



CANNABIS  
CONTROL  
DIVISION  
MONTANA

**QUALITY ASSURANCE SAMPLING PROTOCOL  
FOR USABLE MARIJUANA, MARIJUANA  
CONCENTRATES AND EXTRACTS, ~~AND~~  
MARIJUANA INFUSED PRODUCTS, AND  
MARIJUANA PRE-ROLLS**

SOP-001

Version ~~2.0~~ 3.0

Effective the date of adoption of MAR Notice 42-1071

This SOP applies to testing laboratories regulated and licensed under the Montana Marijuana Regulation and Taxation Act (Mont. Code Ann. §§ 16-12-101, et seq.)

## 1.0 PURPOSE/INTRODUCTION

The purpose of this Standard Operating Procedure (SOP) is to provide a reference sampling protocol in the state of Montana for usable marijuana, marijuana concentrates and extracts, ~~and~~ marijuana infused products, and marijuana pre-rolls in accordance with the Montana Marijuana Regulation and Taxation Act. This SOP provides direction to testing laboratories regarding the collection of random and representative laboratory test samples from test batches and promotes sampling protocol standardization throughout the state.

Analytical data from testing laboratories is only as representative or valid as the sample collected for analysis. Therefore, it is paramount that representative samples which truly characterize a test batch, and by extension a harvest or process lot, are consistently collected. The randomized sampling of a sufficient number of sample increments based on test batch size is extremely important. The implementation of standardized procedures, training, storage, and more, are integral to maintaining sample representativeness and integrity over time.

## 2.0 SCOPE

This SOP describes the equipment, reagents, training, procedures, safety, handling, storage, and recording keeping requirements necessary for the consistent and representative sampling of usable marijuana, marijuana concentrates and extracts, ~~and~~ marijuana infused product, and marijuana pre-roll test batches.

## 3.0 DEFINITIONS

3.1 The definitions set forth in ARM 42.39.601 and ARM 42.39.102 apply to this SOP.

## 4.0 EQUIPMENT AND SUPPLIES

4.1 Laboratory test samples shall be collected using the following equipment and documentation:

- 4.1.1 Laboratory specific sampling protocol SOP.
- 4.1.2 Sampling Report Form. See section 10.1.
- 4.1.3 Permanent ink pens or markers. No pencils.
- 4.1.4 Tongs, spatulas, forceps, spoons, syringes, pipettes, etc., that will not impart any analytes of interest onto sample increments.
- 4.1.5 Analytical balance capable of 0.1g measurements or better.
- 4.1.6 Calibration check weights.
  - 4.1.6.1 Analytical balance calibration weight checks shall be conducted at each licensed facility location prior to sampling.
- 4.1.7 Appropriate sample containers that are free of analytes of interest.
  - 4.1.7.1 Clean sealable plastic bags, amber glass jars, glass vials, glass drams, centrifuge tubes, etc.

- 4.1.8 Clean wipes or equivalent.
- 4.1.9 A temperature-controlled cooler or container capable of storing samples at appropriate temperatures to maintain sample integrity and security.
- 4.1.10 Personal Protect Equipment (PPE) as appropriate to protect the testing laboratory sampler from exposure to potential sample contaminants and to prevent potential contamination to the sample increments from the testing laboratory sampler.
  - 4.1.10.1 Gloves, safety glasses, lab coat, etc.
- 4.1.11 Custody seals.

## 5.0 STANDARDS AND REAGENTS

- 5.1 Cleaning solvents or agents for the sterilization of sampling equipment and surfaces before, during, and after sampling events.
  - 5.1.1 10% bleach, 70-80% IPA, 70-80% denatured alcohol, or equivalent.

## 6.0 TRAINING

- 6.1 Testing laboratories shall detail in their sampling protocol SOP how new and existing sampling personnel are trained and found to be proficient in sampling procedures.
- 6.2 An internal field audit shall be performed annually to ensure consistent and uniform performance over time by each of the testing laboratory's samplers.
  - 6.2.1 The testing laboratory shall conduct this audit at a licensee's facility and for each major matrix type (usable marijuana, concentrates and extracts, and infused products).
  - 6.2.2 One testing laboratory sampler shall silently observe the other testing laboratory sampler from start to finish while collecting the laboratory test sample.
  - 6.2.3 Any observed discrepancies in methodology between testing laboratory samplers shall be recorded and documented. Should field audit findings bring into doubt the validity or correctness of sampling activities, the laboratory shall take timely corrective actions. If it is determined that a deviation from the laboratory sampling protocol SOP or from this SOP may affect the validity of test results, the sampling laboratory shall notify licensees and the Department in writing.
  - 6.2.4 Deviations from the laboratory's sampling protocol SOP and this SOP shall be recorded and documented.
  - 6.2.5 A final assessment shall be made by the testing laboratory. Any significant differences between testing laboratory samplers shall be reviewed and discussed to improve sampling consistency.
  - 6.2.6 Documentation recording this process shall be retained for a period of three (3) years.
- 6.3 The testing laboratory shall ensure each sampler:

- 6.3.1 is trained according to this SOP and the testing laboratory’s employee training protocols.
- 6.3.2 has read the laboratory’s sampling protocol SOP annually and upon revision.
- 6.3.3 has read this SOP.
- 6.3.4 does not have conflicts of interest with any licensees from whom samples are collected.

## 7.0 PROCEDURE

### 7.1 Usable Marijuana: Flower, Bud, Trim, and Shake

- 7.1.1 The licensee shall separate each harvest lot into test batches that are less than or equal to 5.0 lbs. The mass of each test batch shall be provided to the testing laboratory by the licensee upon submission of the testing order. This mass shall match what is entered into the seed-to-sale tracking system.
- 7.1.2 The licensee shall physically locate and present to the testing laboratory sampler the test batch to be sampled.
- 7.1.3 The testing laboratory sampler shall designate a sample collection area. This area shall be cleared of any debris that could cause cross contamination, shall be free from air flow and pressure differences that can cause analytical balance discrepancies, ~~and~~ shall be sanitized with an appropriate solvent or cleaning agent listed in section 5.1.1, and shall be in clear view of video surveillance.
- 7.1.4 The testing laboratory sampler shall randomly select and confirm the weight of at least one entire test batch per licensed location. ~~is presented~~ This shall be done by physically weighing or observing the license representative weigh the test batch and comparing masses with that recorded in the seed-to-sale tracking system provided as disclosed by the licensee upon submission of a testing order.
  - 7.1.4.1 The licensee’s scale may be used.
  - 7.1.4.2 The licensee may weigh and record the tare weight of the empty container for the testing laboratory sampler. This value shall be recorded on the outside of the container. The licensee may also provide an empty equivalent container for the testing laboratory sampler to use as a reference.
  - 7.1.4.3 The percent difference between the mass in the seed-to-sale tracking system ~~provided disclosed~~ by the licensee upon submission of a testing order and that measured or observed by the testing laboratory sampler shall be within ±10.0% and calculated using the equation below:

$$\text{Percent Difference} = \left( \frac{(\text{lab measurement} - \text{client measurement})}{\text{client measurement}} \right) 100\%$$

- 7.1.4.4 The mass in the seed-to-sale tracking system ~~provided disclosed~~ by the licensee upon submission of a testing order, NOT the mass weighed by or observed by the testing laboratory sampler, shall be the mass used to

determine sample size and the number of sample increments collected.  
See section 7.1.89.

- 7.1.5 Sampling of any test batch shall not be conducted if the percent difference between the mass in the seed-to-sale tracking system ~~provided disclosed~~ by the licensee upon submission of a testing order and that recorded or observed by the testing laboratory sampler is greater than  $\pm 10.0\%$  ~~or if the test batch exceeds 5.0 lbs.~~
- 7.1.6 If the weight confirmed test batch exceeds 5.0 lbs as measured or observed by the testing laboratory sampler, an additional test batch shall be created, and an additional laboratory test sample shall be collected.
- 7.1.7 The testing laboratory sampler must review all other pertinent information including, but not limited to, the seed-to-sale tracking ID number, licensee ID number, product/strain name, and harvest date. The testing laboratory sampler must not commence with sampling if any test batch information is absent, misleading, or incorrect.
- 7.1.8 The testing laboratory sampler must visually inspect the test batch for uniformity. If non-uniformity is identified, the sampler must record their observations in the Sampling Report Form.
- 7.1.9 The testing laboratory sampler shall determine the required minimum sample size and minimum number of sample increments necessary to attain a representative laboratory test sample in accordance with Table 1.0.

Test Batch Size in pounds (lbs.)	Required Minimum Laboratory Test Sample Size in grams (g)	Minimum # of Sample Increments
$\leq 1.0$	2.3	6
1.1 – 2.0	4.5	
2.1 – 3.0	6.8	
3.1 – 4.0	9.1	
4.1 – 5.0	11.3	8

**Table 1.0**

- 7.1.10 The testing laboratory sampler shall then divide the test batch into approximately equal divisions, *i.e.* halves, thirds, quarters, etc. This can be done visually or physically. Containers may serve as divisions as long as they are approximately equal in volume/mass.
- 7.1.11 Divide the number of required sample increments by the number of divisions to determine the number of sample increments to collect from each division. To the extent practicable, collect the same number of sample increments from each division and from each container. Collection of additional sample increments and mass is allowable to facilitate this process, provided they are not used to misrepresent the test batch or create sample bias. Testing laboratory samplers may not collect less than the required minimum number of sample increments or mass.

~~7.1.12 The test batch and all storage containers shall be thoroughly mixed by the testing laboratory sampler prior to collecting sample increments.~~

7.1.12 Continue to section 7.76 for sample increment collection.

7.2 Marijuana Concentrates and Extracts – Solids and Semi-solids: Dabs, Wax, Slab, Rosin, Distillates, Kief, Hash, etc.

7.2.1 A process lot is considered a test batch for marijuana concentrates and extracts unless it is stored in multiple containers. When stored in multiple containers, each storage container shall be considered a separate test batch.

7.2.2 The licensee shall physically locate and present to the testing laboratory sampler the test batch to be sampled.

7.2.3 The testing laboratory sampler shall designate a sample collection area. This area shall be cleared of any debris that could cause cross contamination, shall be free from air flow and pressure differences that can cause analytical balance discrepancies, ~~and~~ shall be sanitized with an appropriate solvent or cleaning agent listed in section 5.1.1, and shall be in clear view of video surveillance.

7.2.4 The testing laboratory sampler shall randomly select and confirm the weight of at least one entire test batch per licensed location. ~~is presented.~~ This shall be done by physically weighing or observing the license representative weigh the test batch and comparing masses weights with that recorded in the seed-to-sale tracking system provided as disclosed by the licensee upon submission of a testing order.

7.2.4.1 The licensee's scale may be used.

7.2.4.2 The licensee may weigh and record the tare weight of the empty container for the testing laboratory sampler. This value shall be recorded on the outside of the container. The licensee may also provide an empty equivalent container for the testing laboratory sampler to use as a reference.

7.2.4.3 The percent difference between the mass in the seed-to-sale tracking system provided ~~disclosed~~ by the licensee upon submission of a testing order and that measured or observed by the testing laboratory sampler shall be within ±10.0% and calculated using the equation below:

$$\text{Percent Difference} = \left( \frac{(\text{lab measurement} - \text{client measurement})}{\text{client measurement}} \right) 100\%$$

7.2.4.4 The mass in the seed-to-sale tracking system provided ~~disclosed~~ by the licensee upon submission of a testing order, NOT the mass weighed by or observed by the testing laboratory sampler, shall be the mass used to determine sample size and the number of sample increments collected. See section 7.2.8.

7.2.5 Sampling of any test batch shall not be conducted if the percent difference between the mass in the seed-to-sale tracking system provided ~~disclosed~~ by the licensee upon submission of a testing order and that recorded or observed by

the testing laboratory sampler is greater than  $\pm 10.0\%$ , or if the test batch is stored in more than one container.

- 7.2.6 The testing laboratory sampler must review all other pertinent information including the seed-to-sale tracking ID number, licensee ID number, product/strain name, and production date. The testing laboratory sampler must not commence with sampling if any test batch information is absent, misleading, or incorrect.
- 7.2.7 The testing laboratory sampler must visually inspect the test batch for uniformity. If non-uniformity is identified, the testing laboratory sampler must record their observations in the Sampling Report Form.
- 7.2.8 The testing laboratory sampler shall determine the required minimum sample size and minimum number of sample increments necessary to attain a representative laboratory test sample in accordance with Table 2.0.

Test Batch Size in pounds (lbs)	Test Batch Size in grams (g)	Required Minimum Laboratory Test Sample Size in grams (g)	Minimum # of Sample Increments
$\leq 0.2$	$\leq 90.7$	0.6	2
0.3 – 0.6	90.8 – 272.2	1.0	3
0.7 – 1.0	272.3 – 453.6	1.3	5
1.1 – 2.0	453.7 – 907.2	2.0	8
2.1 – 5.0	907.3 – 2,268.0	3.8	15
5.1 – 15.0	2,268.1 – 6,804.0	5.5	22
15.1 – 50.0	6,804.1 – 22,680.0	8.3	33
50.1 – 100.0	22,680.1 – 45,360.0	10.8	43
100.1 – 250.0	45,360.1 – 113,400.0	13.3	53
$\geq 250.1$	$\geq 113,400.1$	20.0	80

**Table 2.0**

- 7.2.9 Concentrates in slab form may exhibit varying thicknesses throughout the test batch and require special attention to ensure a representative laboratory test sample is collected. The varying thicknesses of the product may influence certain test results as air exposure will be inconsistent.
  - 7.2.9.1 The testing laboratory sampler shall divide the test batch into at least three different divisions based on thicknesses or areas of thickness, *i.e.* thickest, thick, thin or thickest, thick, thin, thinnest. This can be done visually or physically.
- 7.2.10 Solid and semi-solid concentrates not in slab form shall be assumed homogenous unless non-uniformity is observed. Sample increments shall be collected from different divisions from the surface of the product.
- 7.2.11 Divide the number of required sample increments by the number of divisions to determine the number of sample increments to collect from each division. To the extent practicable, collect the same number of sample increments from each division. Collection of additional sample increments and mass is allowable to facilitate this process, provided they are not used to misrepresent the test batch or create sample bias. Testing laboratory samplers may not collect less than the required minimum number of sample increments or mass.
- 7.2.12 Continue to section 7.76 for sample increment collection.

7.3 Marijuana Concentrates and Extracts – Liquids and Semi-liquids: Rick Simpson Oil, Oils, Tinctures, etc.

- 7.3.1 A process lot is considered a test batch for marijuana concentrates and extracts unless it is stored in multiple containers. When using multiple containers for storage, each storage container shall be considered a separate test batch.
- 7.3.2 The licensee shall physically locate and present to the testing laboratory sampler the test batch to be sampled.
- 7.3.3 The testing laboratory sampler shall designate a sample collection area. This area shall be cleared of any debris that could cause cross contamination, shall be free from air flow and pressure differences that can cause analytical balance discrepancies, ~~and~~ shall be sanitized with an appropriate solvent or cleaning agent listed in section 5.1.1, and shall be in clear view of video surveillance.
- 7.3.4 The testing laboratory sampler shall randomly select and confirm the weight of at least one entire test batch per licensed location. ~~is presented~~ This shall be done by physically weighing or observing the licensed representative weigh the test batch and comparing masses weights with that recorded in the seed-to-sale tracking system provided as disclosed by the licensee upon submission of a testing order.
- 7.3.4.1 The licensee's scale may be used.
- 7.3.4.2 The licensee may weigh and record the tare weight of the empty container for the testing laboratory sampler. This value shall be recorded on the outside of the container. The licensee may also provide an empty equivalent container for the testing laboratory sampler to use as a reference.
- 7.3.4.3 The percent difference between the mass in the seed-to-sale tracking system provided disclosed by the licensee upon submission of a testing order and that measured or observed by the testing laboratory sampler shall be within  $\pm 10.0\%$  and calculated using the equation below:
- $$\text{Percent Difference} = \left( \frac{(\text{lab measurement} - \text{client measurement})}{\text{client measurement}} \right) 100\%$$
- 7.3.4.4 The mass in the seed-to-sale tracking system provided disclosed by the licensee upon submission of a testing order, NOT the mass weighed by or observed by the testing laboratory sampler, shall be the mass used to determine sample size and the number of sample increments collected. See section 7.3.8.
- 7.3.5 Sampling of any test batch shall not be conducted if the percent difference between the mass in the seed-to-sale tracking system provided disclosed by the licensee upon submission of a testing order and that recorded or observed by the testing laboratory sampler is greater than  $\pm 10.0\%$  or if the test batch is stored in more than one container.



- 7.3.6 The testing laboratory sampler must review all other pertinent information including the seed-to-sale tracking ID number, licensee ID number, product/strain name, and production date. The testing laboratory sampler must not commence with sampling if any sample information is absent, misleading, or incorrect.
- 7.3.7 The testing laboratory sampler must visually inspect the test batch for uniformity. If non-uniformity is identified, the testing laboratory sampler must record their observations in the Sampling Report Form.
- 7.3.8 The testing laboratory sampler shall determine the required minimum sample size and minimum number of sample increments necessary to attain a representative laboratory test sample in accordance with Table 3.0.

Test Batch Size in pounds (lbs)	Test Batch Size in grams (g)	Required Minimum Laboratory Test Sample Size in grams (g)	Minimum # of Sample Increments
≤0.2	≤90.7	0.6	2
0.3 – 0.6	90.8 – 272.2	1.0	3
0.7 – 1.0	272.3 – 453.6	1.3	5
1.1 – 2.0	453.7 – 907.2	2.0	8
2.1 – 5.0	907.3 – 2,268.0	3.8	15
5.1 – 15.0	2,268.1 – 6,804.0	5.5	22
15.1 – 50.0	6,804.1 – 22,680.0	8.3	33
50.1 – 100.0	22,680.1 – 45,360.0	10.8	43
100.1 – 250.0	45,360.1 – 113,400.0	13.3	53
≥250.1	≥113,400.1	20.0	80

**Table 3.0**

- 7.3.9 Allow sufficient time for liquid and semi-liquid products to equilibrate to room temperature prior to sampling.
- 7.3.10 Prior to sampling, all products shall be homogenized by inversion, stirring, or other means that do not alter or impart contaminants to the product.
  - 7.3.10.1 If the sample is homogenized by inversion, care shall be taken to ensure the product reaches the bottom of the container completely before the following inversion. The container shall be inverted fully a minimum of 5 times.
  - 7.3.10.2 If the sample is homogenized by stirring, the appropriate tools shall be sterilized using the solvent or cleaning agents listed in section 5.1.1. Stirring shall take place for a minimum of 30 seconds. Large storage containers may require more time to fully homogenize.
- 7.3.11 The testing laboratory sampler shall then divide the test batch into approximately equal divisions, *i.e.* halves, thirds, quarters, etc. This can be done visually.
- 7.3.12 Divide the number of required sample increments by the number of divisions to determine the number of sample increments to collect from each division. To the extent practicable, collect the same number of sample increments from each division. Collection of additional sample increments and mass is allowable to facilitate this process provided they are not used to misrepresent the test

batch or create sample bias. Testing laboratory samplers may not collect less than the required minimum number of sample increments or mass.

7.3.13 Continue to section 7.76 for sample increment collection.

#### 7.4 *Marijuana Concentrates and Extracts – Vape Oil*

7.4.1 A process lot is considered a test batch for marijuana vape oil. The process lot shall be packaged into cartridges by the licensee prior to laboratory test sample collection and final quality assurance compliance testing.

7.4.2 The licensee shall physically locate and present to the testing laboratory sampler the test batch to be sampled.

7.4.3 The testing laboratory sampler shall designate a sample collection area. This area shall be cleared of any debris that could cause cross contamination, shall be free from air flow and pressure differences that can cause analytical balance discrepancies, ~~and~~ shall be sanitized with an appropriate solvent or cleaning agent listed in section 5.1.1, and shall be in clear view of video surveillance.

7.4.4 The testing laboratory sampler shall randomly select and confirm the weight of at least one entire test batch per licensed location. ~~is presented~~ This shall be done by physically weighing or observing the licensed representative weigh the test batch and comparing masses weights with that recorded in the seed-to-sale tracking system provided as disclosed by the licensee upon submission of a testing order.

7.4.4.1 The licensee's scale may be used.

7.4.4.2 The licensee may weigh and record the tare weight of an empty cartridge for the testing laboratory sampler. This value shall be recorded on the outside of the cartridge. The licensee may also provide an empty equivalent cartridge for the testing laboratory sampler to use as a reference.

7.4.4.3 The percent difference between the mass in the seed-to-sale tracking system provided disclosed by the licensee upon submission of a testing order and that measured or observed by the testing laboratory sampler shall be within  $\pm 10.0\%$  and calculated using the equation below:

$$\text{Percent Difference} = \left( \frac{(\text{lab measurement} - \text{client measurement})}{\text{client measurement}} \right) 100\%$$

7.4.5 Sampling of any test batch shall not be conducted if the percent difference between the mass in the seed-to-sale tracking system provided disclosed by the licensee upon submission of a testing order and that recorded or observed by the testing laboratory sampler is greater than  $\pm 10.0\%$  or if the test batch is not in its final packaging (cartridge).

7.4.6 Review all other pertinent information including the seed-to-sale tracking ID number, licensee ID number, product/strain name, production date, etc. Do not commence with sampling if any sample information is absent, misleading, or incorrect.

- 7.4.7 Visually inspect the test batch for uniformity. If non-uniformity is identified, record the observations in the Sampling Report Form.
- 7.4.8 The testing laboratory sampler shall determine the required minimum sample size and minimum number of sample increments necessary to attain a representative laboratory test sample in accordance with Table 4.0. One sample increment is equal to one vape cartridge.

Total # of Cartridges per Process Lot	Minimum # of Sample Increments
0 – 100	1
101 – 500	3
501 – 2,500	7
2,501 – 12,500	15
12,501 – 62,500	20
62,501 – 125,000	35

**Table 4.0**

- 7.4.9 The testing laboratory sampler shall then divide the test batch into approximately equal divisions. *i.e.* halves, thirds, quarters, etc. This can be done visually.
- 7.4.10 Divide the number of required sample increments by the number of divisions to determine the number of sample increments to collect from each division. To the extent practicable, collect the same number of sample increments from each division. Collection of additional sample increments is allowable to facilitate this process provided they are not used to misrepresent the test batch or create sample bias. Testing laboratory samplers may not collect less than the required minimum number of sample increments.
- 7.4.11 Continue to section 7.7~~6~~ for sample increment collection.

7.5 Marijuana Infused Products – Edibles and Non-edibles: Baked Goods, Candies, Topicals, Suppositories, etc.

- 7.5.1 The licensee shall separate each process lot into less than or equal to 5,000 unit-of-sale test batches. The process lot shall be in its final packaging and a serving size shall be designated by the licensee.
- 7.5.2 The licensee shall physically locate and present to the testing laboratory sampler the test batch to be sampled.
- 7.5.3 The testing laboratory sampler shall designate a sample collection area. This area shall be cleared of any debris that could cause cross contamination, ~~and~~ shall be sanitized with an appropriate solvent or cleaning agent listed in section 5.1.1, and shall be in clear view of video surveillance.
- 7.5.4 The testing laboratory sampler shall randomly select and confirm at least one test batch per licensed location to ensure the entire process lot or test batch therein is presented. This shall be done by adding units-of-sale by counting boxes, cases, or other means deemed appropriate by the testing laboratory.
- 7.5.5 The testing laboratory sampler must review all other pertinent information including the seed-to-sale tracking ID number, licensee ID number,

product/strain name, and production date. The testing laboratory sampler must not commence with sampling if any test batch information is absent, misleading, or incorrect.

- 7.5.6 The testing laboratory sampler must visually inspect the test batch for uniformity. If non-uniformity is identified, record the observations in the Sampling Report Form.
- 7.5.7 The testing laboratory sampler shall determine the required minimum number of sample increments necessary to attain a representative laboratory test sample. One sample increment is equal to one serving as designated by the licensee. A partial unit-of-sale may be required by the testing laboratory sampler depending on the number of servings packaged into one unit-of-sale. In these scenarios, the testing laboratory sampler may collect more than the required number of servings so as to not leave a partial unit-of-sale at the licensee facility. See Table 5.0.

Total # of Servings Per Process Lot	Minimum # of Sample Increments
0 – 100	1
101 – 500	3
501 – 2,500	7
2,501 – 12,500	15
12,501 – 62,500	20
62,501 – 125,000	35

**Table 5.0**

**Example 1:** A licensed facility has a 5,000 unit-of-sale process lot of hard candies, with each unit-of-sale containing 10 servings of product. The total number of servings in this process lot equals 50,000. Per table 5.0, 20 servings shall be collected meaning 2 units-of-sale are required for the laboratory test sample.

**Example 2:** A licensed facility has a 5,000 unit-of-sale process lot of chocolate brownies with each unit-of-sale containing 1 serving. The total number of servings in this process lot equals 5,000. Per table 5.0, 15 servings shall be collected, meaning 15 units-of-sale are required for the laboratory test sample.

**Example 3:** A licensed facility has a 100 unit-of-sale process lot of gummies with each unit-of-sale containing 2 servings of product. The total number of servings in this process lot equals 200. Per table 5.0, 3 servings shall be collected, meaning 1.5 units-of-sale are required for the laboratory test sample. The testing laboratory sampler may collect 2 units-of-sale or leave the partial unit-of-sale with the licensee. The testing laboratory may not collect less than 1.5 units-of-sale.

- 7.5.8 The testing laboratory sampler shall then divide the test batch into approximately equal divisions, *i.e.* halves, thirds, quarters, etc. This can be done visually or physically. Containers may serve as divisions as long as they are approximately equal in volume/mass.

- 7.5.9 Divide the number of required units-of-sale by the number of divisions to determine the number of units-of-sale to collect from each division. To the extent practicable, collect the same number of sample increments from each division. Collection of additional sample increments is allowable to facilitate this process provided they are not used to misrepresent the test batch or create sample bias. Testing laboratory samplers may not collect less than the required minimum number of sample increments.
- 7.5.10 Continue to section 7.7~~6~~ for sample increment collection.

7.6 Marijuana Pre-rolls: Infused and Non-infused

- 7.6.1 The licensee shall separate each process lot into less than or equal to 5,000 units-of-sale test batches.
- 7.6.2 The licensee shall physically locate and present to the testing laboratory sampler the test batch to be sampled.
- 7.6.3 The testing laboratory sampler shall designate a sample collection area. This area shall be cleared of any debris that could cause cross contamination, shall be sanitized with an appropriate solvent or cleaning agent listed in section 5.1.1, and shall be in clear view of video surveillance.
- 7.6.4 The testing laboratory sampler shall randomly select and confirm at least one test batch per licensed location to ensure the entire process lot or test batch therein is presented. This shall be done by adding units-of-sale by counting boxes, cases, or other means deemed appropriate by the testing laboratory.
- 7.6.5 The testing laboratory sampler must review all other pertinent information including the seed-to-sale tracking ID number, licensee ID number, product/strain name, production date and must not commence with sampling if any test batch information is absent, misleading, or incorrect.
- 7.6.6 The testing laboratory sampler must visually inspect the test batch for uniformity. If non-uniformity is identified, record the observations in the Sampling Report Form.
- 7.6.7 The testing laboratory sampler shall determine the required minimum number of sample increments necessary to attain a representative laboratory test sample. One sample increment is equal to one pre-roll. See Table 6.0.

<u>Pre-roll Process Lot Size</u>	<u>Minimum Number of Sample Increments</u>
<u>≤50</u>	<u>2</u>
<u>51 – 150</u>	<u>3</u>
<u>151 – 500</u>	<u>5</u>
<u>501 – 1,200</u>	<u>8</u>
<u>1,201 – 3,200</u>	<u>13</u>
<u>3,201 – 5,000</u>	<u>20</u>

**Table 6.0**

- 7.6.8 The testing laboratory sampler shall then divide the test batch into approximately equal divisions. i.e., halves, thirds, quarters, etc. This can be done visually or physically. Containers may serve as divisions as long as they are approximately equal in volume/mass.
- 7.6.9 Divide the number of required sample increments by the number of divisions to determine the number of sample increments to collect from each division. To the extent practicable, collect the same number of sample increments from each division and from each container. Collection of additional sample increments or mass is allowable to facilitate this process provided they not used to misrepresent the test batch or create sample bias. Testing laboratory samplers may not collect less than the required minimum number of sample increments.
- 7.6.10 Continue to section 7.7 for sample increment collection.

#### 7.7 Sample Increment Collection for all Matrix Types

- 7.7.1 The sampling event shall be video recorded by the licensee submitting samples for testing and follow the regulations put forth in ARM 39.42.121.
- 7.7.2 Collection of sample increments shall be done at random and independently throughout each division. Use of a grid, random number generator (such as rolling dice, spinning a number wheel, downloadable random number generator applications, etc.), or any other randomized system that provides each potential sample increment the same probability of being selected shall be used.
- 7.7.3 Select the appropriate sampling tool that allows for the collection of sample increments from all locations horizontally and vertically (if possible) within the container.
- 7.7.4 Sampling tools shall be cleaned with the appropriate solvent or cleaning agent found in section 5.1.1 prior to collection, between test batches at the same licensed facility, between different licensed facilities, and any time contamination is suspected. This practice will prevent cross contamination of samples and ensure the representativeness of the test batch. Maintaining multiple sets of sampling tools is highly encouraged.
- 7.7.5 The testing laboratory sampler shall change gloves if they become contaminated, are suspected to be contaminated, or if they come into direct contact with the test batch or sample increments.
- 7.7.6 The testing laboratory sampler shall clean any shared surface between test batches that sample increments come into direct contact with including, but not limited to, balance plates, weigh boats, weigh paper, and sampling tools.
- 7.7.7 All sample increments from the same test batch shall be combined into one sample container to create one laboratory test sample for one complete quality assurance compliance test. Sample increments from different test batches shall not be composited as composite sample testing is prohibited per ARM 42.39.614.

- 7.7.8 Apply a custody seal to each laboratory test sample container or bulk package containing a single facility's laboratory test samples in a manner which prevents tampering between the sampling event, transport, and receipt at the testing laboratory.
- 7.7.9 All laboratory test sample containers shall contain the following minimum information:
  - 7.7.9.1 Licensee's business/trade name and license ID number.
  - 7.7.9.2 The ID number assigned by the seed-to-sale tracking system.
  - 7.7.9.3 The unique laboratory specific ID number assigned to the laboratory test sample to be supplied by the testing laboratory.
  - 7.7.9.4 Strain/product name.
  - 7.7.9.5 Total mass of the laboratory test sample.
  - 7.7.9.6 Sampling date.
  - 7.7.9.7 "LABORATORY TEST SAMPLE" label in bold capital letters in a minimum 12-point font.
  - 7.7.9.8 The designation of the laboratory test sample:
    - 7.7.9.8.1 Compliance testing.
    - 7.7.9.8.2 Research and development testing.
    - 7.7.9.8.3 Re-sample for failed test/remediation testing.
  - 7.7.9.9 ID number of the testing laboratory sampler.
- 7.7.10 After laboratory test sample collection, the test batch shall be labeled with the following minimum information:
  - 7.7.10.1 The testing laboratory name and license ID number.
  - 7.7.10.2 The laboratory specific ID number assigned to the laboratory test sample to be supplied by the testing laboratory.
  - 7.7.10.3 Sampling date.
  - 7.7.10.4 "PRODUCT NOT TESTED" label in bold capital letters in a minimum 12-point font.
    - 7.7.10.4.1 After final laboratory testing the product may be labeled by the licensee with "PRODUCT PASSED TESTING MMDDYY" or "PRODUCT FAILED TESTING MMDDYY". The date listed shall be the date the laboratory certificate of analysis was issued.
    - 7.7.10.4.2 The original "PRODUCT NOT TESTED" label shall not be removed or covered.
- 7.7.11 Finish recording all information in the Sampling Report Form before continuing to the next test batch or licensed facility.  
Record the sample collection event in the seed-to-sale tracking system and create the seed-to-sale tracking manifest.

## 8.0 SAFETY

- 8.1 Due to potential contact with pesticides, microbiologicals, and other unknown sample contaminants, the handling of usable marijuana, marijuana concentrates and extracts, and

- marijuana infused products shall be conducted in a way that protects the testing laboratory sampler from potential exposure. This includes the use of appropriate PPE found in section 4.1.10.1.
- 8.2 Special attention shall be paid to slip and trip hazards while performing sampling duties in a licensed facility.
  - 8.3 Special attention shall be paid to the potential risk of exposure to organic solvents which can be harmful in liquid and vapor forms. Please note organic solvents can be tasteless, odorless, carcinogenic, flammable, explosive, and corrosive.
  - 8.4 Any safety concerns or observations shall be noted in the Sampling Report Form.

## 9.0 PRESERVATION, HANDLING, AND STORAGE

- 9.1 The testing laboratory shall include detailed procedures on maintaining sample custody and integrity during handling and transport in their sampling protocol SOP. These procedures should take into consideration light, temperature, humidity, and other environmental factors.
- 9.2 A temperature-controlled cooler or container shall be used to maintain consistent temperature during sample transport and shall be kept from public view to the extent practical.
- 9.3 Laboratory test samples shall be packaged into the temperature-controlled cooler or container in a fashion that prevents damage and spillage during transport.
- 9.4 Laboratory sample containers shall be designed to prevent damage, contamination, spillage, and spoilage of samples during transport. Sample containers shall be appropriate and of adequate size for the matrix being sampled.
- 9.5 Current law does not permit shipping of usable marijuana, marijuana concentrates and extracts, ~~or~~ marijuana infused products, marijuana pre-rolls, or marijuana items in any form.
- 9.6 Laboratory test samples shall be transported in the most expedient, secure, and legal means possible.
- 9.7 All sampling forms, documents, or paperwork shall be physically transported with the laboratory test samples.
- 9.8 Laboratory test samples that designate specific storage conditions shall be transported and stored at those conditions.

## 10.0 RECORDS AND DOCUMENTATION

- 10.1 Testing laboratories shall create a Sampling Report Form to record the following minimum information from each test batch:
  - 10.1.1 Licensee's business/trade name and license ID number;
  - 10.1.2 Name of the representative submitting product(s) for testing and badge ID number;
  - 10.1.3 Physical address of the sampling location;
  - 10.1.4 Strain/product name;
  - 10.1.5 Product type;
  - 10.1.6 Total mass of the randomly selected test batch;



- 10.1.7 Total mass of the randomly selected test batch confirmed by the testing laboratory sampler;
- 10.1.8 Percent difference between 10.1.6 and 10.1.7 as determined in the formula provided in this SOP;
- 10.1.9 Total number of containers in the test batch if applicable;
- 10.1.10 Total number of assigned divisions;
- 10.1.11 Total number of sample increments collected;
- 10.1.12 Total mass of the laboratory test sample recorded out to 0.1g;
- 10.1.13 Testing laboratory's sampling protocol SOP ID and current revision number referenced;
- 10.1.14 A description of the area where sample collection took place;
- 10.1.15 Date and time the sampling was started and completed;
- 10.1.16 The testing laboratory sampler's badge ID number and signature;
- 10.1.17 The testing laboratory vehicle and license plate number;
- 10.1.18 Signature of the representative submitting product(s) for testing;
- 10.1.19 Any observations that may influence test results such as excessive humidity, heat, suspected adulteration, non-uniformity of the test batch, visible mold, pests, etc.;
- 10.1.20 Safety concerns;
- 10.1.21 Additional observations or comments.

11.0 REVISION HISTORY

Version	Version Date	Description of Changes
1.0	Effective 1/15/2022	Original document
2.0	Effective 7/1/2023	Transferred from DPHHS to CCD at DOR
<u>3.0</u>	<u>Effective the date of adoption of MAR Notice 42-1071</u>	<u>Test batch weight verifications once per location. Licensee shall submit test batch weight with testing order. Allow license representative to weigh test batch while laboratory sampler observes. Removed flower mixing requirement section 7.1.11. Added pre-roll sampling section 7.6. Added video footage requirement section 7.7.1. Clarified section 7.1.5 by adding 7.1.6. Included ARM 42.39.601(3)(d) in section 10.1.17 to reduce redundancy between SOP-001 and ARM 42.39.601(3).</u>

PROPOSED DRAFT