CARO ANALYTICAL SERVICES

AN INTRODUCTION TO LABORATORY TESTING IN THE CANNABIS INDUSTRY

Environmental Manager's Association of BC
Nov 21st, 2019

WHY TESTING?

- It’s the law
- A safe product is essential for building trust
- Potency testing; why it is important to patients
- Safety and Liability

WHAT TESTING IS REQUIRED?

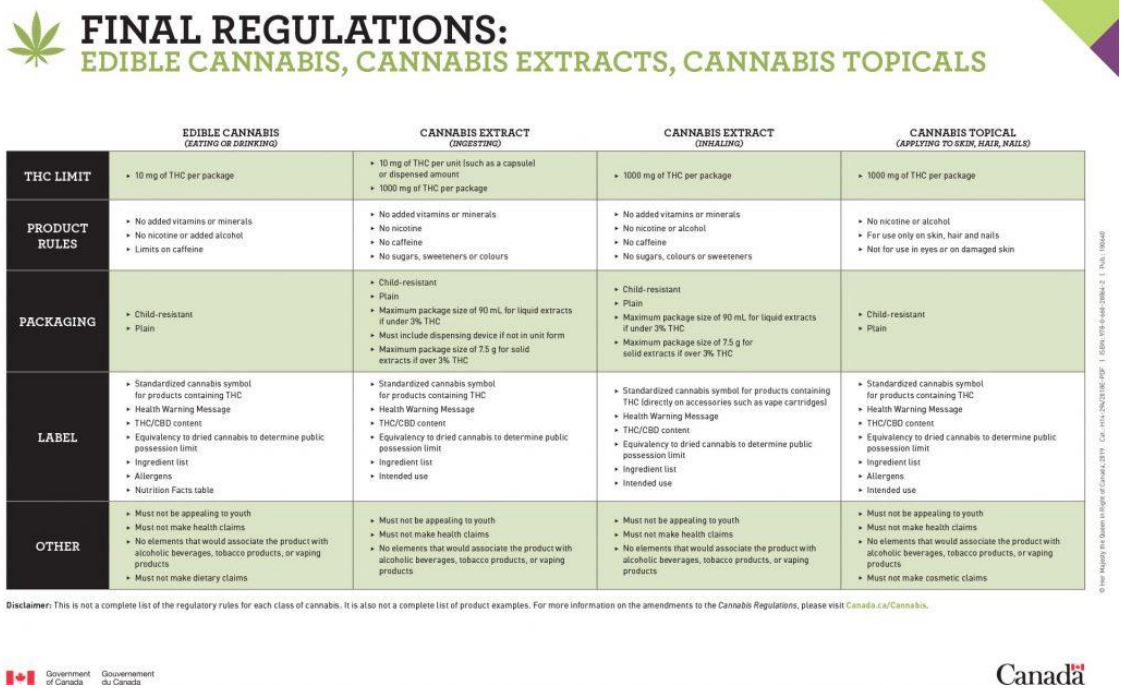
- Microbiology; total aerobic microbial count, total combined yeasts and moulds count, bile-tolerant gram negative bacteria, E-Coli, Salmonella and aflatoxins
- Heavy Metals; Cadmium, Arsenic, Lead, Mercury
- Potency; delta-9-tetrahydrocannabinol and cannabidiol
- Pesticides
- Residual Solvents

EDIBLES

- There will be a requirement that any water (including ice or steam used in the production of a cannabis product) coming into contact with cannabis or an ingredient be potable, unless the water does not present a risk of contamination

- Dissolution or disintegration testing on discrete units.

- For edible cannabis, there will be a limit of 10 milligrams of THC per discrete unit and per immediate container.



FINAL REGULATIONS:
EDIBLE CANNABIS, CANNABIS EXTRACTS, CANNABIS TOPICALS

	EDIBLE CANNABIS (EATING OR DRINKING)	CANNABIS EXTRACT (INGESTING)	CANNABIS EXTRACT (INHALING)	CANNABIS TOPICAL (APPLYING TO SKIN, HAIR, NAILS)
THC LIMIT	▸ 10 mg of THC per package	▸ 10 mg of THC per unit (such as a capsule) or dispensed amount ▸ 1000 mg of THC per package	▸ 1000 mg of THC per package	▸ 1000 mg of THC per package
PRODUCT RULES	▸ No added vitamins or minerals ▸ No nicotine or added alcohol ▸ Limits on caffeine	▸ No added vitamins or minerals ▸ No nicotine ▸ No caffeine ▸ No sugars, sweeteners or colours	▸ No added vitamins or minerals ▸ No nicotine or alcohol ▸ No caffeine ▸ No sugars, colours or sweeteners	▸ No nicotine or alcohol ▸ For use only on skin, hair and nails ▸ Not for use in eyes or on damaged skin
PACKAGING	▸ Child-resistant ▸ Plain	▸ Child-resistant ▸ Plain ▸ Maximum package size of 90 mL for liquid extracts if under 3% THC ▸ Must include dispensing device if not in unit form ▸ Maximum package size of 7.5 g for solid extracts if over 3% THC	▸ Child-resistant ▸ Plain ▸ Maximum package size of 90 mL for liquid extracts if under 3% THC ▸ Maximum package size of 7.5 g for solid extracts if over 3% THC	▸ Child-resistant ▸ Plain
LABEL	▸ Standardized cannabis symbol for products containing THC ▸ Health Warning Message ▸ THC/CBD content ▸ Equivalency to dried cannabis to determine public possession limit ▸ Ingredient list ▸ Allergens ▸ Nutrition Facts table	▸ Standardized cannabis symbol for products containing THC ▸ Health Warning Message ▸ THC/CBD content ▸ Equivalency to dried cannabis to determine public possession limit ▸ Ingredient list ▸ Intended use	▸ Standardized cannabis symbol for products containing THC (directly on accessories such as vape cartridges) ▸ Health Warning Message ▸ THC/CBD content ▸ Equivalency to dried cannabis to determine public possession limit ▸ Ingredient list ▸ Intended use	▸ Standardized cannabis symbol for products containing THC ▸ Health Warning Message ▸ THC/CBD content ▸ Equivalency to dried cannabis to determine public possession limit ▸ Ingredient list ▸ Allergens ▸ Intended use
OTHER	▸ Must not be appealing to youth ▸ Must not make health claims ▸ No elements that would associate the product with alcoholic beverages, tobacco products, or vaping products ▸ Must not make dietary claims	▸ Must not be appealing to youth ▸ Must not make health claims ▸ No elements that would associate the product with alcoholic beverages, tobacco products, or vaping products	▸ Must not be appealing to youth ▸ Must not make health claims ▸ No elements that would associate the product with alcoholic beverages, tobacco products, or vaping products	▸ Must not be appealing to youth ▸ Must not make health claims ▸ No elements that would associate the product with alcoholic beverages, tobacco products, or vaping products ▸ Must not make cosmetic claims

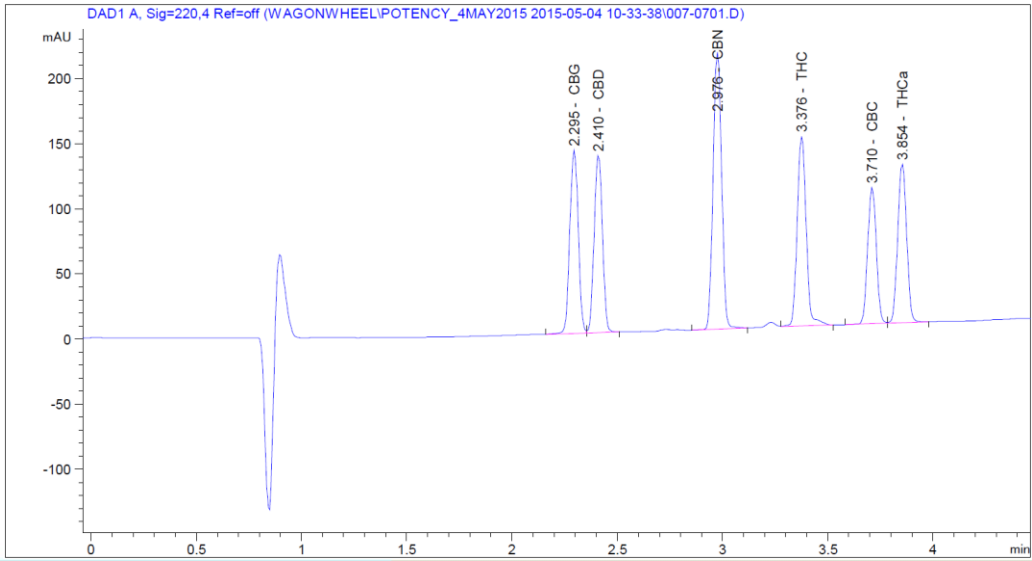
Disclaimer: This is not a complete list of the regulatory rules for each class of cannabis. It is also not a complete list of product examples. For more information on the amendments to the *Cannabis Regulations*, please visit Canada.ca/Cannabis.

Government of Canada / Gouvernement du Canada

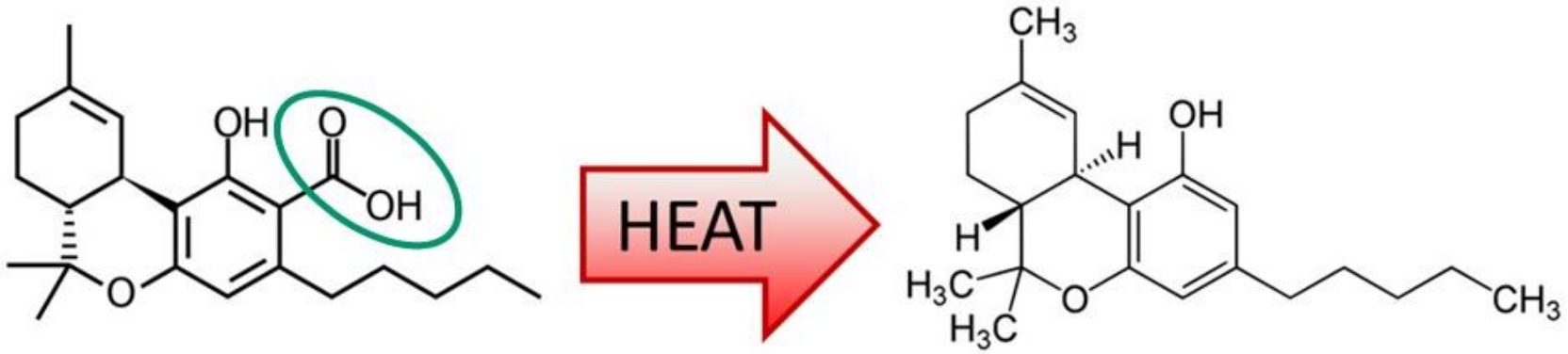
Canada

POTENCY TESTING

- Cannabinoid Analysis; delta 9 – THC and CBD required
- Many other cannabinoids can be reported; CBN, CBG, CBDa, THCa, etc.
- Reported as a percentage of weight: 16% = 160mg/g
- Dry weight vs wet weight
- Do you add the THC and THCa together?



DECARBOXYLATION



THCA (CBDA, CBGA, etc.)

THC (CBD, CBG, etc.)

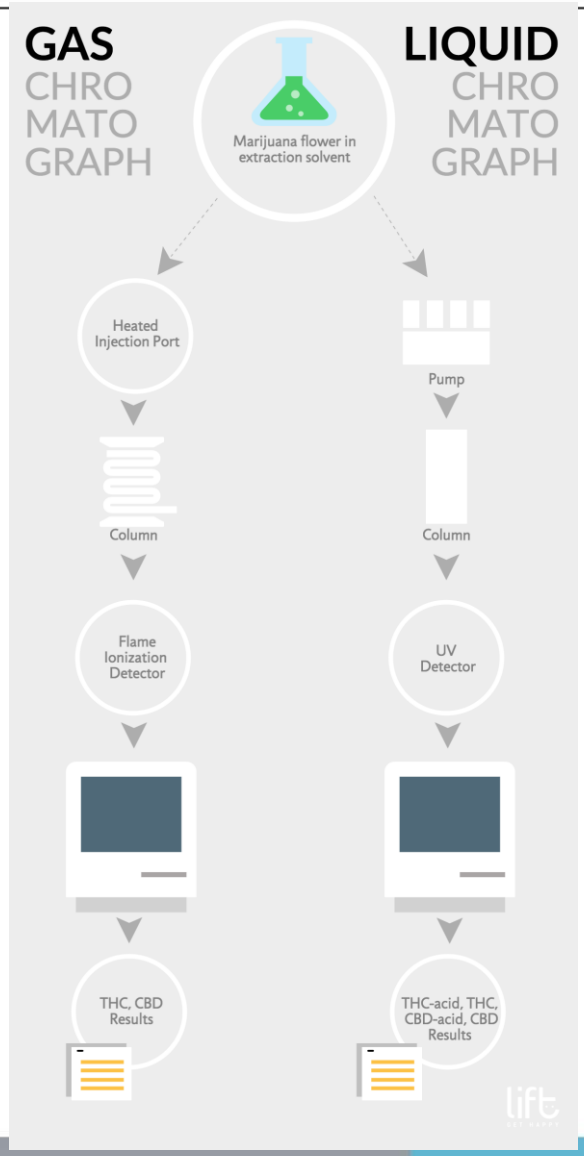
CHROMATOGRAPHY

Gas Chromatography

Thin Layer Chromatography

Liquid Chromatography

CHROMATOGRAPHY



http://blog.liftcannabis.ca/2015/03/17/chromatography-and-cannabinoid-potency-testing/

PESTICIDES

Pesticides that are of the most concern or are most likely to be used on cannabis have been added to this pesticide active ingredients list if they:

- Were detected on cannabis in Canada or in American states that have regulated its production
- Are used against pests that can be found on cannabis
- Were observed by inspectors of Health Canada or the Canadian Border Services Agency
- Were identified because of their risk to health orbecause of other factors

Updated detection limits for the 96 regulated pesticides come into effect Dec 2, 2019.

Source: Health Canada MANDATORY CANNABIS TESTING FOR PESTICIDE ACTIVE INGREDIENTS

HEAVY METALS

- Lead, arsenic, cadmium, mercury
- Limit tests; contaminants must be within generally accepted tolerance limits for herbal medicines for human consumption, as established in pharmacopeia methods (EP, USP, BP, etc)
- ICPOES, ICPMS, AA

RESIDUAL SOLVENTS

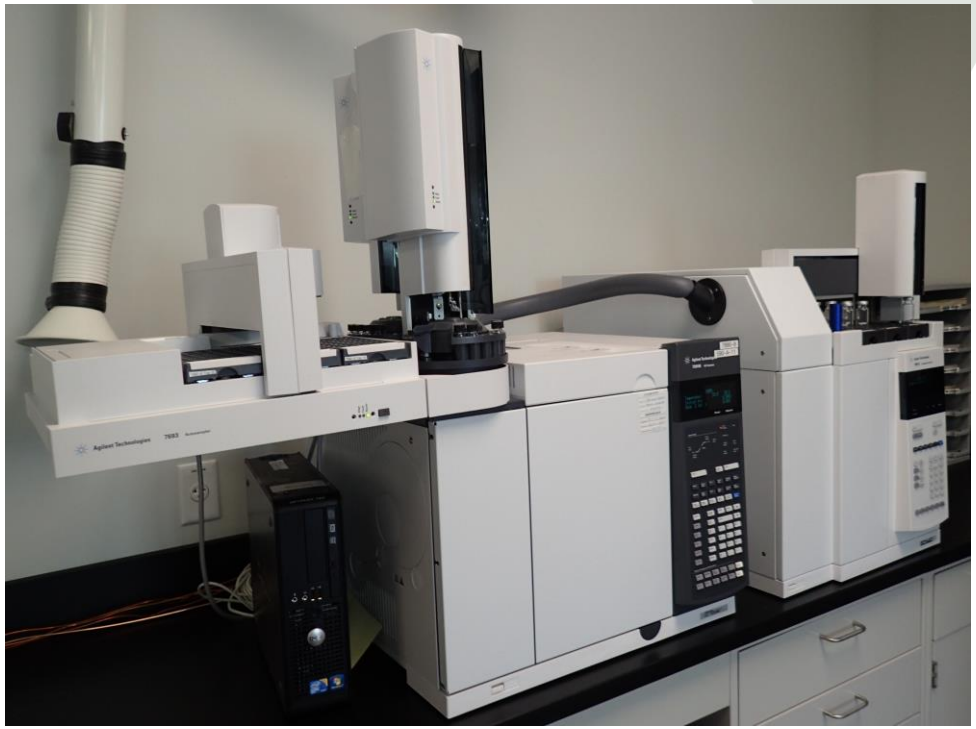
- Cannabis extraction uses solvents; CO_2, ethanol, butane
- How do we know the extract is safe for consuming?
- Residual Solvent test for Class 1, 2 and 3 solvents
- Based on toxicity

MICROBIOLOGY

- Microbiology; total aerobic microbial count, total combined yeasts and moulds count, bile-tolerant gram negative bacteria, E-Coli, Salmonella and aflatoxins
- Immunocompromised patients may be more susceptible
- Limit tests; contaminants must be within generally accepted tolerance limits for herbal medicines for human consumption, as established in pharmacopeia methods (EP, USP, BP, etc)

TERPENES

- Terpenes or terpenoids; organic volatile molecules
- Not a legal requirement to test
- Terpene profiling growing
- GCMS (Headspace, liquid injection)
- Medical benefits, entourage effect

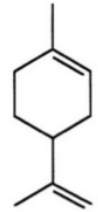


http://blog.liftcannabis.ca/2015/04/01/testing-for-terpenes-in-cannabis/

CARO ANALYTICAL SERVICES

TERPENES

Limonene



Smell :
Citrus

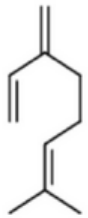
Medical Use :
May possess Anti-bacterial (3), anti-cancer (2) and anti-fungal (4) properties

α-Pinene

Smell :
Pine trees

Medical Use :
May exhibit bronchodilator (5), increased focus (6), anti-inflammatory (7) effects

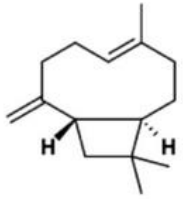
β-Myrcene



Smell :
Hops

Medical Use :
May have analgesic (8) and muscle relaxant (9) properties

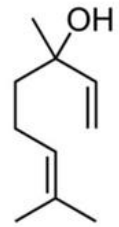
β-Caryophyllene



Smell :
Woody, black pepper, clove

Medical Use :
May possess anti-inflammatory (12) and anti-malarial (13) effects

Linalool



Smell :
Floral (lavender)

Medical Use :
May possess anti-anxiety (10) and sedative (11) effects

CARO ANALYTICAL SERVICES

VOCS IN AIR

BCMOE CSR Schedule 3.3 Substance	MRL	General Numerical Vapour Standards							
		Ag, UP, Res		Commercial		Industrial		Parkade	
	µg	µg/m³	min vol (L)	µg/m³	min vol (L)	µg/m³	min vol (L)	µg/m³	min vol (L)
Volatile Organic Compounds (VOCs) – Thermal Desorption (TD) Tube[4]									
Acetone	0.01	2,500	0.5	7,000	0.5	25,000	0.5	20,000	0.5
Acrylonitrile	0.001	0.5	2	0.5	2	1.5	0.7	1	1
Allyl chloride	0.001	1	1	3	0.5	9	0.5	8	0.5
Benzene	0.002	1.5	1.4	4	0.5	10	0.5	10	0.5
Bromobenzene	0.001	60	0.5	200	0.5	550	0.5	500	0.5
Bromodichloromethane	0.001	50	0.5	150	0.5	550	0.5	400	0.5
Bromoform	0.001	9	0.5	30	0.5	85	0.5	75	0.5
1,3-Butadiene	0.004	2	2	2	2	3	1.4	2.5	1.6
Carbon disulfide	0.01	700	0.5	2,000	0.5	6,500	0.5	5,500	0.5
Carbon tetrachloride	0.001	1.5	0.7	5	0.5	15	0.5	15	0.5
Chlorobenzene	0.001	10	0.5	30	0.5	90	0.5	80	0.5
Chloroethane	0.005	10,000	0.5	30,000	0.5	90,000	0.5	80,000	0.5
Chloroform	0.001	100	0.5	300	0.5	900	0.5	800	0.5
2-Chlorotoluene	0.002	50	0.5	150	0.5	550	0.5	400	0.5
n-Decane	0.003	2,500	0.5	8,000	0.5	25,000	0.5	20,000	0.5
1,2-Dibromo-3-chloropropane	0.001	1	1	1	1	2	0.5	1.5	0.7
Dibromochloromethane	0.001	50	0.5	150	0.5	550	0.5	400	0.5
1,2-Dibromoethane	0.0005	0.5	1	0.5	1	0.5	1	0.5	1
Dibromomethane	0.001	4	0.5	10	0.5	35	0.5	30	0.5
1,2-Dichlorobenzene	0.001	200	0.5	600	0.5	2,000	0.5	1,500	0.5
1,3-Dichlorobenzene	0.001	80	0.5	250	0.5	850	0.5	600	0.5
1,4-Dichlorobenzene	0.001	800	0.5	2,500	0.5	7,500	0.5	6,500	0.5
Dichlorodifluoromethane	0.002	100	0.5	300	0.5	900	0.5	800	0.5
1,1-Dichloroethane	0.001	500	0.5	1,500	0.5	4,500	0.5	4,000	0.5
1,2-Dichloroethane	0.001	5	0.5	15	0.5	45	0.5	40	0.5
1,1-Dichloroethylene	0.001	200	0.5	600	0.5	2,000	0.5	1,500	0.5
cis-1,2-Dichloroethylene	0.001	60	0.5	200	0.5	550	0.5	500	0.5
trans-1,2-Dichloroethylene	0.001	60	0.5	200	0.5	550	0.5	500	0.5
Dichloromethane	0.01	600	0.5	2,000	0.5	5,500	0.5	5,000	0.5
1,2-Dichloropropane	0.001	4	0.5	10	0.5	35	0.5	30	0.5
1,3-Dichloropropane	0.001	1.5	0.7	4	0.5	15	0.5	10	0.5
1,3-Dichloropropene, cis+trans	0.002	2.5	0.8	7.5	0.5	25	0.5	20	0.5
Diethyl ether	0.002	500	0.5	1,500	0.5	5,500	0.5	4,000	0.5
Ethyl acetate	0.005	70	0.5	200	0.5	650	0.5	550	0.5
Ethylbenzene	0.005	1,000	0.5	3,000	0.5	9,000	0.5	8,000	0.5
Ethyl methacrylate	0.001	300	0.5	900	0.5	2,500	0.5	2,500	0.5
Hexachlorobutadiene	0.001	1	1	1.5	0.7	4	0.5	3.5	0.5
Hexachloroethane	0.004	30	0.5	90	0.5	250	0.5	250	0.5
n-Hexane	0.01	700	0.5	2,000	0.5	6,500	0.5	5,500	0.5
Isopropylbenzene	0.001	400	0.5	1,000	0.5	3,500	0.5	3,000	0.5
Methacrylonitrile	0.001	30	0.5	90	0.5	250	0.5	250	0.5

BCMOE CSR Schedule 3.3 Substance	MRL	General Numerical Vapour Standards							
		Ag, UP, Res		Commercial		Industrial		Parkade	
	µg	µg/m³	min vol (L)	µg/m³	min vol (L)	µg/m³	min vol (L)	µg/m³	min vol (L)
Volatile Organic Compounds (VOCs) – Thermal Desorption (TD) Tube[4]									
(CONTINUED FROM PAGE 1)									
Methyl acrylate	0.005	20	0.5	60	0.5	200	0.5	150	0.5
Methyl cyclohexane	0.005	2,000	0.5	7,000	0.5	25,000	0.5	20,000	0.5
Methyl ethyl ketone (MEK)	0.005	5,000	0.5	15,000	0.5	45,000	0.5	40,000	0.5
Methyl isobutyl ketone (MIBK)	0.002	3,000	0.5	9,000	0.5	25,000	0.5	25,000	0.5
Methyl methacrylate	0.002	700	0.5	2,000	0.5	6,500	0.5	5,500	0.5
Methyl tert-butyl ether (MTBE)	0.002	3,000	0.5	9,000	0.5	25,000	0.5	25,000	0.5
Naphthalene	0.001	3	0.5	9	0.5	25	0.5	25	0.5
Nitrobenzene	0.001	1	1	1	1	2.5	0.5	2	0.5
Styrene	0.001	1,000	0.5	3,000	0.5	9,000	0.5	8,000	0.5
1,1,1,2-Tetrachloroethane	0.001	1.5	0.7	4	0.5	10	0.5	10	0.5
1,1,2,2-Tetrachloroethane	0.001	50	0.5	150	0.5	550	0.5	400	0.5
Tetrachloroethylene (PERC)	0.005	40	0.5	100	0.5	350	0.5	300	0.5
Tetrahydrofuran	0.001	3.5	0.5	10	0.5	30	0.5	25	0.5
Toluene	0.01	5,000	0.5	15,000	0.5	45,000	0.5	40,000	0.5
1,2,4-Trichlorobenzene	0.001	7	0.5	20	0.5	65	0.5	55	0.5
1,1,1-Trichloroethane	0.001	5,000	0.5	15,000	0.5	45,000	0.5	40,000	0.5
1,1,2-Trichloro-1,2,2-trifluoroethane	0.002	30,000	0.5	90,000	0.5	250,000	0.5	250,000	0.5
1,1,2-Trichloroethane	0.001	0.5	2	0.6	1.7	2	0.5	1.5	0.7
Trichloroethylene (TCE)	0.001	2	0.5	6	0.5	20	0.5	15	0.5
Trichlorofluoromethane	0.001	700	0.5	2,000	0.5	6,500	0.5	5,500	0.5
1,2,3-Trichloropropane	0.001	0.5	2	0.9	1.2	2.5	0.5	2.5	0.5
1,2,4-Trimethylbenzene	0.005	7	0.8	20	0.5	65	0.5	55	0.5
1,3,5-Trimethylbenzene	0.005	4.5	1.2	15	0.5	45	0.5	35	0.5
Vinyl Chloride	0.002	1	2	3.5	0.6	10	0.5	9	0.5
Xylenes, total	0.015	100	0.5	300	0.5	900	0.5	800	0.5
VPHv *	2	1,000	2	3,000	0.7	11,500	0.5	8,000	0.5

IN HOUSE LAB

- Access to testing
- Control of services
- Method validation
- Staffing and training
- Large cost upfront

3RD PARTY LAB

- On going costs
- Diverted liability
- Audits
- Turn Around Time
- Required

QUESTIONS TO ASK YOUR LAB

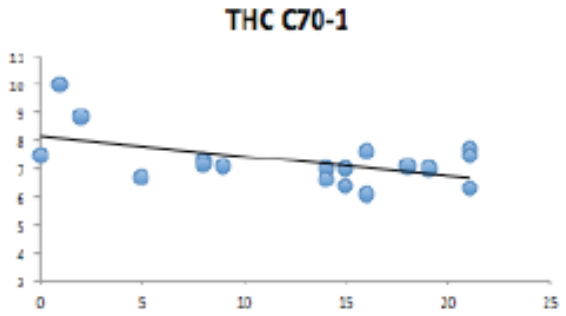
- Accreditation and licensing
- Method Validation Data
- Instrumentation and reference methods
- Audits
- Contracts
- Proficiency Testing

QUESTIONS TO ASK YOUR LAB

7.1 THC Sample C70-1

N	Assigned Value	Assigned Stdev	Acceptance Limits
19	7.1	0.607	5.28 – 8.92

Lab ID	Method	Analysis Date	Reported %	± U
C02	HPLC	14-Jun-19	7.06	
C03	RP-HPLC	26-Jun-19	6.2945	0.00788
C04	LC-QQQ	21-Jun-19	6.11	0.953
C05		23-Jun-19	7.10	0.49
C07	NMR	26-Jun-19	7.7	1.1
C08	NMR	26-Jun-19	7.5	1.1
C09	UHPLC	27-Jun-19	6.7	0.1
C10	UPLC, SOP-0642	20-Jun-19	7.04	0.042
C11	HPLV-UV	20-Jun-19	6.4	1.9
C12	HPLC-UV	5-Jun-19	7.44	0.065
C13	LC-MS/MS	10-Jun-19	6.69	1.88
C14	UPLC-UV	19-Jun-19	7.00	0.237
C15	MSC-SOP-041 Rev.2	19-Jun-19	6.6	0.7
C17	HPLC	13-Jun-19	7.34	0.79
C18	LC-MS/MS	6-Jun-19	10	0.5
C20	C-LC-1001	7-Jun-19	8.89	0.4
C21	L-001-04	13-Jun-19	7.1925	0.2552
C22	HPLC	24-Jun-19	7.005	0.350
C24	AC-090	21-Jun-19	7.614	



ACKNOWLEDGEMENTS

Emily Kirkham – Technical Manager CARO

QUESTIONS

Caring About Results... Obviously!

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