

UregonEnvironmental Laboratory Accreditation Program

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Proficiency Testing (PT) in Oregon Cannabis Laboratories

Disclaimer: The information below is a selected highlight of the Oregon cannabis PT reporting requirements. For complete PT reporting requirements, refer to OAR 333-064 and 2016 TNI V1M1.

According to Oregon Administrative Rule (OAR) 333-064-0120, "A laboratory accredited to test marijuana items must at all times have two successful PT studies out of the most recent three attempts for each field of accreditation for which the laboratory holds accreditation."

In addition, "A PT study for a particular field of accreditation that has an opening date less than seven days from the closing date of the previous PT study for that same field of accreditation" may not be counted toward the laboratory's PT history of the most recent three attempts and "The closing dates of a PT study for a particular field of accreditation can be no more than seven months apart", else the laboratory is charged one missed/failed PT sample. The correct method code must be entered with each PT result, per OAR 333-064-0120(3)(a)(C), or the result will not be counted towards the laboratory's PT history.

Cannabis plant material (usable marijuana) falls under the Biological Tissue (BT) matrix. Concentrates, extracts, and products fall under the Solid (S) matrix.

Unless otherwise stated, the laboratory must analyze PT samples for each field of accreditation (FOA), meaning each combination of matrix, method/technology, and analyte. See additional requirements on reporting of PT results following the FOA table in this document.

Unless otherwise stated, for potency, pesticides, and mycotoxins in biological tissue (BT), the laboratory must use PT samples made from a usable marijuana matrix.

The laboratory must select a PT vendor approved by The NELAC Institute (TNI): http://nelac-institute.org/content/NEPTP/ptproviders.php.

ORELAP currently accredits laboratories for the following FOAs for cannabis testing.

Cannabinoids (Potency)							
Analyte Code	Analyte Name	BT	S	PTRL (%)			
5405	Delta-9 Tetrahydrocannabinol (d9 THC)	X	X	0.15			
7386	Delta-8 Tetrahydrocannabinol (d8 THC)	X	0.15				
5410	Delta-9 Tetrahydrocannabinolic acid (d9 THCA)	X	X	0.15			
5415	Cannabidiol (CBD)	X	X	NA			
5420	Cannabidolic acid (CBDA)	X	X	NA			
	Water Activity / Moisture Content						
Analyte Code	Analyte Name	BT	S	PTRL			
8068	Water activity	X		NA			
3850	Moisture content	X		NA			
	Pesticides						
Analyte Code	Analyte Name	BT	S	PTRL (ppm)			
7366	Abamectin	X	X	0.25			
7000	Acephate	X	X	0.2			
7002	Acequinocyl	X	1				
7003	Acetamiprid	X	X	0.1			
7010	Aldicarb	X	X	0.2			
7076	Azoxystrobin	X	X	0.1			
7116	Bifenazate	X	X	0.1			
7117	Bifenthrin	X	X	0.1			
7128	Boscalid	X	X	0.2			
7195	Carbaryl		X	0.1			
7205	Carbofuran	X	X	0.1			
7247	Chlorantraniliprole X X						
7329	Chlorfenapyr	X	X	0.5			
7300	Chlorpyrifos	X	X	0.1			
7966	Clofentezine	X	X	0.1			
7345	Cyfluthrin	X	X	0.5			
7346	Cypermethrin	X	X	0.5			
7348	Daminozide	X	X	0.5			

Pesticides continued							
Analyte Code	Analyte Name	S	PTRL (ppm)				
8610	DDVP (Dichlorvos)	/P (Dichlorvos) X X					
7410	Diazinon	X					
7475	Dimethoate	X	X				
7570	Ethoprophos	X	X	X 0.1			
7573	Etofenprox	X	X	0.2			
7574	Etoxazole	X	X	0.1			
7597	Fenoxycarb	X	X	0.1			
7598	Fenpyroximate	X	X	0.2			
7623	Fipronil	X	X	0.2			
7628	Flonicamid	X	X	0.5			
7629	Fludioxonil	X	X	0.2			
7707	Hexythiazox	X	X	0.5			
7718	Imazalil	X	X	0.1			
7702	Imidacloprid	X	X	0.2			
7747	Kresoxim-methyl	X	X				
7770	Malathion	X	X				
7790	Metalaxyl	X	X				
7800	Methiocarb	X	X	0.1			
7805	Methomyl	X	X	X 0.2			
7825	Methyl parathion	X	X	X 0.1			
7860	MGK-264	X	X	X 0.1			
7893	Myclobutanil	X	X	X 0.1			
7905	Naled	X	X 0.25				
7940	Oxamyl	X	X				
7947	Paclobutrazol	X	X				
7975	Permethrins	X	X				
8000	Phosmet	X	X				
9550	Piperonyl butoxide	X	X				
8022	Prallethrin	X	X	0.1			
8077	Propiconazole	X	X	0.2			
8080	Propoxur	X	X	0.1			
8247	Pyrethrins	X	X				
8097	Pyridaben	X	X				
8136	Spinosad	X	X				
8137	Spiromesifen	X	X	0.1			

	Pesticides continued						
Analyte Code	Analyte Name	BT	S				
8139	Spirotetramat	X	X	0.1			
8141	Spiroxamine	X	0.2				
8174	Tebuconazole X X						
8214	Thiacloprid	X	X	0.1			
8216	Thiamethoxam	X	X	0.1			
8287	Trifloxystrobin	X	X	0.1			
	Heavy Metals						
Analyte Code	Analyte Name	BT	S	PTRL (μg/g)			
1010	Arsenic	X	X	0.1			
1030	Cadmium	X	X	0.1			
1075	Lead	X	X	0.25			
1095	Mercury	X	X	0.05			
	Microbiology						
Analyte Code	Analyte Name	S	PTRL				
5465	Aspergillus	X	X	NA			
5466	Aspergillus flavus *						
5467	Aspergillus fumigatus *	X	X X NA				
5468	Aspergillus niger *	NA					
5469	Aspergillus terreus *	NA					
2572	Shiga-toxin producing Escherichia coli (STEC)	X	NA				
2570	Salmonella	X	X	NA			
	Mycotoxins						
Analyte Code	Analyte Name	ВТ	S	PTRL (μg/g)			
5445	Aflatoxin B1	X	X	0.01			
5450	Aflatoxin B2	X X 0		0.01			
5455	Aflatoxin G1	X	X	X 0.01			
5460	Aflatoxin G2 X X		0.01				
5412	Total Aflatoxins X X						
5473	Ochratoxin A	X	X	0.01			
	Residual Solvents						
Analyte Code	Analyte Name	ВТ	S	PTRL (μg/g)			
5250	1,2-Dimethylbenzene (o-Xylene)		X	1085			
5240	m+p-Xylene		X	1085			
4735	1,4-Dioxane		X	190			

Residual Solvents continued							
Analyte Code	Analyte Name	ВТ	S	PTRL (μg/g)			
9607	2-Butanol (Sec-butyl alcohol)	X	2500				
5866	2-Ethoxyethanol (Cellosolve)	2-Ethoxyethanol (Cellosolve) X 80					
4941	2-Methylpentane (Isohexane)	X 145					
4895	2-Propanol (IPA)		X	2500			
4666	2,2-Dimethylbutane		X	145			
4669	2,3-Dimethylbutane		X	145			
4534	3-Methylpentane		X	145			
4315	Acetone		X	2500			
4320	Acetonitrile		X	205			
4375	Benzene		X	1			
5007	n-Butane		X	2500			
4900	Cumene (Isopropyl benzene)		X	35			
4555	Cyclohexane		X	1940			
4975	Dichloromethane (Methylene chloride)	300					
4755	Ethyl acetate		2500				
4725	Ethyl ether (Diethyl ether)		2500				
4765	Ethylbenzene	X		1085			
4785	Ethylene glycol	thylene glycol X		310			
4795	Ethylene oxide	25					
4825	Heptane						
4855	n-Hexane	X 145					
4942	Isobutane (2-Methyl propane)		X	2500			
4938	Isopentane (2-Methyl butane) X		2500				
4890	Isopropyl acetate		X	2500			
4930	Methanol X		1500				
9511	Neopentane X		2500				
5028	n-Pentane		X	2500			
5029	n-Propane X		2500				
5120	Tetrahydrofuran (THF) X		360				
5140			445				
5143	Total Butanes X 25						
9469	Total Hexanes						
5148	Total Pentanes X 250						
5260	Total Xylenes X 108						

Reporting PT results:

ORELAP now electronically tracks cannabis laboratory PT results through the ORELAP Data Input and Edit (ODIE) database. Laboratories may now also view their PT history directly in ODIE. For PT results to be properly recognized in ODIE, the analyte and method codes used in the PT submission must exactly match those listed in the laboratory's FOA within ODIE. For reference, OAR 333-064-0120(3)(a) outlines the specific details laboratories must include when reporting PT results to PT providers. Laboratories are responsible for ensuring PT results are accurately submitted to the PT providers.

The laboratory's EPA identification (ID) also needs to be reported to the PT provider. The laboratory's EPA IDs may be found on your FOA sent with each ORELAP certificate or in the Identification tab in the laboratory's most recent Primary Renewal Application in ODIE. The PT Providers may have the laboratory's EPA ID already. In the case of NSI Lab Solutions, the vendor stated the EPA code should be entered into the "State code" field and the method codes should be entered into the "Method Technology" fields. See page 8 for how to enter EPA ID for NSI Lab Solutions PTs.

The 2016 TNI Standard V1M1 4.2.2 requires analyzing and reporting PT results in accordance with the laboratory's routine Standard Operating Procedures (SOPs), using the same quality control (QC), acceptance criteria, and staff used for the analysis of routine samples. Additionally, for chemistry PTs, the 2016 TNI Standard V1M1 4.3.7.b) and c) indicate the laboratory must report either the determined numeric value or less than the Limit of Quantitation (LOQ), where the LOQ is a numerical value equal to the laboratory's normal sample LOQ. If a result is above the calibration range of the analysis, the PT extract or digestate must be diluted and reanalyzed or the PT must be reprepared. Additional requirements are summarized below:

Report numerical values or < X, where X = the numerical value equal to the LOQ

- o Greater than (>) results will not be accepted by ORELAP. If a PT provider grades a greater than result as acceptable, ORELAP will change the grade to not acceptable.
- Less than (<) results will only be accepted if the less than value is a numerical value equal to or less than the laboratory's required LOQ (< X, where X= numerical value equal to the LOQ) and the requirements in 2016 TNI Standard V1M1 Section 4.3.7 are met. Do not report "0", the symbol "<LOQ" or "ND" (not detected) for quantitative PT results.

- o In addition to the requirements in 2016 TNI Standard V1M1 4.2.2, which requires laboratories to analyze PT samples using their routine SOPs, including reporting results to the method's normal LOQ, 2016 TNI Standard V1M1 Section 4.3.7.b states:
 - If the analytical result is a numeric value below the PTRL, the laboratory shall report one of the following:
 - i. < PTRL or,
 - ii. the obtained analytical result, if the result is between the LOQ and the PTRL, or,
 - iii. < LOQ, if the analytical result is below the LOQ and the PTRL.
 - See examples of 'Not acceptable' and 'Acceptable' PT reporting for mycotoxin results in the table below:

Analyte	Reported	Assigned	Acceptance	PT Result
·	Value (μg/g)	Value (μg/g)	Range (µg/g)	Acceptable?
Aflatoxin B1	> 50.0	51.1	36.1 – 56.7	Not acceptable
Aflatoxin B2	< 10.0*	9.92	8.80–11.2	Acceptable
				or
				Not
				acceptable*
Aflatoxin G1	< LOQ	< 10.0		Not acceptable
Aflatoxin G2	0	6.05	3.8 - 8.2	Not acceptable
Total Aflatoxins	63.3	67.1	45.2 – 90.5	Acceptable
Ochratoxin A	< 10.0	< 10.0		Acceptable

^{*} The acceptability of this result depends on the laboratory's LOQ for routine samples. If the laboratory's LOQ for routine samples is below the PTRL, the laboratory must evaluate results to their normal LOQ. ORELAP may request supporting records.

Method codes are required when submitting PTs

- Method codes can be found on your laboratory's ORELAP FOA in the method code column (right side).
- o If the method code is missing or incorrect, the laboratory's PT result will not count towards the laboratory's PT history.

- Analyte codes change for each analyte. The analyte code is not entered by the laboratory with PT results.
- Do not mistake analyte code and method code! The method code is the same for all analytes in a method. Be aware of typos in method codes!
- If you have questions, email ORELAP and/or the PT provider.
- The method code must exactly match what is on the laboratory's FOA

 see example below of how to find method code '805' for 'Pesticides by LC-MS-MS'.

MATRIX	Reference	Analyte Code	Analyte	Re	vision	Rev. Date	Method Code	Description
Biological								
Tissue	AOAC 2007.01 & EN						805	Pesticides by LC-MS-MS
	15662: LC-	7366	Abamectin					
	MS/MS	7000	Acephate					
		7002	Acequinocyl					
		7003	Acetamiprid	TO PER	~ ~	The state of the s		
		5445	Aflatoxin B1	OKE				

- Enter State Lab Code if reporting to NSI Lab Solutions
 - State Lab Code = EPA Code on FOA
 - o EPA Code/State Lab Codes start with 'TNI' or 'OR'
 - Example: 'TNI001234' or 'OR100001'
 - o Look for EPA Code in ODIE or on your FOA under EPA Code
 - o Enter EPA Code in State Lab Code box under Accreditation Agency



- Residual solvents total calculations vs individual analytes (total xylenes, pentanes, hexanes, butanes)
 - Some PT providers prompt to report each individual analyte, others may only have total calculations. Submit based on PT provider instructions.
 - o Results for totals will be applied to each individual analyte.
 - If the total calculated result fails, each analyte fails.
 - o Results for the individuals will be applied to the total calculated result.
 - If any individual analyte fails, the failure is also applied to the total.

Total Calculation	Sum of Individual Analytes
Total Butanes	n-butane; iso-butane
Total Hexanes	n-hexane; 2-methylpentane; 3-methylpentane; 2,2-dimethylbutane; 2,3-dimethylbutane
Total Pentanes	pentane; iso-pentane; neo-pentane
Total Xylenes*	m+p xylene; o-xylene

^{*}ethylbenzene is not included as a Total Xylene in PTs, report ethylbenzene separately.

Mycotoxins individual analytes and total aflatoxins

o Report each individual analyte and the calculated value for total aflatoxins.

Two microbiology methods under same technology

- o If a laboratory is accredited for two microbiology methods under the same technology (i.e., PCR) for an analyte (e.g. *Salmonella*, STEC), the laboratory may alternate the method used in each PT round. For example, in the spring study use method one and in the fall study use method two.
 - **Note:** If the laboratory alternates microbiology methods for PTs, not acceptable results will be applied to both methods. If there is a history of two out of three not acceptable results, the laboratory will be suspended for both microbiology methods.
- The laboratory may also choose not to alternate microbiology method PTs, and analyze separate PTs for each microbiology method, but must ensure it uses separate PT lots for each method.

• The time between PTs must not exceed seven months!

o If more than seven months passes for an analyte, the laboratory will have a "not acceptable" result on its PT record.

- Seven months is based on closing dates! "The closing date of a PT study for a particular field of accreditation can be no more than seven months apart."
- The seven months is from the closing date of the previous PT to the closing date of the following PT.

Suspension and Revocation due to PT failures

 A laboratory may be suspended for a FOA when it does not have a history of two out of three acceptable PT results for a FOA. A laboratory may be revoked for a FOA if there are three not acceptable results in a row for a FOA.

Suspension

- Suspension is a temporary removal of a laboratory's accreditation for a period not to exceed six months or the period of accreditation, whichever is longer. Suspension allows a laboratory time to correct deficiencies or areas of noncompliance. ORELAP may request corrective action plans.
- A suspended laboratory may not continue to perform testing services for the affected scope of accreditation.
- If the cause of the suspension has not been corrected within six months or the period of accreditation, whichever is longer, the affected FOAs will be revoked.

Revocation

- Revocation is the removal of a laboratory's accreditation for all or part of the current fields of accreditation.
- Once the laboratory has made the appropriate correction(s), it may reapply for accreditation. A new application fee must accompany the new application.