



STATE OF RHODE ISLAND
DEPARTMENT OF BUSINESS REGULATION
Office of Cannabis Regulation
560 Jefferson Blvd. Ste. 204
Warwick, Rhode Island 02886

Information Testing Session FAQs

Issued on March 19, 2021
Amended September 3, 2021

1. Why are we testing now?

Enforcing required tests on medical marijuana products is one of the most important steps in ensuring that patients have access to clean, safe and reliable medicine. The Office of Cannabis Regulation in collaboration with the Rhode Island Department of Health will continue to enforce and ensure that all products available for sale have passed all required tests.

2. At what point do products have to undergo required testing?

All products must be tested at the end stage. This means if you need to perform any other action/conversion to your product before it is ready to be packaged and sold, you should wait until that final action/conversion is performed before testing. This excludes both having to roll flower/trim into the pre-roll state and having to put the concentrate into a final container for inhalation. Please adhere to the guidance below.

Pre-rolls

A licensee may continue to have the product sampled at the end stage (in its rolled form) OR they may choose to have the flower/trim that has been ground and batched together for the rolled end stage weighing less than or equal to 15lbs sampled by a licensed lab for all required testing. Those results would then apply to the end products created from it. These batches do not have to be strain specific.

Concentrates

A licensee may continue to have the product sampled at the end stage (in the container intended for use) OR they may choose to have the concentrate sampled from a homogenized batch in its final state (prior to filling without having to put the end stage final state product into the container intended for use).

3. If a concentrate is not tested after it is put into the cartridge intended to be used for inhalation, how does the OCR ensure that those cartridges are safe for use?

Pursuant to § 1.5.2(F) of the Rules and Regulations Related to the Medical Marijuana Program Administered by the Office of Cannabis Regulation at the Department of Business Regulation (230-RICR-80-05-1), cartridges and any other devices, as determined by DBR, shall receive a product safety certificate which is subject to DBR review.

4. Why is the DOH mandating petri dish testing methods vs qPCR DNA?

Microbiological culture-based tests are required to assay a broader range of potentially harmful microbes which is more protective of public health. PCR and qPCR methodology are not approved for these broader assays because the variety of DNA primer and probe markers required total aerobic microbes and total yeast and mold are not readily available. In addition, qPCR and PCR require complex algorithms to account for the variety of responses among species and the effects of matrix interferences in the final calculated result. The algorithms (some are proprietary) are developed by the manufacturer specifically for their instrument's design and performance. Laboratories must rely on their instrument's algorithm to convert qPCR and PCR replications into estimated colony forming units (CFU). These differences can lead to variation among testing laboratories.

5. Why aren't pesticides being tested?

Pesticide testing will be enforced at a later date. Enforced testing bulletins will continue to be issued until all testing is enforced.

6. How many labs are currently licensed to test microbials?

Three licensed labs are available to perform microbiological contaminant testing.

7. Has the labs' throughput been evaluated to ensure bottlenecking does not occur?

Enforced potency testing on flower has been in effect since February 15th. OCR and RIDOH have been in close communication with the labs and no bottlenecking has occurred. As the required microbiological testing will not result in additional samples and only in additional tests, we anticipate that bottlenecking will continue to not be an issue.

8. How do we know that the labs Tech's are not bringing contaminants when sampling?

Labs are required to be licensed for sampling. This means that in addition to the protective equipment and sterile equipment that must be utilized for each sample collection, the lab's sampling SOPs are reviewed and approved by RIDOH.

9. Why is T.A.C (total amount of cannabinoid's) not being informed to the patients?

At this time only total THC (THCa and THC) and total CBD (CBDa and CBD) are required to be tested by a licensed lab and displayed on the label of a product available for sale. Other cannabinoids and terpenes may be required as the industry and program progress.

10. Why were microbials phased in much faster than potency testing? 1-month vs 6 months?

The 6-month period with no enforcement action was implemented for two reasons. The first being that OCR wanted to give licensees a chance to reach out to labs and to OCR/RIDOH to ask questions and clarify any requirements regarding required testing. Secondly, OCR wanted to ensure that a bottleneck of product did not occur. However, during this period, very few questions were asked and very little mandatory testing including sampling was conducted. Consequently, on December 15th a second bulletin went out that enforced potency testing. On February 16th a third bulletin was issued enforcing potency on concentrates and microbiological testing on flower. This phase-in process is to allow the capacity of the labs to increase in order to perform the tests over time as to not create a bottleneck situation. Licensees have been aware since 2018 that testing was required.

11. If a flower batch does not pass a required test, can that batch be remediated and then retested as flower/trim?

It depends on what mandatory test was failed.

For flower/trim that has failed microbiological contaminant testing or water activity the batch can be remediated and retested as flower. However, the batch must pass all required testing before being available for sale at a compassion center. The batch can also be extracted or sold for extraction purposes. However, this is not a requirement and is a business decision on the licensee's end. The batch can also be destroyed.

For flower/trim or concentrate that has failed heavy metal testing, the batch may be retested however, no remediation (including extraction) is allowable which includes extraction of flower/trim.

12. I've heard from labs there are a number of samples that have failed mold. We are concerned about allowing samples to be collected by people entering our facility. Why is it that you are less concerned about a person going in and out of every facility to collect samples than us just providing samples to the labs?

Labs are licensed to perform sampling. They are required to wear protective gear and utilize sterile equipment. Their SOPs are reviewed and approved by RIDOH. Additionally, in other states where cultivators submit their own samples to the licensed labs for testing, those states have identified sampling as a main cause of variance in test results.

13. When will moisture content be controlled for in potency testing?

Moisture content is not a required test. However, water activity is required and enforced for all flower/trim that was harvested on or prior to May 24, 2021.

14. It's been said that the 10,000 CFU limit is very realistic to achieve without remediation measures. I have been hearing otherwise both from IAQ engineers and other anecdotal situations. Where is this opinion coming from?

The maximum threshold of 10,000 CFU/g for total yeast and mold in cannabis samples is based on the maximum threshold limit set by USP – United States Pharmacopeia and the AHPA – American Herbal Products Association for non-sterile dried or powdered botanicals and powdered botanical extracts.

15. What are sampling personnel required to wear for microbiological control? I would assume tyvex, mask, hairnet, etc. We are very concerned about outside contamination

All of the above is required per facility and sterile instruments for sampling.

16. Can the enforcement date(s) be pushed back?

All Bulletins for enforced testing are available on the [website](#). No enforcement date has been extended.

17. What is the remediation process?

If a sample fails microbiological testing or water activity, the licensee may request to remediate the failed batch in writing from the OCR. If a sample fails heavy metals, a licensee cannot remediate. They can only request a retest (see Question 17) or destroy the batch.

The licensee must include the below information and the COA issued by the lab.

- *Subject Line: Cultivator Trade Name- Request for Remediation*
- *Cultivator/Compassion Center Tradename requesting the remediation*
- *Cultivator/Compassion Center Tradename performing the remediation*
- *Batch#*
- *Lab that performed the test*
- *Remediation process to be used*
- *Failed Test:*

The Department will review the request and approve/deny it.

18. What is the retesting process?

If a sample fails microbiological contaminant testing or water activity or heavy metals, the licensee may request to retest the failed batch in writing from the OCR. The retest request can be sent without remediation or after remediation has occurred (if allowable).

Licensee must include the below information and the COA issued by the lab.

- *Subject Line: Cultivator Trade Name- Request for Remediation*
- *Cultivator/Compassion Center Tradename requesting the remediation*
- *Cultivator/Compassion Center Tradename performing the remediation*
- *Batch#*
- *Lab that performed the test*
- *Remediation process used* (if allowable per a previous request made to OCR)*
- *Failed Test:*

The Department will review the request and approve/deny it.

Any questions regarding testing should be submitted in writing to DBR.MMPCCompliance@dbr.ri.gov. The Office of Cannabis Regulation and the Rhode Island Department of Health will continue to update this document with any relevant questions and responses.