Be Lab Ready - USDA's Hemp Testing Rules Have Changed

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AGENDA

The estimated value of the global industrial hemp market in 2021 was $4.13 billion. With the legalization of hemp, the market is projected to increase at a CAGR of 16.8% from 2022 to 2030.

Source: Industrial Hemp Market Size & Share Report, 2022-2030, Grand View Research, Inc.

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The Journey of Hemp Legalization

- In 1937, hemp production was banned in the U.S. after the Marijuana Act was enacted.
- The Agricultural Act of 2014 reintroduced industrial hemp production in the U.S.
- U.S. industrial hemp acreage increased from 0 in 2013 to over 90,000 acres in 2018.

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The Journey of Hemp Legalization

- The Agricultural Improvement Act of 2018 brought about significant changes in the agricultural sector.

- Hemp was legalized at the federal level in 2018.

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What was in the 2018 Farm Bill?

- The U.S. Farm Bill was signed on December 20, 2018.
- Hemp fell into the same class as other agricultural commodities.
- Due to its close relationship with cannabis hemp production is heavily regulated.

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The USDA's Final Rule

The USDA published the Final Rule that became effective from March 22, 2021.

Hemp testing labs need to get acquainted with these changes and be ready to implement them.

Several changes were introduced in the Final Rule that affects how hemp should be tested in the U.S.

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Why?

Legally Required in All 50 States

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Why?

Penalties for Hot Hemp

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Hemp Testing Methods

- Hemp testing labs should use post-decarboxylation or other similar reliable methods to determine total THC concentration.

- THC is determined and reported on a dry-weight basis.

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Total THC Limit

The THC threshold was maintained at 0.3% in the USDA's final rule

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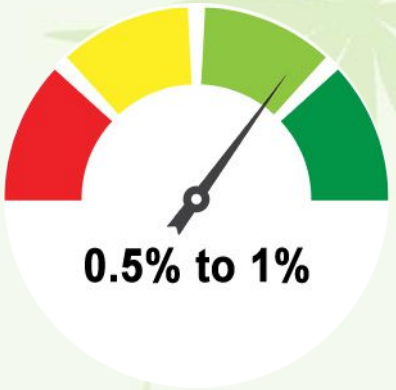
Negligent Violation

Hemp that tests above 0.3% THC but below 1 % THC can be remediated

This is not considered a violation of the law



This limit has been increased from 0.5% to 1%

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Measurement of Uncertainty (M.U.)

Labs should calculate the Measurement of Uncertainty (M.U.) when reporting THC concentration

The M.U. should be reported as a ± value; it is expressed in the same unit as the hemp THC threshold (e.g. +/- 0.05)

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Operational Changes Introduced in the Final Rule

Hemp testing labs must use validated test methods

Labs should have appropriate quality assurance protocols in place

The USDA encourages hemp testing labs to be ISO/IEC 17025 accredited

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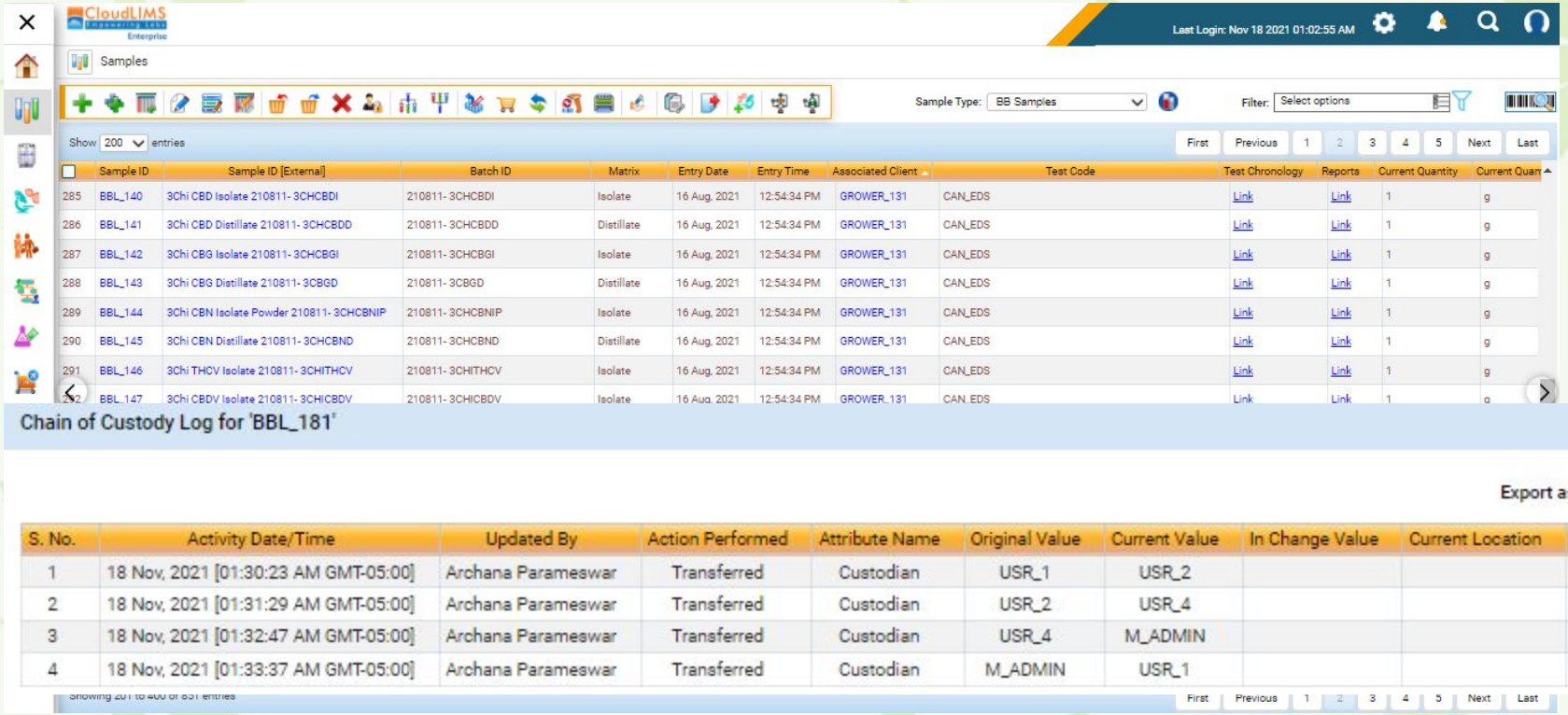
Manage Samples Through Their Lifecycle

Manage samples and maintain a chain of custody of all samples for complete traceability



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Reporting of Total THC

- THC must be reported as total THC.
- This means “total THC on a dry weight basis”.
- This means the total of delta-9 tetrahydrocannabinolic acid (THCA) and THC.

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Configure Formula Expressions

Configure formula expressions for calculation of total THC

View Existing Dependencies

32	Mapped Value & Replica	CBG~Result % From File	CBG~Result %	
33	Formula Expression		Total Cannabinoids~Result %	CBDVA~Result %+CBDV~Result %+CBDA~Result %+CBGA~Result %+CBG~Result %+CBD~Result %+THCV~Result %+THCVA~Result %+CBN~Result %+CBNA~Result %+D9-THC~Re
34	Formula Expression		Total CBG~Result %	CBGA~Result %*0.877+CBG~Result %
35	Formula Expression		CBGA~Result (mg/g)	CBGA~Result %*10
36	Formula Expression		CBL~Result (mg/g)	CBL~Result %*10
37	Formula Expression		CBN~Result (mg/g)	CBN~Result %*10
38	Formula Expression		CBNA~Result (mg/g)	CBNA~Result %*10
39	Formula Expression		D8-THC~Result (mg/g)	D8-THC~Result %*10
40	Formula Expression		CBC~Result (mg/g)	CBC~Result %*10
41	Formula Expression		Total THC~Result %	THCA~Result %*0.877+D9-THC~Result %
42	Formula Expression		D9-THC~Result (mg/g)	D9-THC~Result %*10
43	Formula Expression		THCA~Result (mg/g)	THCA~Result %*10
44	Formula Expression		THCV~Result (mg/g)	THCV~Result %*10
45	Formula Expression		THCVA~Result (mg/g)	THCVA~Result %*10
46	Formula Expression & Replica	THCA~Result %	Total THC~Result %	
47	Replica	Total THC~Result %	Total THC~Flag Based on this column	
48	Formula Expression & Replica	CBDA~Result %	Total CBD~Result %	
49	Formula Expression & Replica	CBDVA~Result %	Total Cannabinoids~Result %	
50	Formula Expression & Replica	CBGA~Result %	Total CBG~Result %	
51	Formula Expression		CBCA~Result (mg/g)	CBCA~Result %*10
52	Formula Expression		Total CBD~Result %	CBDA~Result %*0.877+CBD~Result %
53	Formula Expression		CBD~Result (mg/g)	CBD~Result %*10
54	Formula Expression		CBDA~Result (mg/g)	CBDA~Result %*10
55	Formula Expression		CBDV~Result (mg/g)	CBDV~Result %*10
56	Formula Expression		CBDVA~Result (mg/g)	CBDVA~Result %*10
57	Formula Expression		CBG~Result (mg/g)	CBG~Result %*10
58	Formula Expression & Replica	CBGA~Result %	CBGA~Result (mg/g)	
59	Formula Expression		Total Cannabinoids~Result (mg/g)	CBDVA~Result (mg/g)+CBDV~Result (mg/g)+CBDA~Result (mg/g)+CBGA~Result (mg/g)+CBG~Result (mg/g)+CBD~Result (mg/g)+THCV~Result (mg/g)+THCVA~Result (mg/g)+CB
60	Formula Expression		Total CBG~Result (mg/g)	CBGA~Result (mg/g)*0.877+CBG~Result (mg/g)
61	Formula Expression & Replica	CBL~Result %	CBL~Result (mg/g)	
62	Formula Expression & Replica	CBN~Result %	CBN~Result (mg/g)	

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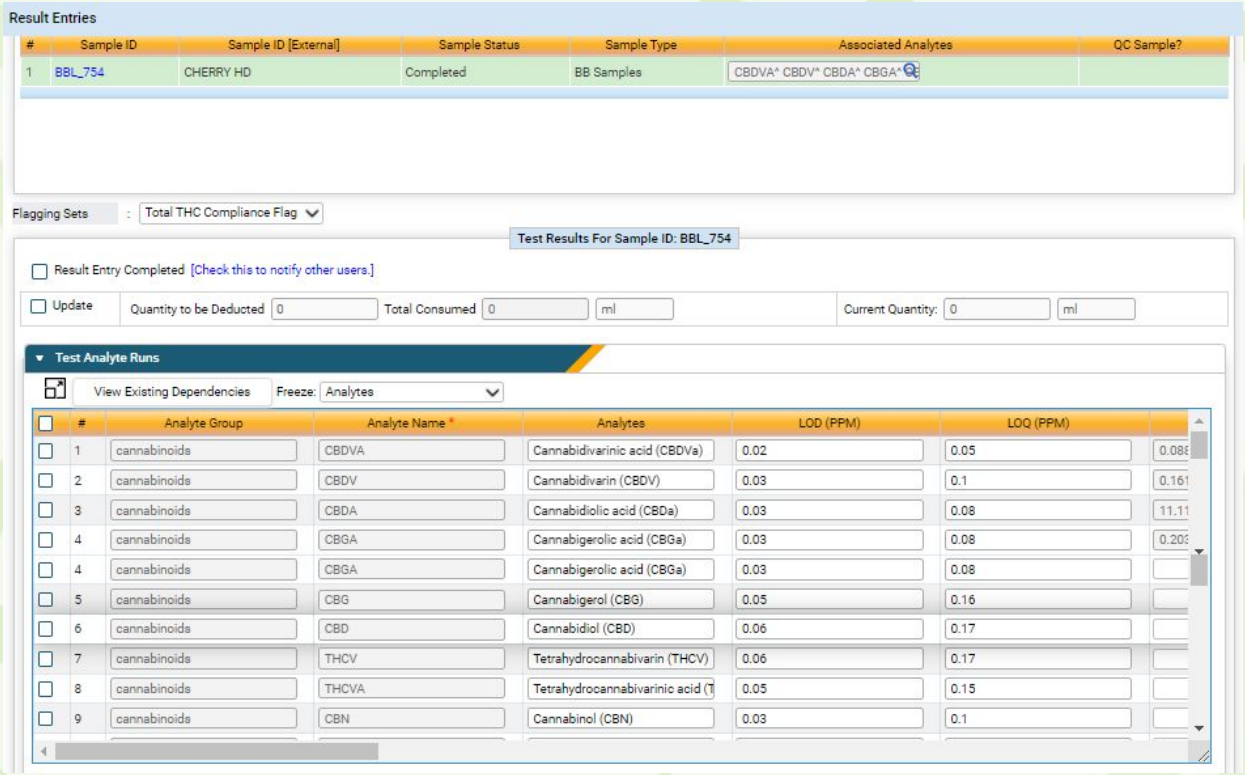
Manage Test Results

Manage multi-analyte test results using a LIMS



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Flag Out-of-Specification Results

Flag hemp that tests more than 0.3% THC

#	Analytes	LOD (PPM)	LOQ (PPM)	Result %	Result (mg/g)	Flag	Minimum	Maximum
1	Cannabidivarinic acid (CBDVa)	0.02	0.05	0.0887	0.89			
2	Cannabidivarin (CBDV)	0.03	0.1	0.161	1.61			
3	Cannabidiolic acid (CBDa)	0.03	0.08	11.1199	111.2			
4	Cannabigerolic acid (CBGa)	0.03	0.08	0.2036	2.04			
5	Cannabigerol (CBG)	0.05	0.16	0.0533	0.53			
6	Cannabidiol (CBD)	0.06	0.17	1.2897	12.9			
7	Tetrahydrocannabivarin (THCV)	0.06	0.17	ND	ND			
8	Tetrahydrocannabivarinic acid (T	0.05	0.15	ND	ND			
9	Cannabinol (CBN)	0.03	0.1	ND	ND			
10	Cannabinolic acid (CBNa)	0.08	0.26	<LoQ	<LoQ			
11	D9-Tetrahydrocannabinol (D9-TH	0.12	0.36	0.1405	1.4			
12	D8-Tetrahydrocannabinol (D8-TH	0.15	0.45	ND	ND			
13	Cannabicyclol (CBL)	0.13	0.38	<LoQ	<LoQ			
14	D9-Tetrahydrocannabinolic acid	0.09	0.28	0.4017	4.02			
15	Cannabichromene (CBC)	0.06	0.19	0.1532	1.53			
16	Cannabichromenic acid (CBCa)	0.22	0.67	0.6013	6.01			
17	Total THC (THCa * 0.877 + THC)			0.49	4.93	Compliance Fail		0.3
18	Total CBD (CBDa * 0.877 + CBD)			11.04	110.42			
19	Total CBG (CBGa * 0.877 + CBG)			0.23	2.32			
20	Total Cannabinoids			14.21	142.13			

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Manage QC Samples & Their Test Results

Manage quality control samples and monitor their results to detect anomalies

- Blanks
- Spikes
- Duplicate

Result Entries

Flagging Sets :

Test Results For Sample ID: QC_Sample_1

Result Entry Completed [Check this to notify other users.]

Update Quantity to be Deducted 0 Total Consumed 0 ml Current Quantity: 0 ml

Test Analyte Runs

Test Runs: QC Sample Analyte Template QC_Hemp Freeze: Analyte Name

#	Analyte Group	Analyte Name *	Analytes	LOD (PPM)	LOQ (PPM)	F
1	cannabinoids	CBDVA	Cannabidivarinic acid (CBDVa)	0.02	0.05	144
2	cannabinoids	CBDV	Cannabidivarin (CBDV)	0.03	0.1	
3	cannabinoids	CBDA	Cannabidiolic acid (CBDa)	0.03	0.08	
4	cannabinoids	CBGA	Cannabigerolic acid (CBGa)	0.03	0.08	
5	cannabinoids	CBG	Cannabigerol (CBG)	0.05	0.16	
6	cannabinoids	CBD	Cannabidiol (CBD)	0.06	0.17	
7	cannabinoids	THCV	Tetrahydrocannabivarin (THCV)	0.06	0.17	
8	cannabinoids	THCVA	Tetrahydrocannabivarinic acid (T	0.05	0.15	
9	cannabinoids	CBN	Cannabinol (CBN)	0.03	0.1	

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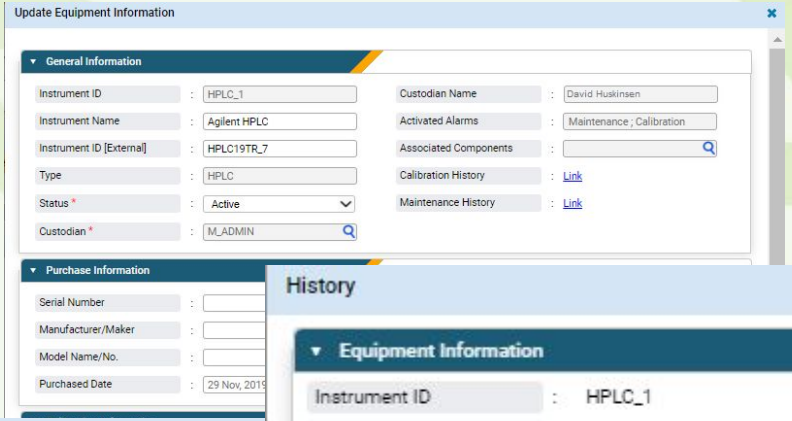
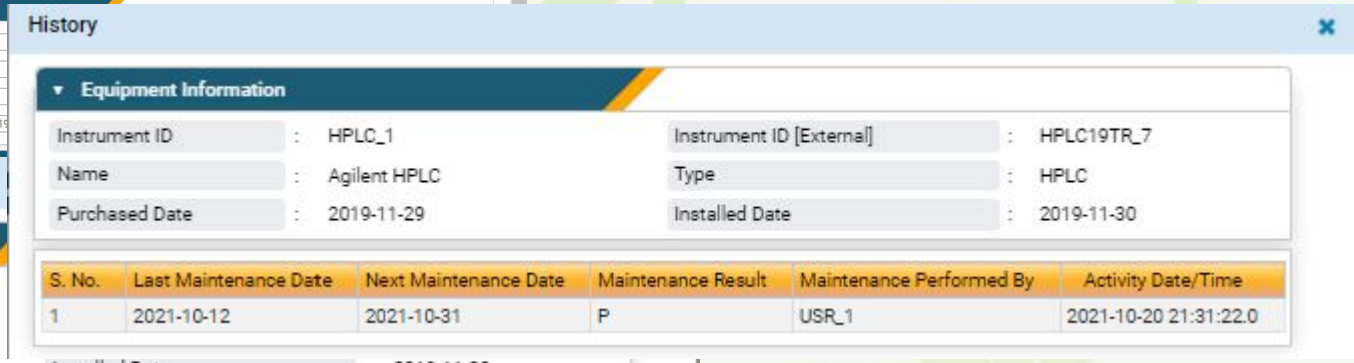
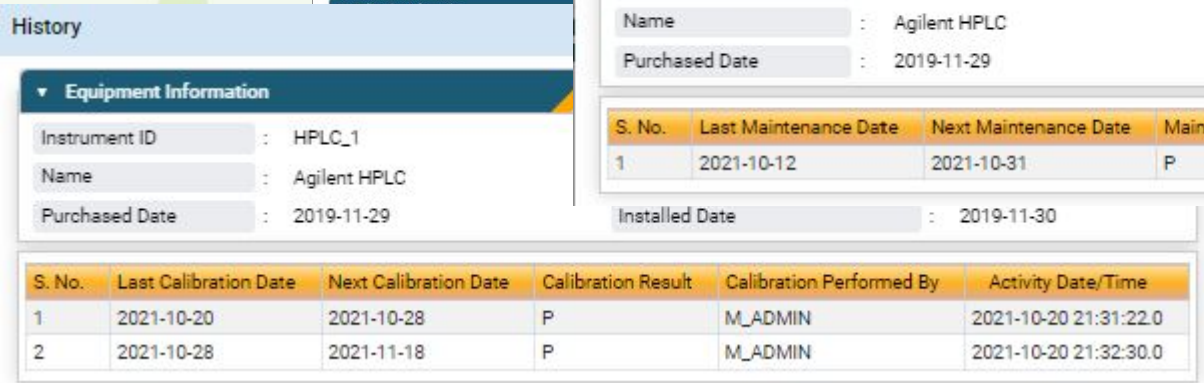
Instrument: Calibration and Maintenance

Schedule instrument calibration, manage maintenance data & assign instrument handling to staff based on their competency







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Personnel: Staff Training & Competency

	Training ID	Title	Type	Venue	Trainer	Custodian	Associated User/Staff	View Competency	Training Start Date	Training End Date	Tr
1	TRNG_4	Staff Safety	Demo	Lab A	James Smith	M_ADMIN	M_ADMIN , USR_1 , USR_2	Link	01 Feb, 2022	04 Feb, 2022	Con
2	TRNG_3	Waste Management	Demo	Meeting Hall	William Smith	M_ADMIN	USR_1 , USR_2 , USR_3	Link	08 Feb, 2021	12 Feb, 2021	Con
3	TRNG_2	Equipment Calibration & Handling	Demo	Training Hall	Kerry Jones	M_ADMIN	USR_1 , USR_2	Link	01 Apr, 2022	05 Apr, 2022	Con

	A	B	C	D	E	F	G
1		M_ADMIN	Aaron Townsend	John Smith	Adam Lallana	Joe Gomez	John Smith
2	Staff Safety	5	4	0	3	4	1
3	Equipment Calibration	0	0	0	0	0	0
4	Waste Management	4	4	0	3		

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DEA Registration

- All hemp testing must be performed by labs that are registered with the DEA.
- However, labs were given up to December 31, 2022, to comply with this requirement.

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Sharing of Test Results

Labs performing THC testing for compliance purposes must share test results with the following:

Licensed Producer

Appropriate State Department of Agriculture or Tribe

The USDA

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Generate Custom CoAs

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ABC LABS

ABC Labs Certificate of Analysis

675 Valley View Ln, Dallas, TX 75234, United States | License: TL5220015

ISO/IEC 17025:2017 Certification L65-20-5 | Accreditation #

Sample 210621_2

Compliance Fail

Sample ID:	BBL_170	**Matrix:**	Tinctures	**Cultivar:**	ABC
Company:	Rps2	**Registration#:**		**Email:**	johan@cannabistech.com
Phone:	9187915521	**Sampler:**	Smith	**Sampled:**	12:30
Receiver:	Smith	**Received:**	21 Jun, 2021	**Reported:**	23 Jul, 2021
Address:	Address	**GPS:**	23:23	**Acreage:**	ARC
Description:	DES	**Lot Crop Permit ID:**		**Analyses Executed:**	NOTHC

Lab Notes:

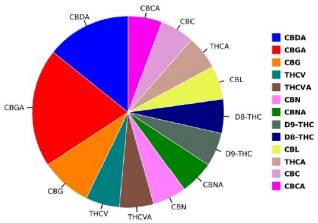
*NOTHC - Cannabinoid Profile Analysis

Analyzed 22 Jul, 2021 | Instrument HPLC-DAD | Method
Measurement Uncertainty at 95% confidence 10.0%

Analyte	LOD	LOQ	Result %	Result mg/g
Cannabidivarinic acid (CBDVa)	0.020	0.050	ND	ND
Cannabidivarin (CBDV)	0.030	0.100	NR	NR
Cannabidiolic acid (CBDa)	0.030	0.080	5	50.0
Cannabigerolic acid (CBGa)	0.030	0.080	7	70.0
Cannabigerol (CBG)	0.050	0.160	3	30.0
Cannabidiol (CBD)	0.060	0.170	>=99%	>=99%
Tetrahydrocannabivarin (THCV)	0.060	0.170	2	20.0
Tetrahydrocannabivarinic acid (THCVa)	0.050	0.150	2	20.0
Cannabinol (CBN)	0.030	0.100	2	20.0
Cannabinolic acid (CBNa)	0.080	0.260	2	20.0
D9-Tetrahydrocannabinol (D9-THC)	0.120	0.360	2	20.0
D8-Tetrahydrocannabinol (D8-THC)	0.150	0.450	2	20.0
Cannabicyclol (CBL)	0.130	0.380	2	20.0
D9-Tetrahydrocannabinolic acid (THCa)	0.090	0.280	2	20.0
Cannabichromene (CBC)	0.060	0.190	2	20.0
Cannabichromenic acid (CBCa)	0.220	0.670	2	20.0
Total THC			3.754	37.54
Total CBD			4.385	43.85
Total CBG			9.139	91.39
Total Cannabinoids			35.0	350.0

*Dry Weight

Sample Photography



ND Not Detected
N/A Not Applicable
NT Not Reported
LOD Limit of Detection
LOQ Limit of Quantification
<LOQ Detected
>ULOL Above upper limit of linearity
CFU/g Colony Forming Units per 1 gram
TNTC Too Numerous to Count

Accreditation #

Authorized Signature

Jack Spencer, PhD
Senior Technician
25 Jul, 2021 02:05:15 PM

"This report shall not be reproduced except in full, without the written approval of the lab. "This report is for informational purposes only and should not be used to diagnose, treat or prevent any disease. Results are only for samples and batches indicated. Results are reported on an "as received" basis, unless indicated otherwise. All required LQC (Laboratory Quality Control) samples were included in the performance of these analyses and met the acceptance criteria for ISO/IEC Regulations.

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Sharing of Test Results

Appropriate State Department of Agriculture or Tribe

Test Results

The USDA

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Other Significant Changes to Hemp Testing

- The samples must be homogenous.

- A lab should have an internal SOP for testing and retesting hemp.

- Testing protocols should specify a disposal procedure for hot hemp.

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How to Choose the Right LIMS for Your Lab

Here's a Checklist of Essential Functionality:

- ✓ Integrate with the reporting system of USDA & state department of agriculture
- ✓ Streamline and automate QA/QC processes
- ✓ Generate custom Certificates of Analysis (CoA)
- ✓ Manage staff training and their competency
- ✓ Manage documents, SOPs, and track their version history
- ✓ Schedule instrument calibration & manage maintenance data
- ✓ Maintain a chain of custody of all samples through their lifecycle

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Benefits of Deploying a Hemp LIMS

TEST RESULT ACCURACY

PRODUCTIVITY

QUALITY

LOWER COSTS

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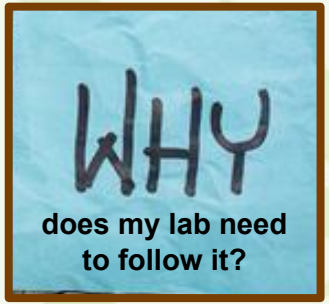
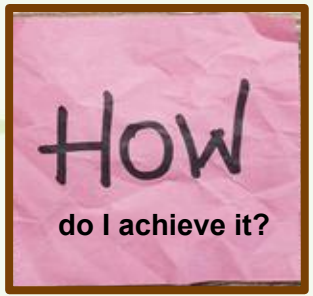
In Conclusion...

Important Federal Rules



Legally Required



Deploy a LIMS

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Thank You For Your Attention!

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