

OREGON ADMINISTRATIVE RULES
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION CHAPTER 333

DIVISION 64

ACCREDITATION OF LABORATORIES

Oregon Environmental Laboratory Accreditation Program (ORELAP)

333-064-0100

Marijuana Item Sampling Procedures and Testing

(1) For purposes of this rule the definitions in OAR 333-007-0310 apply unless the context indicates otherwise.

(2) Sampling.

(a) A laboratory must prepare marijuana item sampling policies and procedures that contain all of the information necessary for collecting and transporting samples from a marijuana item in a manner that does not endanger the integrity of the sample for any analysis required by this rule. These policies and procedures must be appropriate to the matrix being sampled.

(b) Sampling policies and procedures must be accredited by ORELAP prior to any marijuana samples being taken. The policies and procedures must be consistent with the following ORELAP sampling protocols approved by the accrediting body, incorporated by reference:

(A) Usable Marijuana: ORELAP-SOP-001 Rev 2.0;

(B) Concentrates and Extract: ORELAP-SOP-002 Rev 2.0; and

(C) Cannabis Products: ORELAP-SOP-003 Rev 2.0.

[Sampling protocols may be found on the ORELAP and Cannabis Testing webpage, public.health.oregon.gov/LaboratoryServices/EnvironmentalLaboratoryAccreditation/Pages/cannabis-info.aspx]

(c) Care should be taken by laboratory personnel while sampling to avoid contamination of the non-sampled material. Sample containers must be free of analytes of interest and appropriate for the analyses requested.

(d) A sufficient sample size must be taken for analysis of all requested tests and the quality control performed by the testing laboratory for these tests.

(e) A laboratory must comply with any recording requirements for samples and subsamples in the accredited policies and procedures and at a minimum:

(A) Record the location of each sample and subsample taken.

(B) Assign a field identification number for each sample, subsample and field duplicate that have an unequivocal link to the laboratory analysis identification.

(C) Assign a unique identification number for the test batch in accordance with OAR 333-007-0370 and TNI EL standard requirements.

(D) Have a documented system for uniquely identifying the samples to be tested to ensure there can be no confusion regarding the identity of such samples at any time. This system must include identification for all samples, subsamples, preservations, sample containers, tests, and subsequent extracts or digestates.

(E) Place the laboratory identification code as a durable mark on each sample container.
 (F) Enter a unique identification number into the laboratory records. This number must be the link that associates the sample with related laboratory activities such as sample preparation. In cases where the sample collector and analyst are the same individual, or the laboratory pre-assigns numbers to sample containers, the unique identification number may be the same as the field identification code.

(f) Combining subsamples.

(A) Subsamples collected from the same batch must be combined into a single sample by a laboratory prior to testing unless the batch is undergoing process validation or has not yet gone through process validation.

(B) Subsamples and samples collected from different batches may not be combined.

(C) Field duplicates may not be combined with the primary samples.

(3) THC and CBD testing validity. When testing a sample for THC and CBD a laboratory must comply with additional method validation as follows:

(a) Run a laboratory control standard in accordance with TNI standards requirements within acceptance criteria of 70 percent to 130 percent recovery.

(b) Analyze field duplicates of samples within precision control limits of plus or minus 20 percent RPD, if field duplicates are required.

(4) 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:

$$M_{\text{total delta-9 THC}} = M_{\text{delta-9 THC}} + 0.877 \times M_{\text{delta-9 THCA}}$$

(b) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA:

$$M_{\text{total CBD}} = M_{\text{CBD}} + 0.877 \times M_{\text{CBDA}}$$

(c) Each test report must include the total THC and total CBD.

(5) Report total THC and total CBD as Dry Weight. A laboratory must report total THC and Total CBD content by dry weight calculated as follows:

$$P_{\text{total THC(dry)}} = P_{\text{total THC(wet)}} / [1 - (P_{\text{moisture}}/100)]$$

$$P_{\text{total CBD(dry)}} = P_{\text{total CBD(wet)}} / [1 - (P_{\text{moisture}}/100)]$$

(6) Calculating RPD and RSD.

(a) A laboratory must use the following calculation for determining RPD:

$$RPD = \frac{(\text{sample result} - \text{duplicate result})}{(\text{sample result} + \text{duplicate result})/2}$$

(b) A laboratory must use the following calculation for determining RSD:

$$\% RSD = \frac{s}{x} \times 100\%$$

$$s = \sqrt{\frac{\sum_{i=0}^n (x_i - \bar{x})^2}{(n - 1)}}$$

(c) For purposes of this section:

(A) S = standard deviation.

- (B) n = total number of values.
- (C) x_i = each individual value used to calculate mean.
- (D) \bar{x} = mean of n values.
- (d) For calculating both RPD and RSD if any results are less than the LOQ the absolute value of the LOQ is used in the equation.
- (7) Tentative Identification of Compounds (TIC).
 - (a) If a laboratory is using a gas chromatography mass spectrometry instrument for analysis when testing cannabinoid concentrates or extracts for solvents and determines that a sample may contain compounds that are not included in the list of analytes the laboratory is testing for the laboratory must attempt to achieve tentative identification.
 - (b) Tentative identification is achieved by searching NIST 2014 or an equivalent database (>250,000 compounds).
 - (c) A laboratory shall report to the licensee or registrant and the Authority or the Commission, depending on which agency has jurisdiction, up to five tentatively identified compounds (TICS) that have the greatest apparent concentration.
 - (d) Match scores for background subtracted or deconvoluted spectra should exceed 90 percent compared to library spectrum.
- (A) The top five matches over 90 percent must be reported by the lab
- (B) TIC quantitation is estimated by comparing analyte area to the closest internal standard area and assuming a response factor (RF) =1.
- (8) A laboratory must provide:
 - (a) Any pesticide test result to the Department of Agriculture upon that agency's request.
 - (b) A sample or a portion of a sample to the Department of Agriculture upon that agency's request, document the chain of custody from the laboratory to the Department, and document that the sample or portion of the sample was provided to the Department in the Commission's seed to sale tracking system.
- (9) A laboratory performing tests for a licensee must enter any information required by the Commission in the Commission's seed to sale tracking system.
- (10) A laboratory performing tests for a registrant must comply with the documentation requirements in OAR 333-007-0370.
- (11) The Authority may, in its discretion, deviate from TNI Standards in order to comply with OAR 333-007-0400 to 333-007-0490 and these rules based on the state's needs.
 Stat. Auth.: ORS 438.605, 438.610, 438.615 & 438.620, ORS 475B.555.
 Stats. Implemented: ORS 438.605, 438.610, 438.615 & 438.620, ORS 475B.555.

333-064-0110

Reporting Marijuana Item Test Results

- (1) For purposes of this rule the definitions in OAR 333-007-0310 apply unless the context indicates otherwise.
- (2) Within 24 hours of completion of the laboratory's data review and approval procedures a laboratory must report all failed tests for testing required under OAR 333-007-0300 to 333-007-0490 except for failed water activity, whether or not the lab is reanalyzing the sample under OAR 333-007-0450:
 - (a) Into the Commission's seed to sale tracking system if performing testing for a licensee; and
 - (b) To the Authority electronically at www.healthoregon.org/ommp if performing testing for a registrant.

(3) The laboratory must report all test results required under OAR 333-007-0300 to 333-007-0490 that have not been reported under section (2) of this rule into the Commission's seed to sale tracking system if performing testing for a licensee.

(4) A laboratory must determine and include on each test report its limit of quantification (LOQ) for each analyte listed in OAR 333-007-0400 Table 3 and OAR 333-007-0410 Table 4.

(5) When reporting pesticide testing results the laboratory must include in the report any target compound that falls below the LOQ that has a signal to noise ratio of greater than 3:1 and meets identification criteria with a result of "detected."

(6) A test report must include any associated test batch numbers and the date each test was completed.

(7) A laboratory that is reporting failed test results to the Commission or the Authority in accordance with section (2) of this rule must report the failed test at the same time or before reporting to the licensee or registrant.

(8) In addition to reporting failed test results in accordance with section (2) of this rule a laboratory conducting testing for a registrant must report to the Authority electronically at www.healthoregon.org/ommp any pesticide testing report with a "detected" as described in section (5) of this rule.

(9) Test results expire after one year.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555