxin A: 20 µg/kg of substance.

(e) Residual solvent screening. Except as otherwise provided in this subsection, a sample and related lot or batch fail quality assurance testing for residual solvents if the results exceed the limits provided in the table below.

Solvent*	**ppm**
Acetone	5,000
Benzene	2
Butanes	5,000
Cyclohexane	3,880
Chloroform	2
Dichloromethane	600
Ethyl acetate	5,000

Solvent*	ppm
Heptanes	5,000
Hexanes	290
Isopropanol (2-propanol)	5,000
Methanol	3,000
Pentanes	5,000
Propane	5,000
Toluene	890
Xylene **	2,170

* And isomers thereof.

** Usually 60% *m*-xylene, 14% *p*-xylene, 9% *o*-xylene with 17% ethyl benzene.

(f) Pesticides. A sample and related lot or test batch fail quality assurance testing for pesticides if the results exceed the limits provided in the table below.

Analyte	Chemical Abstract Services (CAS) Registry Number	Action Level ppm; Unprocessed/Dry Flower	Action Level ppm; Extract
Abamectin	71751-41-2	0.5	2.5
Acequinocyl	57960-19-7	2	10
Bifenazate	149877-41-8	0.2	1
Bifenthrin	82657-04-3	0.2	1
Chlormequat chloride	999-81-5	1	5
Cyfluthrin	68359-37-5	1	5
Daminozide	1596-84-5	1	5
Etoxazole	153233-91-1	0.2	1
Fenoxycarb	72490-01-8	0.2	1
Imazalil	35554-44-0	0.2	1
Imidacloprid	138261-41-3	0.4	2
Myclobutanil	88671-89-0	0.2	0.6
Paclobutrazol	76738-62-0	0.4	2
Permethrins †	52645-53-1	0.2	1
Spinosad	168316-95-8	0.2	1
Spiromesifen	283594-90-1	0.2	1
Spirotetramat	203313-25-1	0.2	1
Trifloxystrobin	141517-21-7	0.2	1

† Permethrins should be measured as cumulative residue of cis- and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8).
† Pyrethrins should be measured as the cumulative residues of pyrethrin 1, cinerin 1 and jasmolin 1 (CAS numbers 121-21-1, 25402-06-6, and 4466-14-2 respectively).

(g) Heavy metal screening (random schedule to be determined by DPHHS). A sample and related lot or batch fail quality assurance testing for heavy metals if the results exceed the limits provided in the table below.

Metal	**µg/daily dose (5 grams)**
Inorganic arsenic	10.0
Cadmium	4.1
Lead	6.0
Mercury	2.0

(4) Quality assurance testing required. The following quality assurance tests are the minimum required tests for each of the following marijuana end products, respectively. Licensees and certified labs may elect to do multiple quality assurance tests on the same lot or testing for mycotoxin, pesticides, or heavy metals.

(a) General quality assurance testing requirements for certified labs.

(i) Certified labs must record an acknowledgment of the receipt of samples from producers or processors in the DPHHS seed to sale traceability system. Certified labs must also verify if any unused portion of the sample was destroyed or returned to the licensee after the completion of required testing.

(ii) Certified labs must fail a sample if the results for any limit test are above allowable levels.

(b) End products. All marijuana, marijuana-infused products, marijuana concentrates, marijuana mix packaged, and marijuana mix infused end products require the following quality assurance tests:

Testing Requirements

Product Type	Testing Requirement if intended for sale from a dispensary	Testing Requirement if intended for further processing
Usable marijuana, including trim and manicure	• Pesticide • Moisture content • Cannabinoid profile/Potency • Microbiological • Mycotoxin • Filth and foreign matter • Heavy metals (Random)	

Product Type	Testing Requirement if intended for sale from a dispensary	Testing Requirement if intended for further processing into cannabinoid products
Extract / concentrate	• Pesticides • Residual solvents • Cannabinoid profile/Potency • Microbiological • Mycotoxin • Heavy metals (Random) • Residual Solvents	• Pesticides • Residual Solvents • Mycotoxin
Cannabinoid products intended for human consumption, ingestion and cannabinoid suppositories, topicals and transdermal patches	• Cannabinoid Profile • Microbiological	

(i) No lot of usable flower, batch of marijuana concentrate, or batch of marijuana-infused product may be sold or transported until the completion and successful passage of quality assurance testing as required in this section, except:

(5) Samples, lots, or batches that fail quality assurance testing.

(a) Retesting. At the request of the licensee or lab, DPHHS may authorize a retest to validate a failed test result on a case-by-case basis. All costs of the

retest will be borne by the provider or lab requesting the retest. Potency retesting will generally not be authorized.

(b) Remediation. Licensees may remediate failed harvests, lots, or batches so long as the remediation method does not impart any toxic or deleterious substance to the usable marijuana, marijuana concentrates, or marijuana-infused product. The entire harvest, lot, or batch the failed sample(s) were deducted from must be remediated using the same remediation technique. No remediated harvest, lots or batches may be sold or transported until the completion and successful passage of quality assurance testing as required in this section.

(6) Certified labs are not limited in the amount of usable marijuana and marijuana products they may have on their premises at any given time, but a certified lab must have records proving all marijuana and marijuana-infused products in the certified lab's possession are held only for the testing purposes described in this section.

(7) Upon the request of DPHHS, a licensee or a certified lab must provide samples of marijuana or marijuana products or samples of the growing medium, soil amendments, fertilizers, crop production aids, pesticides, or water for random compliance checks. Samples may be screened for pesticides and chemical residues, unsafe levels of heavy metals, and used for other quality assurance tests deemed necessary by the DPHHS.