

Cannabis Proficiency Testing: Design, Issues and Implementation

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Phenova, Inc

- Golden, CO
- Established 2001
- ISO 17043, ISO 17034, ISO 17025 and TNI Chapt 3 accredited
- First accredited 17043 PT provider to have Cannabis accredited on scope
- Core business Environmental PTs as dictated by TNI
- Certified Reference/Calibrant Provider

PT Programs: What they should look like to participants/AA's.....

- Independent, third party
- Designed specifically to the regulatory requirements labs are accredited to or have to meet
- Best effort for matrix matching or duplication
- Evaluations applicable to the analyte, method, matrix, and regulatory specifics
- Qualitative *and* Quantitative approach
- Ease of use for analysis and reporting
- Responsive to participants and accrediting agencies, dynamic to changing requirements



What a PT Program looks like to a Provider.....

- Standards Manufacture Step #1
 - Meeting ISO 17043 requirements
 - Verification/Homogeneity/Stability testing
 - Packaging and lot traceability
- Report Generation Step #2
 - Ease of Data Entry for Customers
 - Reviewing of Results, valid evaluations
 - Reporting to participants and AA's
 - Participant support (corrective action)



Cannabis PT Roadblocks

Illegal to ship matrix

State specific analytes/action levels

Stability of standards

Lack of Historical Data for Evaluations



Roadblock Solution: Matrix

- Oregon began in-state manufacturing in real matrices early 2016
- Currently manufacturing in-matrix PTs where matrix is critical in analysis (ie Pests, Potency)
- Manufacture PTs in alternative matrices where matrix does not create an analytical challenge (ie Metals, RSO, WA, Terpenes)



Roadblock Solution: Matrix

- Oregon OHA authorizes larger purchase of material
- Utilize licensed host lab facility for manufacturing and PT analytical validation (timeframe for all activities ~5 days)
- ORELAP assumes custody of in matrix PTs, stores appropriately, does distribution from their facility at study opening
- Labs travel to ORELAP for in matrix PT pickup



Roadblock Solution: State Specificity

- Internal database system allows for analyte classification based on state action levels and evaluation criteria
- State specific PT programs can be created using regulated analyte lists, action levels an evaluation criteria
- Manufactured PTs represent the specific state regulatory requirements.



Roadblock Solution: State Specificity



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ADDITIONAL INFORMATION

The PT sample will contain a subset of the following analytes:

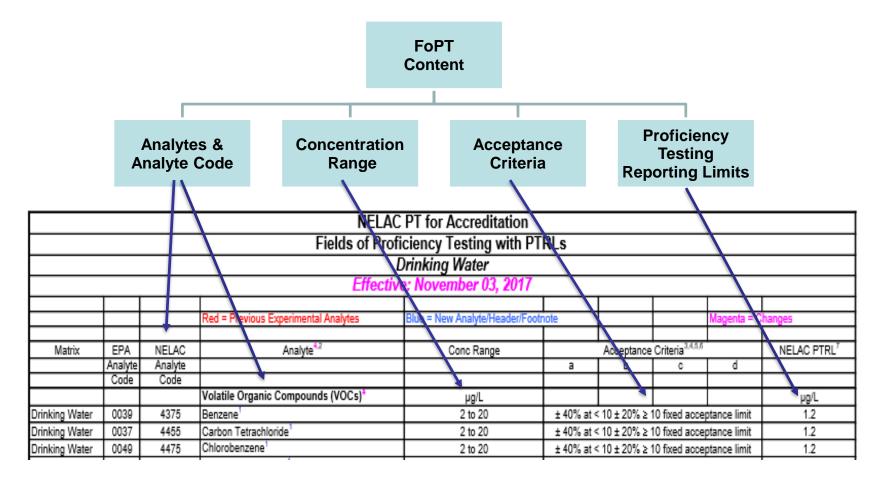
Analyte ¹	PTRL ²	Range ³		ge ³	Analyte ¹	PTRL ²	I	Range ³		Analyte ¹	PTRL ²	I	Range ³	
1,4-Dioxane	380	50	-	500	Ethyl Acetate	5000	50	-	6000	Total Pentanes ⁵	5000	50	-	6000
2-Ethoxyethanol	160	50	-	200	Ethylbenzene ⁷	2170	50	-	2600	Methanol	5000	50	-	6000
Acetone	5000	50	-	6000	Ethyl Ether	5000	50	-	6000	Tetrahydrofuran	720	50	-	900
Acetonitrile	410	50		500	Ethylene Glycol	620	50	-	800	Toluene	890	50	-	1000
Benzene	2	1	-	20	Ethylene Oxide	50	50		100	Total Xylenes ⁶	2170	50	-	2600
Cumene	70	50	-	100	n-Heptane	5000	50	-	6000	2-Butanol	5000	50	-	6000
Cyclohexane	3880	50	-	5000	Total Hexanes ⁴	290	50	-	400	2-Propanol (IPA)	5000	50	-	6000
Dichloromethane	600	50	-	800	Ispropyl Acetate	5000	50	-	6000					

Footnotes: 1- Analytes in this list are specified in the Oregon Medical Marijuana Dispensary Program Rules and Statutes. However, due to technical challenges of analyte inclusion, the following analytes have been left off of this list: Propane isomers and Butane isomers; 2- "PTRL" refers to the Action Level specified in the Oregon Medical Marijuana Dispensary Program Rules and Statutes in ug/g; 3- "Range" refers to concentration potentially spiked in PT sample, ug/g; 4- "Total Hexanes" include the sum of isomers n-Hexane, 2-Methylpentane, 3-Methylpentane, 2,2-Dimethylpentane and 2,3-Dimethylpentane; 5- "Total Pentanes" include the sum of isomer n-Pentane, iso-Pentane and neo-Pentane (2,2-Dimethylpenzene (p-Xylene); 7- Ethylbenzene per OAR requirements should be reported separately from Total Xylenes but considered in combination with Total Xylenes against the published action limit. For this reason and for the purpose of this PT, Ethylbenzene has been given the same Action Level ("PTRL") and potentially spiked concentration range as Total Xylenes.

Certified Reference Materials

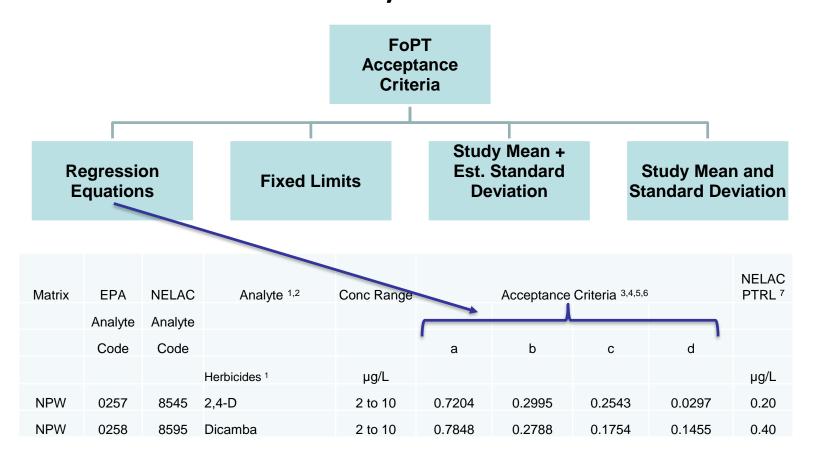
Lack of Historical Data Roadblock

Field of Proficiently Testing (FoPT) Tables: PT Blueprint



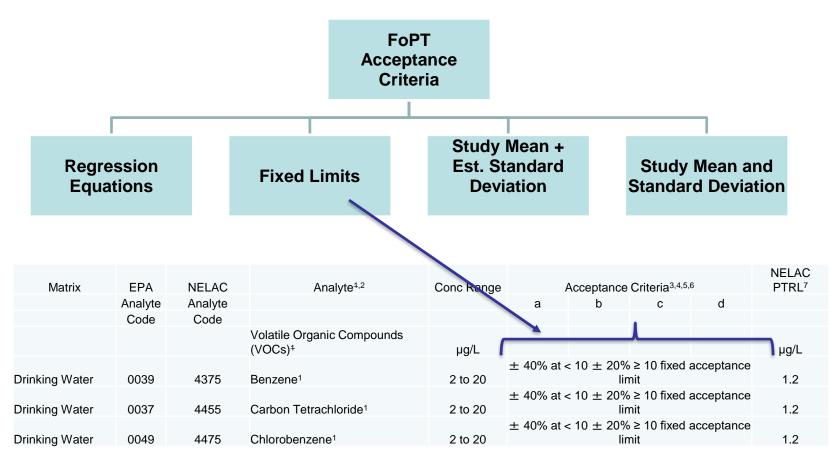


PT Providers determine Acceptance Criteria w/ FoPT Tables



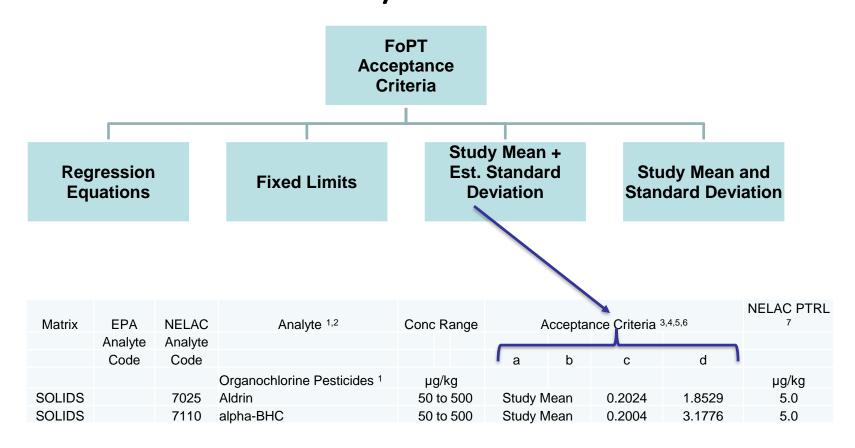


Criteria w/ FoPT Tables





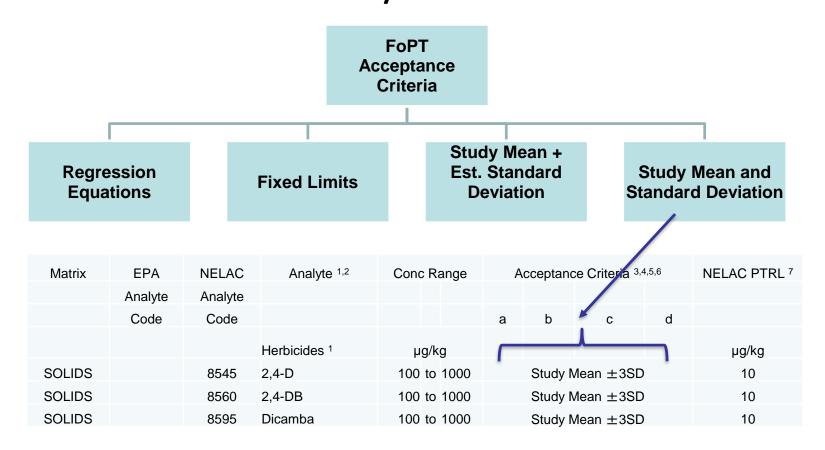
PT Providers determine Acceptance Criteria w/ FoPT Tables





PT Acceptance Criteria

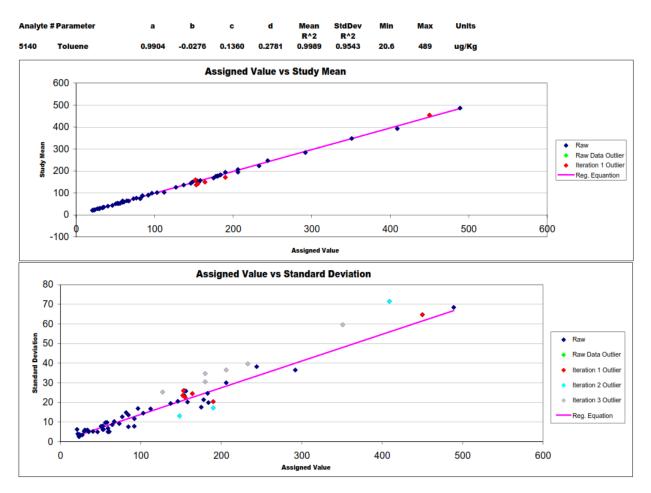
PT Providers determine Acceptance Criteria w/ FoPT Tables



Constructing a FoPT Table – Predicted Recoveries and Standard Deviations

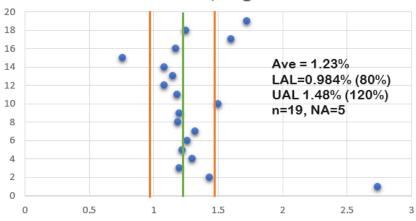
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Reference Materials



Cannabinoids in Flower - OR

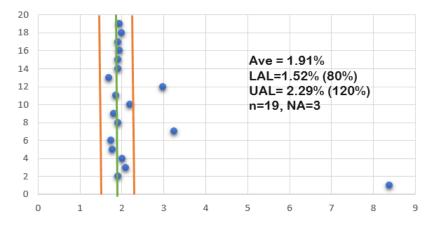
CBD in Flower, August 2016



CBDA in Flower, August 2016

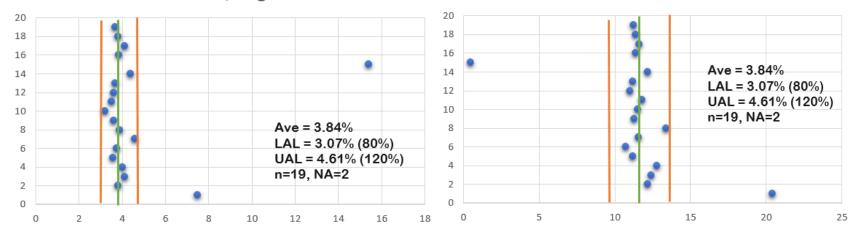
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THC in Flower, August 2016

THCA in Flower, August 2016



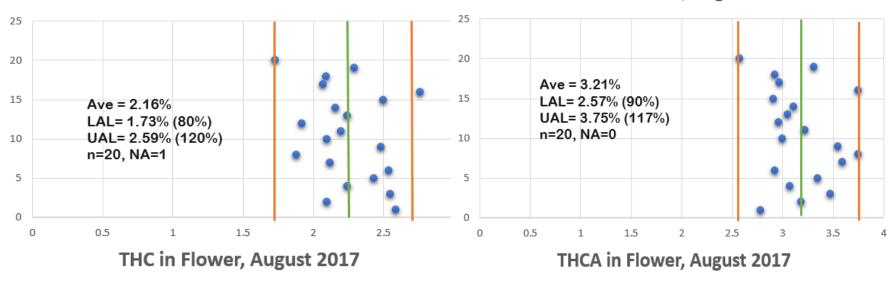
Cannabinoids in Flower - OR

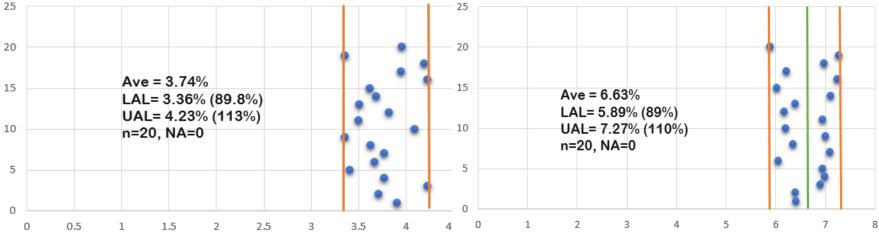
CBD in Flower, August 2017

CBDA in Flower, August 2017

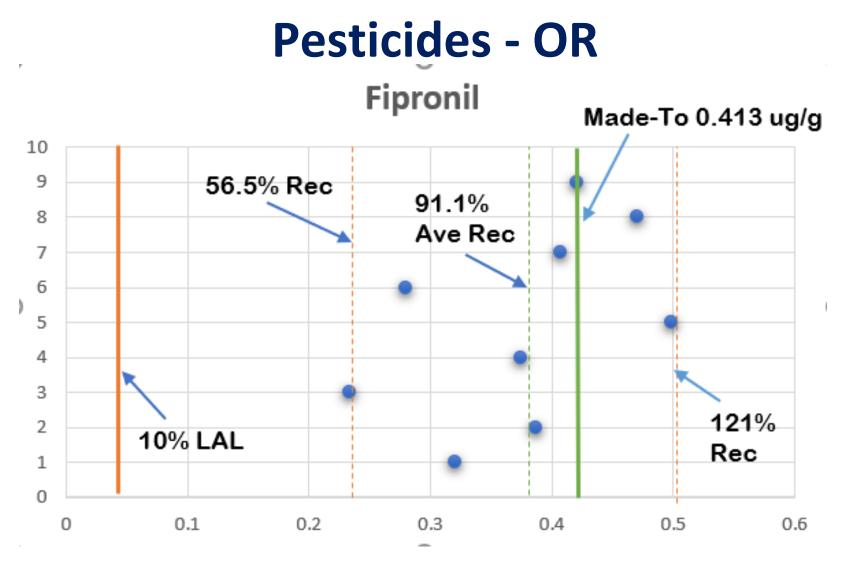
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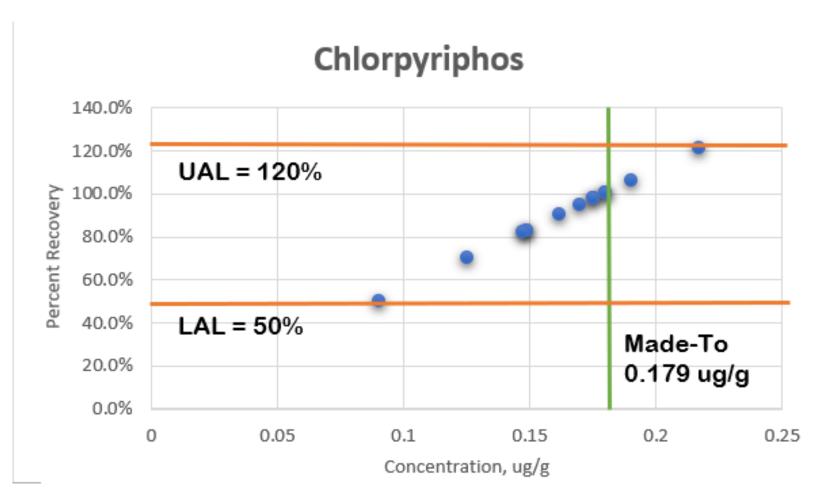






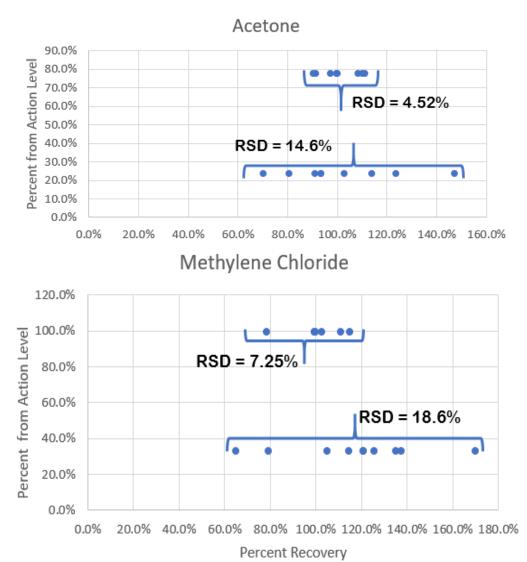


Pesticides - OR





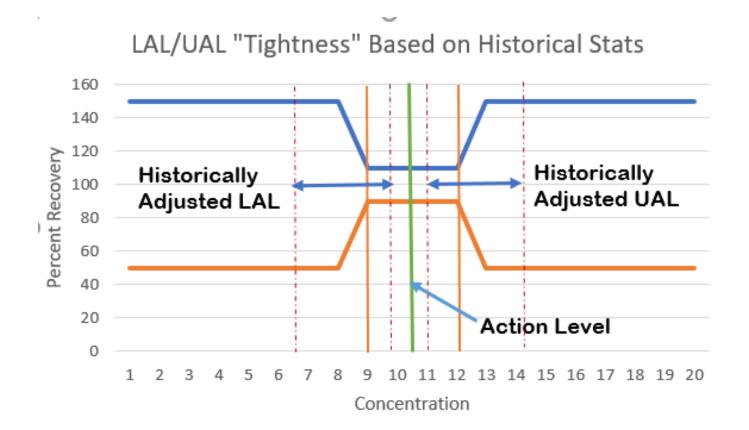
Residual Solvents - OR



Closer to Action Level: Tighter Standard Deviations



Action Level vs. Eval Criteria





Benefits of a Phenova Cannabis PT Program



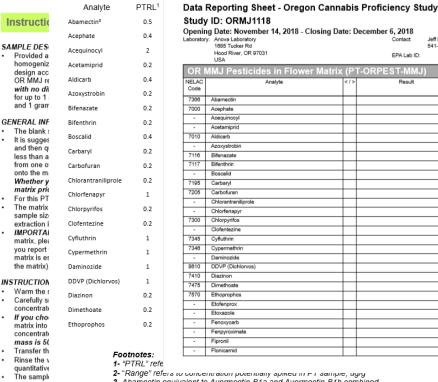
- Well developed and robust lab user interface and Dashboard
 - ✓ Account management and privilege rights
 - ✓ Ease of Data Entry/Upload
 - ✓ Historical study review and custom report creation

GC/MS Pesticio	le Residues (Part #:	PT-GO	PEST-MMJ)						.ot #: MMJ1-02
Method Num	ber: <mark>1 🗸</mark> OF		Add	d New Metho	pd +	Delete	Method - Copy	/ Method +	Autofill Em	pty Rows
					Autofill D	efault Val	ues		Cop	oy previous row
Press 'Enter	' After Typing	Result	To Use	e Autofill		?	SOP 54-43 GC/MS	04/04/2016	THG	
Analyte	Result	Unit	PTRL	Conc. Range	NELAC/A Method	gency Code	Method Description	Analysis Date	Analyst	Prep Method
cephate	2.36	µg/g	0.400	0.800 - 8.00		?	SOP 54-43 GC/MS	04/04/2016	THG	
cequinocyl		µg/g	2.00	4.00 - 40.0		?				
ifenthrin	1.88	µg/g	0.200	0.400 - 4.00		?	SOP 54-43 GC/MS	04/04/2016	THG	
hlorfenapyr	<0.5	µg/g	1.00	2.00 - 20.0		?	SOP 54-43 GC/MS	04/04/2016	THG	
hlorpyrifos	3.95	µg/g	0.200	0.400 - 4.00		?	SOP 54-43 GC/MS	04/04/2016	THG	
yfluthrin	15.2	µg/g	1.00	2.00 - 20.0		?	SOP 54-43 GC/MS	04/04/2016	THG	
ypermethrin	6.54	µg/g	1.00	2.00 - 20.0		?	SOP 54-43 GC/MS	04/04/2016	THG	
thoprophos	<0.1	µg/g	0.200	0.400 - 4.00		?	SOP 54-43 GC/MS	04/04/2016	THG	
Etofenprox		µg/g	0.400	0.800 - 8.00		?				
ipronil	<0.25	µg/g	0.400	0.800 - 8.00		?	SOP 54-43 GC/MS	04/04/2016	THG	
ludioxonil	<0.1	µg/g	0.400	0.800 - 8.00		?	SOP 54-43 GC/MS	04/04/2016	THG	
lethyl parathion	1.87	µg/g	0.200	0.400 - 4.00		?	SOP 54-43 GC/MS	04/04/2016	THG	
IGK-264	3.22	µg/g	0.200	0.400 - 4.00		?	SOP 54-43 GC/MS	04/04/2016	THG	
ermethrins, Tota	3.98	µg/g	0.200	0.400 - 4.00		?	SOP 54-43 GC/MS	04/04/2016	THG	
yrethrins, Total	11.6	plan	1.00	2.00 - 20.0		?	SOP 54-43 GC/MS	04/04/2016	THG	



- Concise and complete study documentation
 - ✓ Introductory information
 - ✓ Instructions
 - ✓ Reference Data Reporting Sheets

Benefits of a Phenova Cannabis PT Program - Participants ADDITIO Company ACCREDITED Certified Reference Materials Certificate # 2427.0 The PT sa 6390 Joyce Drive Phone 303-940-0033 # 100 Fax 866-283-0269 Golden, CO 80403 www.phenova.com



Laborator	y: Anova Laboratory 1885 Tucker Rd Hood River, OR 97031 USA		Contact: Jeff Fetkenh 541-388-024 EPA Lab ID:		
OR I	MMJ Pesticides in Flower Ma	trix (P	T-ORPEST-MMJ)		
NELAC Code	Analyte		Result	NELAC / Agency Method Code	Method Description
7366	Abamectin		9/94		
7000	Acephate		9/g4		
-	Acequinocyl		6/6H		
-	Acetamiprid		0/84		
7010	Aldicarb		6/6rl		
-	Azoxystrobin		9/g4		
7116	Bifenazate		0/94		
7117	Bifenthrin		6/6H		
-	Boscalid		6/6H		
7195	Carbaryl		9/g4		
7205	Carbofuran		6/6rl		
-	Chlorantraniliprole		0/g4		
-	Chlorfenapyr		0/84		
7300	Chlorpyrifos		6/6H		
-	Clofentezine		0/94		
7345	Cyfluthrin		0/94		
7346	Cypermethrin		0/04		
-	Daminozide		6/6H		
8610	DDVP (Dichlorvos)		9/g4		
7410	Diazinon		0/94		
7475	Dimethoate		0/04		
7570	Ethoprophos		9/94		
	Etofenprox	_	9/g4		
	Etoxazole		P/84		
	Fenoxycarb		p/g4		
-	Fenpyroximate	_	P.64		
-	Fipronil		P/64		

µg/g



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Lot #: ORMJ11-0

Analyst (Optional)

Analysis Date

Certified Reference Materials

3- Abamectin equivalent to Avermectin-B1a and Avermectin-B1b combined

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quantitative The sample



- Quick results turnaround and support
 - ✓ Reports issued no more than 5 days after study closing
 - Readily accessible pre and post study support
 - Advisement on study outcome/corrective action

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Final Report - Oregon Cannabis Proficiency

Study: ORMJ1118

Opening Date: November 14, 2018 - Closing Date: December 7, 2018

Laboratory: Cascadia Labs 7405 SW Tech Center Drive Suite A160 Portland, OR 97223 USA Contact: Mr. Evan Mohr, Quality Manager 5037438587 EPA Lab ID:

ORI	MMJ Pesticides in Flower I	Matrix (P1	F-ORPEST	-MMJ)					Lot #: Ol	RMJ11-01
NELAC Code	Analyte	Analysis Date	Analyst	Method Code	Method Description	Units	Assigned Value	Result	Acceptance Limits	Evaluation
7366	Abamectin	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	hð\ð	<0.8	<0.20		Acceptable
7000	Acephate	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	µg/g	0.352	0.33	0.0352 - 0.563	Acceptable
-	Acequinocyl	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	hð\ð	<3	<0.39		Acceptable
-	Acetamiprid	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	hð/ð	<0.3	<0.10		Acceptable
7010	Aldicarb	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	µg/g	<0.6	<0.20		Acceptable
-	Azoxystrobin	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	hð/ð	<0.3	<0.10		Acceptable
7116	Bifenazate	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	hð/ð	0.221	0.17	0.0928 - 0.278	Acceptable
7117	Bifenthrin	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	µg/g	<0.3	<0.10		Acceptable
-	Boscalid	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	hð/ð	0.429	0.42	0.270 - 0.571	Acceptable
7195	Carbaryl	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	µg/g	<0.3	<0.10		Acceptable
7205	Carbofuran	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	µg/g	<0.3	<0.10		Acceptable
-	Chlorantraniliprole	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	hð/ð	<0.3	<0.10		Acceptable
-	Chlorfenapyr	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	µg/g	1.47	1.37	0.632 - 2.18	Acceptable
7300	Chlorpyrifos	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	µg/g	0.183	0.17	0.0183 - 0.292	Acceptable
-	Clofentezine	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	hð/ð	<0.3	<0.10		Acceptable
7345	Cyfluthrin	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	µg/g	1.02	0.81	0.428 - 1.60	Acceptable
7346	Cypermethrin	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	hð/ð	<2	<0.39		Acceptable
-	Daminozide	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	hð/ð	3.11	4.09	0.497 - 4.98	Acceptable
8610	DDVP (Dichlorvos)	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	µg/g	<2	<0.39		Acceptable
7410	Diazinon	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	hð/ð	< 0.3	<0.10		Acceptable
7475	Dimethoate	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	hð/ð	0.259	0.25	0.186 - 0.365	Acceptable
7570	Ethoprophos	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	µg/g	0.162	0.15	0.115 - 0.217	Acceptable
-	Etofenprox	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	hð/ð	<0.6	<0.10		Acceptable
-	Etoxazole	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	µg/g	<0.3	<0.10		Acceptable
-	Fenoxycarb	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	µg/g	0.195	0.18	0.146 - 0.238	Acceptable
-	Fenpyroximate	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	hð/ð	<0.6	<0.10		Acceptable
-	Fipronil	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	µg/g	<0.6	<0.20		Acceptable
-	Flonicamid	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	µg/g	<2	<0.39		Acceptable
-	Fludioxonil	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	µg/g	0.590	0.65	0.354 - 0.785	Acceptable
-	Hexythiazox	11/19/2018	HMS	805	AOAC 2007.01 Rev.1 2007	hð/ð	<2	<0.39		Acceptable



- Complete PT program management
- In matrix programs are no cost to AA agreements/contracts
- Dynamic and immediate response to changing program requirements and criteria
- Receipt of participant reports no later than 5 days after study closing
- Optional EDD formats, ie state database uploads
- Provides a valuable program risk management piece, especially when using real matrix PTs



Thank you for your attention!