	Management System Procedure HiRes Labs	Revision Number: 1	Date of Revision: 05/01/2023
	MSP-7.3.1b – Processed Samples sampling Plan and Method	Controlled Copy #: 1	Controlled Copy Issue Date: 02/15/2021

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Reviewed by: Board of Directors

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Approved by: Board of Directors



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Document control:

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1. Purpose

The purpose of the medical cannabis products sampling procedure is to outline best practices for the sampling of regulated medical cannabis products for analysis by a OMMA licensed medical cannabis Testing Facility. It is meant to provide the medical cannabis Testing Facility with samples representative of the Production Batch.

Regulated Medical Cannabis Products contain cannabis and other Ingredients and are intended for use or consumption, such as, but not limited to, edible products, ointments, and tinctures. The category also includes Audited Products. Each product may have different Ingredients, chemical and physical characteristics, and production methods.

2. Scope / Field of Application


The scope of this method describes the breadth of coverage of the plan, products to be covered, factors to be controlled and where sampling will be done.

The plan and method are made available at the site where sampling is undertaken.

Sub-sampling performed in the laboratory is described in the appropriate standard operating procedure or test method.

3. Representative

Sample type

	Management System Procedure HiRes Labs	Revision Number: 1	Date of Revision: 05/01/2023
	MSP-7.3.1b – Cannabis Products Sampling Plan and Method	Controlled Copy #: 1	Controlled Copy Issue Date: 02/15/2021

Production sample: primary and reserve.

Sample Frequency

Timing and frequency of sampling shall be completed for each Production Batch. Namely, “a Licensee shall not collect Sample Increments or submit Test Batches for testing until the Test Batch has completed all required steps and is in its final form as outlined in the standard operating procedures of the Licensee submitting the Test Batch, with the exception of packaging and labeling requirements.

Sample Size

A total of 0.5% of the batch is collected from different areas of the batch. The sample is then homogenized and aliquoted into a primary sample and reserve sample. An amount sufficient to be aliquoted into a primary sample and a reserve sample, which shall be equal in amounts, e.g. 7 grams each.

Sample Increment and Test Batch Amount


The Sample Increments shall be collected, packaged into units, and the units submitted as a single Test Batch for submission to the Medical Cannabis Testing Facility.

4. Responsibilities

The individual collecting samples is called sampler. The sampler must be trained on how to collect samples in accordance with the standard operating procedures of the laboratories that will be conducting the testing on the samples collected and shall have access to a copy of the standard operating procedures while they are collecting the samples.

The sampler is responsible for:

- Sample contents and history;
- Collecting samples at the location of the growers or processors.
- Samples must be delivered the day of collection.
- Samples shall only be collected from harvest batches and production batches in final form.
- Collecting both a primary sample and a reserve sample from each harvest batch and production batch.
- Sample shall be clearly and conspicuously labeled, and the label shall include at least the following information:
 - “Primary Sample” or “Reserve Sample”.
 - Name and license number of grower or processor from whom the sample was taken.
 - The batch number of harvest batch or production batch from which the sample was taken.

	Management System Procedure HiRes Labs	Revision Number: 1	Date of Revision: 05/01/2023
	MSP-7.3.1b – Cannabis Products Sampling Plan and Method	Controlled Copy #: 1	Controlled Copy Issue Date: 02/15/2021

- Creating and using a sample field log to record the following information for each sample:
 - Laboratory’s name, address, and license number
 - Title and version of the laboratory’s standard operating procedure(s) followed when collecting the sample
 - Sampler’s name(s) and title(s) and the names of others onsite.
 - Date and time sampling started and ended
 - Grower’s or processor’s name, address, and license number
 - Batch number of the batch from which the sample was obtained.
 - Sample matrix
 - Total batch size, by weight or unit count.
 - Total weight or unit count of the primary sample
 - Total weight or unit count of the reserve sample.
 - The unique sample identification number of the person who transports the samples to the laboratory.
 - Requested analyses.
 - Sampling conditions, including temperature.
 - Problems encountered and corrective actions taken during the sampling process.
 - Any other observations from sampling, including major inconsistencies in the medical cannabis color, size, or smell.


5. Materials Required

Equipment (items used repeatedly)

- Analytical balance or scale
 - The scale used to weigh product to be transported shall be tested and approved.
- Permanent ink pen

Supplies (items used only once)

- Final unit package(s) in which the Regulated Marijuana Product will be sold
- Plastic bag(s) or equivalent to hold Test Batch(es)
- IPA (70-80%), denatured alcohol (70-80%), 10% bleach, or equivalent disinfectant for sterilization
- Nitrile, latex, rubber or equivalent gloves
- Metrc radio-frequency identification (RFID) tags
- Metrc manifest
- Sample labels, if required label information is not included on Metrc tags
- Custody seals and/or tamper-evident tape
- Box or cooler
- Ice/cold packs

	Management System Procedure HiRes Labs	Revision Number: 1	Date of Revision: 05/01/2023
	MSP-7.3.1b – Cannabis Products Sampling Plan and Method	Controlled Copy #: 1	Controlled Copy Issue Date: 02/15/2021

6. Procedure

This procedure is designed to ensure that each sampling event shall produce Test Batches as representative as possible of the Production Batch specified by collecting Sample Increments from different areas in the Production Batch.

Sample plan

A Sample Plan generated by the sampler responsible for the sampling event will be reviewed by testing lab director. The Plan shall ensure that sample Increments are collected from the maximum number (all, if possible) of the Production Batch's storage containers. An example sample plan shall include, at minimum, the following information:

1. Identity of Designated Test Batch sampler(s) performing the sampling and their company affiliation.
2. Time and date of sampling.
3. Product name
4. Product type (edible, tincture, topical, transdermal, etc.)
5. Metrc Harvest Batch ID.
6. Production date
7. Room ID (as the ID appears in Metrc, if applicable).
8. Production Batch size (in lbs.).
9. Amounts/weights of each Sample Increment collected.
10. Number and location of storage containers from which Sample Increments were collected.
11. List of remediation, if applicable.
12. A description of the procedure followed, as well as any deviations from the SOP, if applicable.
13. Medical cannabis testing facility performing the analyses.
14. Additional Comments – Note anything that may affect the quality of the data analysis, including whether the plant is fresh or fresh frozen, remediated, etc.
15. Any other additional information necessary to guide the Designated Test Batch samplers through event-to-project specifications

	Management System Procedure HiRes Labs Inc.	Revision Number: 1	Date of Revision: 05/01/2023
	MSP-7.3.1b – Cannabis Products Sampling Plan and Method	Controlled Copy #: 1	Controlled Copy Issue Date: 02/15/2021

16. Identity of Designated Test Batch sampler(s) reviewing the sampling process and documentation and their company affiliation

Testing lab director shall review the labeled Test Batch(es) and Metrc manifest prior to the Test Batches leaving the Regulated medical cannabis Business for transport to the medical cannabis Testing Facility. The witness shall initial the manifest indicating that the labels and manifest are accurate.

Pre-sampling procedure

Equipment Preparation and Environmental Controls

The Designated Sample Collection Area shall be cleaned, sanitized, and cleared of any debris that could potentially cause cross-contamination during preparation of Test Batches. Sampling equipment shall be collected and organized into the Designated Sample Collection Area and cleaned, sanitized, and inspected prior to use. All work areas, contact surfaces, utensils, and equipment shall be washed with IPA (70-80%), denatured alcohol (70-80%), 10% bleach, or equivalent, rinsed with filtered water, and dried completely prior to sampling each Test Batch. Solvents used for disinfectants may contaminate products during sampling if adequate rinsing and drying are not performed. Aseptic Technique shall be used during the entire sampling process to minimize cross-contamination.

Final unit packages and Test Batch Containers shall be new and inspected to be clean and dry prior to the sampling event. They shall be labeled prior to Sample Increment Collection to avoid confusion.

All required paperwork shall be pre-populated with pertinent information, as much as possible, prior to the sampling event.

Sample collection


Samples shall be collected in as random as possible. This can be accomplished by using Stratified Random Sampling or an equivalent sampling scheme.

The Sample Increments shall be collected from the Production Batch in its final form as outlined in the SOP of the Regulated medical cannabis business submitting the Test Batch.

The Designated Test Batch sampler(s) performing the sampling shall wear a pair of fresh nitrile, latex, or equivalent gloves during Sample Increment Collection. Gloves shall be changed between each Production Batch to minimize potential cross-contamination.

The Regulated medical cannabis Product Sample Increments (or servings) shall be packaged into final, ready-to-sale units, using sterile utensils or equipment and then units combined into one Test Batch Container for transport.

Test batch packaging and labeling

	Management System Procedure HiRes Labs	Revision Number: 1	Date of Revision: 05/01/2023
	MSP-7.3.1b – Cannabis Products Sampling Plan and Method	Controlled Copy #: 1	Controlled Copy Issue Date: 02/15/2021

Packaging requirement for Test Batches from Production Batches.

1. Shall be placed into the Container(s) in which the rest of the Production Batch will be sold. The Container may but is not required to be child-resistant.

Labeling requirements for Test Batches from Production Batches which shall be included on the Metrc RFID Tag and another label, if necessary.

1. The license number of the Medical Cannabis Products Manufacturer that produced the Regulated Medical Cannabis Product.
2. The Production Batch Number(s) assigned to the Regulated Medical Marijuana Product.
3. The net contents, using a standard of measure compatible with Metrc, of the Regulated Medical Marijuana Product prior to its placement in the Container.
4. The serving size, number of serving per package, and the Target Potency as required for a Regulated Medical Marijuana Testing Facility to assess potency variance.

Post-sampling procedure

Sample Increment Collection Review


All Sample Increments collected shall be reviewed in accordance with the Metrc manifest and Chain of Custody (if applicable) in a timely fashion prior to transport to the medical cannabis Testing Facility. This review must be conducted by a testing lab director.

Clean-up of Designated Sample Collection Area

The Designated Sample Collection Area, sampling equipment, and any non-disposable utensils shall be cleaned, washed with IPA (70-80%), denatured alcohol (70-80%), 10% bleach, or equivalent, rinsed with filtered water, and dried after Sample Increment Collection.

Test Batch Storage and Retention

Test Batches may be individually sealed with tamper-evident tape or if multiple Test Batches are being transported to the same medical cannabis Testing Facility at the same time, multiple Test Batches may be placed in a larger bag, box, or similar transport container and that container sealed with tamper-evident tape or custody seal.

	Management System Procedure HiRes Labs	Revision Number: 1	Date of Revision: 05/01/2023
	MSP-7.3.1b – Cannabis Products Sampling Plan and Method	Controlled Copy #: 1	Controlled Copy Issue Date: 02/15/2021

Immediately store Test Batches under refrigeration or on ice and retain in a cool environment to ensure that the Test Batches arrive at the Marijuana Testing Facility at $6^{\circ} \pm 4^{\circ}$ C. **The temperature is under monitoring using hygrometer.**

Other than thermal preservation and custody seal taping, no other protection or preservation protocols have been developed or are required for Test Batches.

Test Batches shall be stored in a manner to prevent unauthorized access to Test Batches and kept under custody seal until acceptance by the Medical Marijuana Testing Facility.

Test Batches shall be destroyed, when necessary, per applicable MED disposal rules.

Transport

Transport shall be via a method to ensure that the Test Batches arrive within two days to the Marijuana Testing Facility at $6^{\circ} \pm 4^{\circ}$ C. Test Batches may only be transported by appropriately licensed personnel. **The temperature is under monitoring using hygrometer.**

Contaminants

Due to potential contact with solvents, pesticides, and other contaminants, all handling of Sample Increments and Test Batches must be in accordance with the Regulated Marijuana Business' Hazard Communication Plan and sampling SOP.

All waste must be disposed of in accordance with local, state, and federal regulations.

Solvents


Use of solvents shall only be carried out in a well-ventilated area or fume hood.

7. Documentation

Completed sample submission forms are received at sample reception and forwarded to the laboratory.

8. References

"Marijuana Products Sampling Procedure", Laboratory Service Division, Colorado Department of Public Health and Environment.

	<p style="text-align: center;"><i>Management System Procedure</i> HiRes Labs</p>	<p>Revision Number: 1</p>	<p>Date of Revision: 05/01/2023</p>
<p style="text-align: center;"><i>MSP-7.3.1b – Cannabis Products Sampling Plan and Method</i></p>		<p>Controlled Copy #: 1</p>	<p>Controlled Copy Issue Date: 02/15/2021</p>

“Agricultural Food Products – Layout for a Standard Method of Sampling from a Lot,”
ISO7002:1986 ISO Catalog, International Organization for Standardization, Geneva, Switzerland.

ISO/IEC 17025:2017. Section 7.3.1.

9. Revision History

Revision 1

