Tina Kotek, Governor



April 18, 2023 CANNABIS TESTING INFORMATION BULLETIN 2023-02

Subject: Microbiological Contaminant Testing

The Oregon Health Authority's Oregon Medical Marijuana Program (OMMP) and Oregon Environmental Laboratory Accreditation Program (ORELAP) write rules for testing marijuana items and industrial hemp-derived vapor items for both the medical and adult use cannabis markets. This bulletin serves to clarify confusion the agency has heard around microbiological contaminant testing.

Microbiological contaminant testing is required for any cannabis item harvested or manufactured on or after March 1, 2023. The microbiological contaminant compliance testing looks specifically for Shiga toxin-producing *Escherichia coli*, *Salmonella* species, and four pathogenic species of *Aspergillus*: *Aspergillus flavus*, *A. fumigatus*, *A. niger and A. terreus*. The current requirements for *Aspergillus* testing is not a general *Aspergillus* test. The rules for microbiological contaminant testing may be found under OAR <u>333-007-0390</u> and testing rules in full may be found at <u>healthoregon.org/ommprules</u>.

Purpose of testing for Aspergillus:

The pathogenic *Aspergillus* molds are harmful to humans via two different mechanisms. The molds have been shown to cause infection of body tissues, most commonly in terms of cannabis use through inhalation of living *Aspergillus* cells or inhalation of spores into the respiratory system. *Aspergillus* infection most commonly affects people who are immunocompromised. However, people with allergies to the molds can also be affected by inhaling living or dead cells or by inhaling spores. Almost all states with legal marijuana markets require testing for *Aspergillus*. The addition of this test was recommended from an <u>Oregon Secretary of State audit</u> in 2019.

Aspergillus Testing

The testing rules require a laboratory to use a molecular approach such as qPCR or other technologies that can detect sequences of DNA specific to the four species of *Aspergillus* described as pathogenic to humans and found in cannabis materials.

A batch fails if the presence of any of the four described species of pathogenic *Aspergillus* molds is detected in one gram of sample. This specificity of the described testing is what rules out all the other types of *Aspergillus* that could be present. The molecular approach to testing for Aspergillus does not differentiate between living and dead cells as it only detects DNA. Some of the approved testing methods laboratories are using include a process that can eliminate extra-cellular DNA that may be present if dead cells have been broken open. At

this time, the vast majority of compliance samples for the microbiological contaminant panel have passed compliance testing.

Failed Aspergillus Testing

If a sample from a batch of marijuana or usable marijuana fails microbiological contaminant testing, the batch may either be remediated using a sterilization process or used to make a cannabinoid concentrate or extract if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon solvent or CO₂ extraction system.

If a sample from a batch of a cannabinoid concentrate, extract, finished inhalable cannabinoid product, or industrial hemp-derived vapor item fails microbiological contaminant testing, the batch may be further processed if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon solvent or CO₂ extraction system.

A batch that is remediated through a sterilization process as outlined above must be resampled and re-tested for all required tests. A batch that fails microbiological contaminant testing after undergoing remediation through a sterilization process as outlined above must be destroyed in a manner specified by the OHA or OLCC.

Sterilization means to remove all microorganisms and other pathogens from a marijuana item by treating it with approved chemicals, subjecting it to high heat, or other process.

Risk Factors and Prevention

Contamination can occur at growth, harvest, extraction, or storage. *Aspergillus* can thrive at a wide range of temperatures and in low relative humidity. Environmental monitoring of facilities used for growing, storing, and curing can help monitor for microbial growth. This is a process that is heavily used within the food industry. It is encouraged that cannabis companies be proactive to ensure clean input materials and quality management practices. This could include testing their raw material, including growing substrates (soil or coco coir) and nutrient water to ensure it is free of microbial contamination. Being proactive could help eliminate a potential problem in the future.

As with implementation of any new testing requirements, OHA and OLCC monitor testing results for trends and outcomes to ensure implementation of rules is being followed. As a reminder, R&D testing performed for any test must be tracked and reported in Metrc. Questions may be emailed to <u>ommp.labs@odhsoha.oregon.gov</u>