Setting Up a Cannabis Testing Lab? - Achieve ISO 17025 Accreditation Using a LIMS

Arun Apte
CEO, CloudLIMS.com

CANNABIS
SCIENCE
CONFERENCE

CloudLIMS
Empowering Labs

AGENDA

ISO/IEC 17025 serves as a pillar to any global cannabis testing laboratory to boost its market competency and credibility - a market expected to reach $1.8B by 2025.

Source: MarketsandMarkets Report

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So, let’s explore the challenges of the ISO 17025 accreditation!

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ISO 17025 Accreditation & Its Importance

It is the most important standard for calibration and testing labs across the globe.

It demonstrates that a lab meets global standards and has passed a rigorous examination of quality, methods, facilities, and staff.

ISO 17025:2017

It assures that a testing laboratory is capable of producing accurate, traceable, and reproducible data.

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What's New in ISO/IEC 17025:2017

Wondering why ISO 17025 accreditation is so important?

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Why ISO/IEC 17025 Accreditation?

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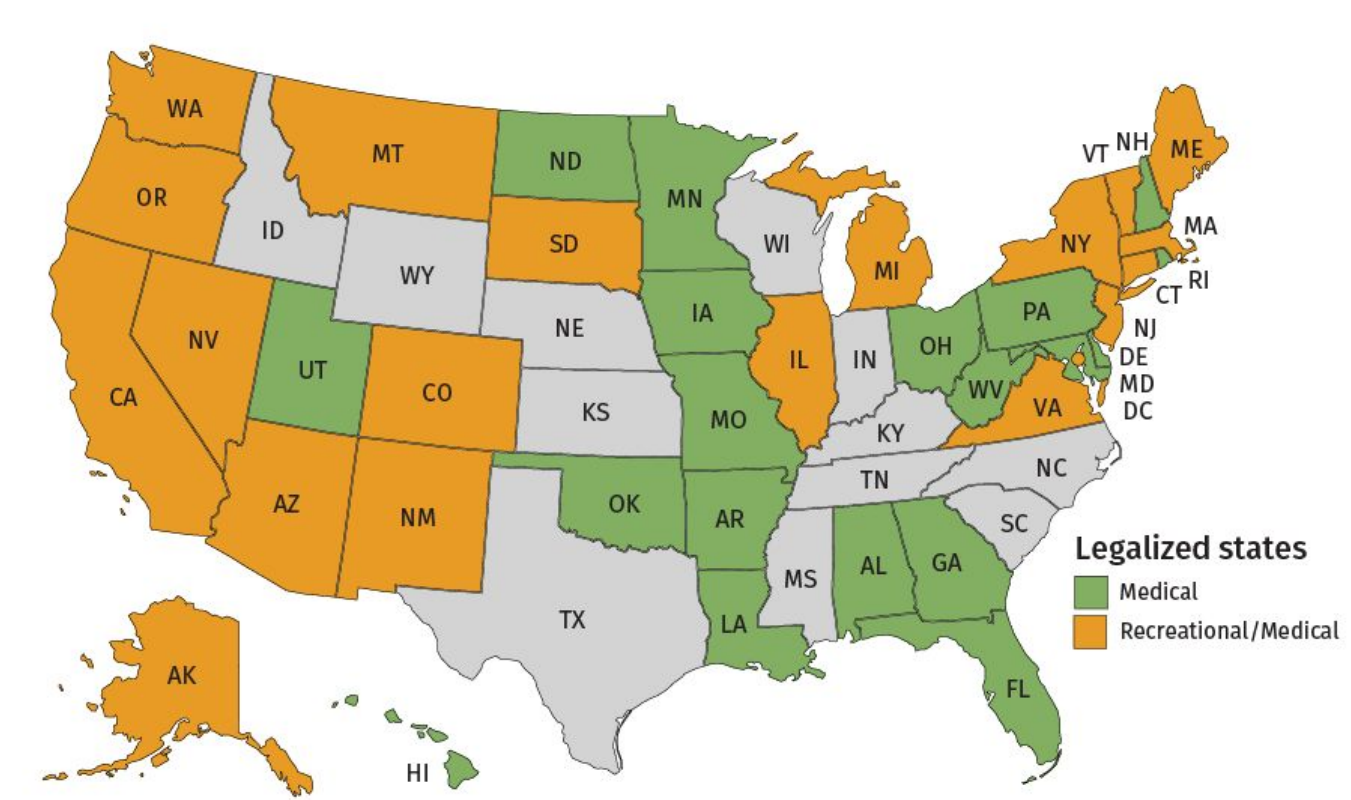
Why? Legally Required in Many States



Source: MJBizDaily research

Note: Does not include states that have legalized only CBD-based oils.

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Why? Lab Credibility to Manufacturers

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Why? Increases Defensibility

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Why? Lower Operational Cost

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So, let’s walk through the process of achieving ISO 17025 accreditation for your lab!

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How? ISO/IEC 17025 General Requirements

- Testing activities are conducted impartially and confidentially.
- Laboratory must securely manage data to prevent unauthorized access.

Confidentiality of Information

✔ Clause 4.2

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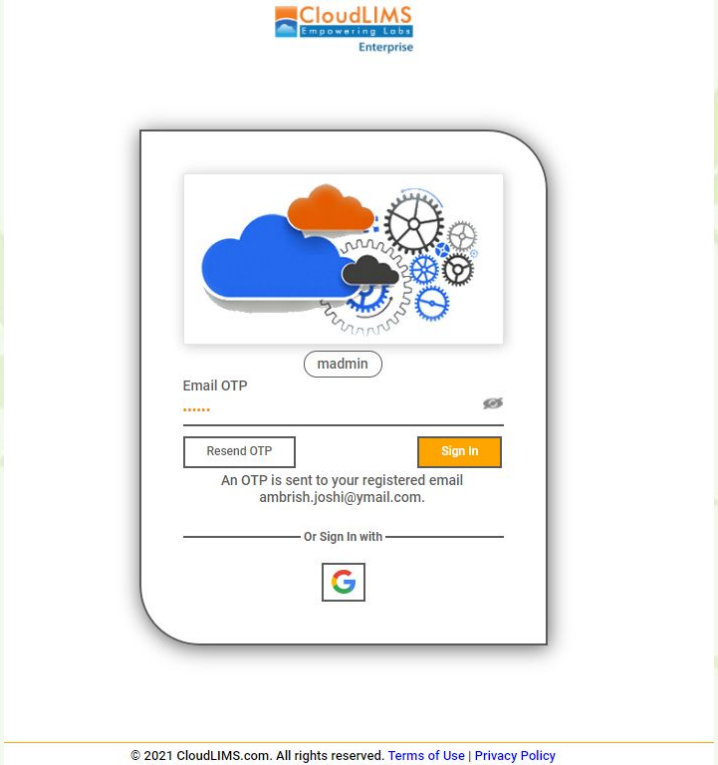
Two-Factor Authentication for Secure Data Access

Enable users to leverage two-factor authentication mechanism (OTP and password-based login) for secure data access



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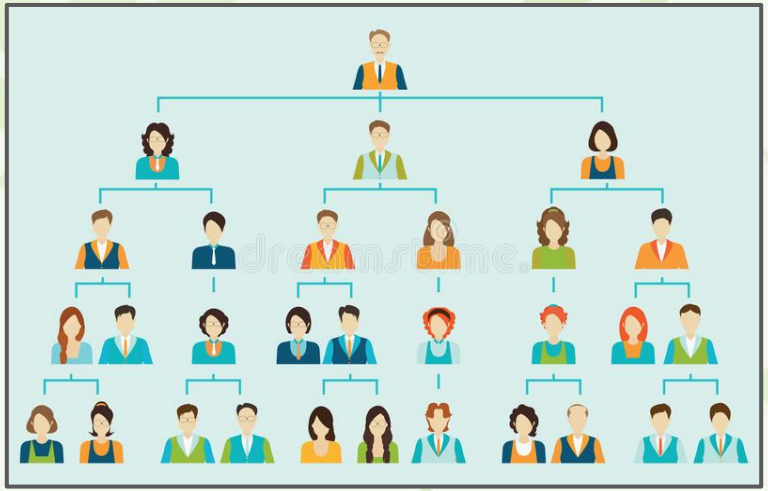
How? ISO/IEC 17025 Structural Requirements

Cannabis testing laboratories should define their management structure and document all activities for which it claims conformity to the standard. Additionally, laboratories should clearly define the responsibility, authority and interrelationship of all staff.

Organizational Structure

✔ Clause 5.5



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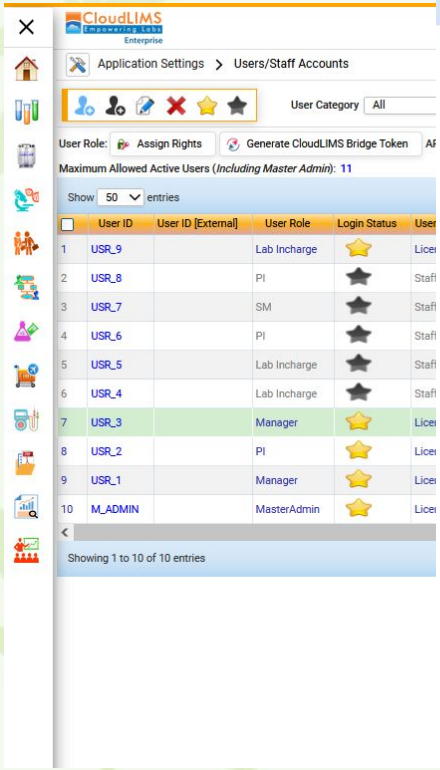
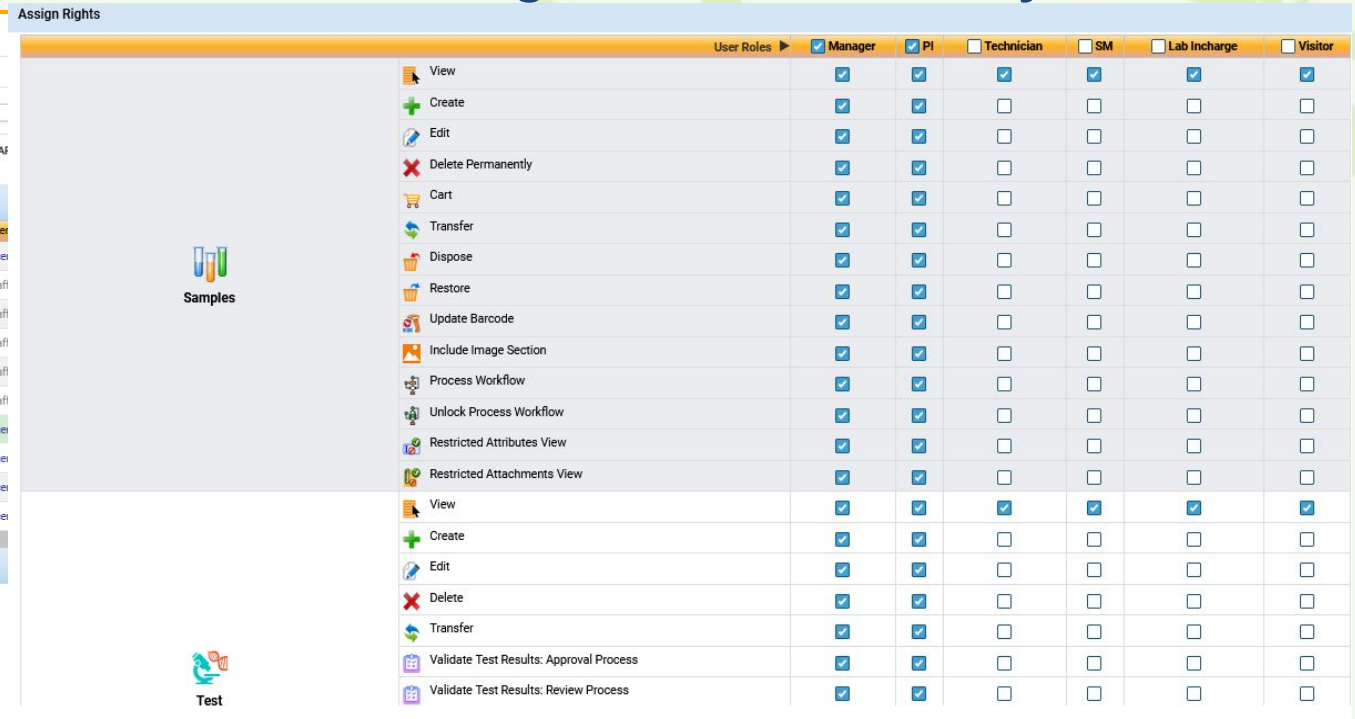
Organizational Structure: Role-based Permission to Staff

Lab Personnel can be granted/revoked access to/from various activities based on their role in an organization's hierarchy





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How? ISO/IEC 17025 Resource Requirements

The resource requirements emphasize the importance of resources such as the personnel, facilities and environmental conditions, equipment, and externally provided products and services used to support the operation of a laboratory.

Personnel

✔ **Clause 6.2**

Equipment

✔ **Clause 6.4**

Externally provided products & services

✔ **Clause 6.6**

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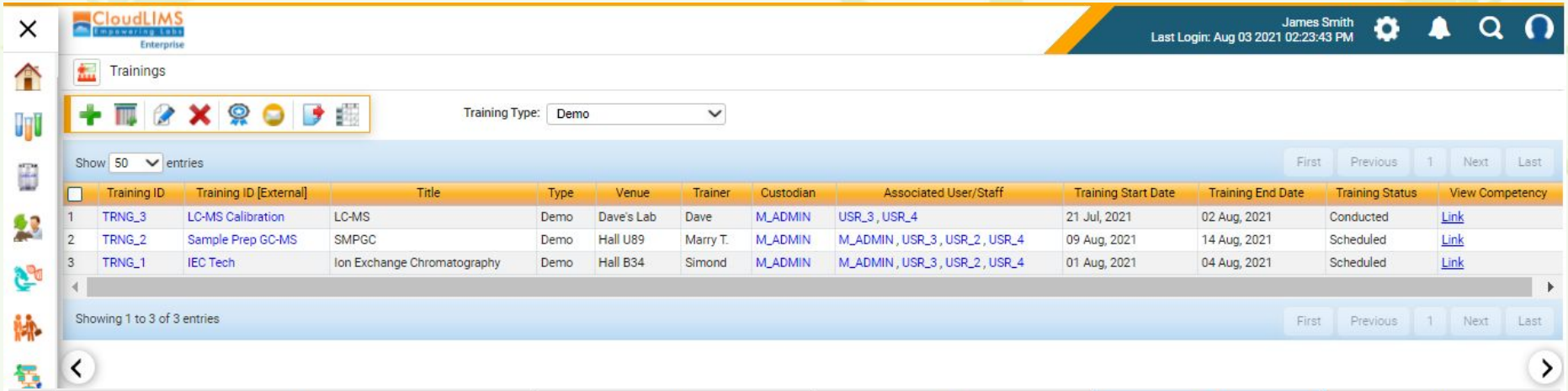
Personnel: Staff Training

Manage staff training & generate training competency matrix



	A	B	C	D	E
1	**Trainings**	**James Smith**	**William Smith**	**Kerry Jones**	**Adam Paul**
2	Ion Exchange Chromatography	4	5	3	5
3	Sample Prep GC-MS	3	4	2	3
4	LC-MS Calibration	2	4	4	2

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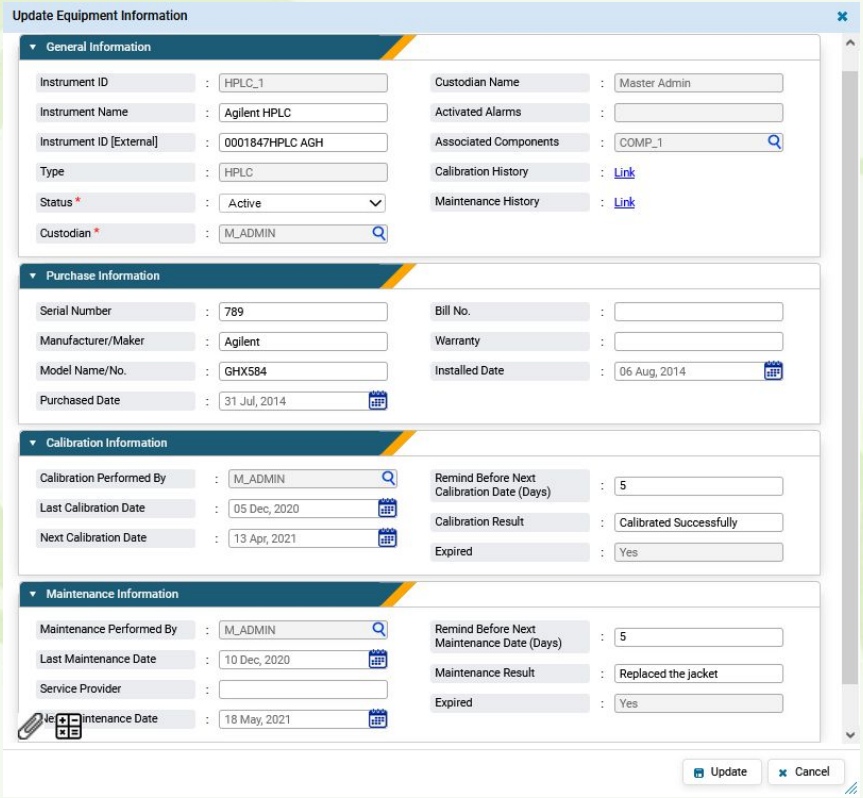
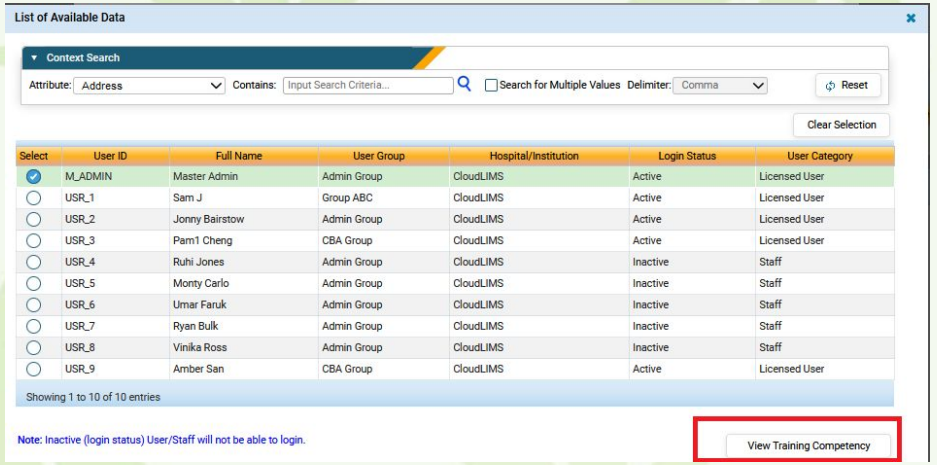
Equipment: Calibration and Maintenance

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





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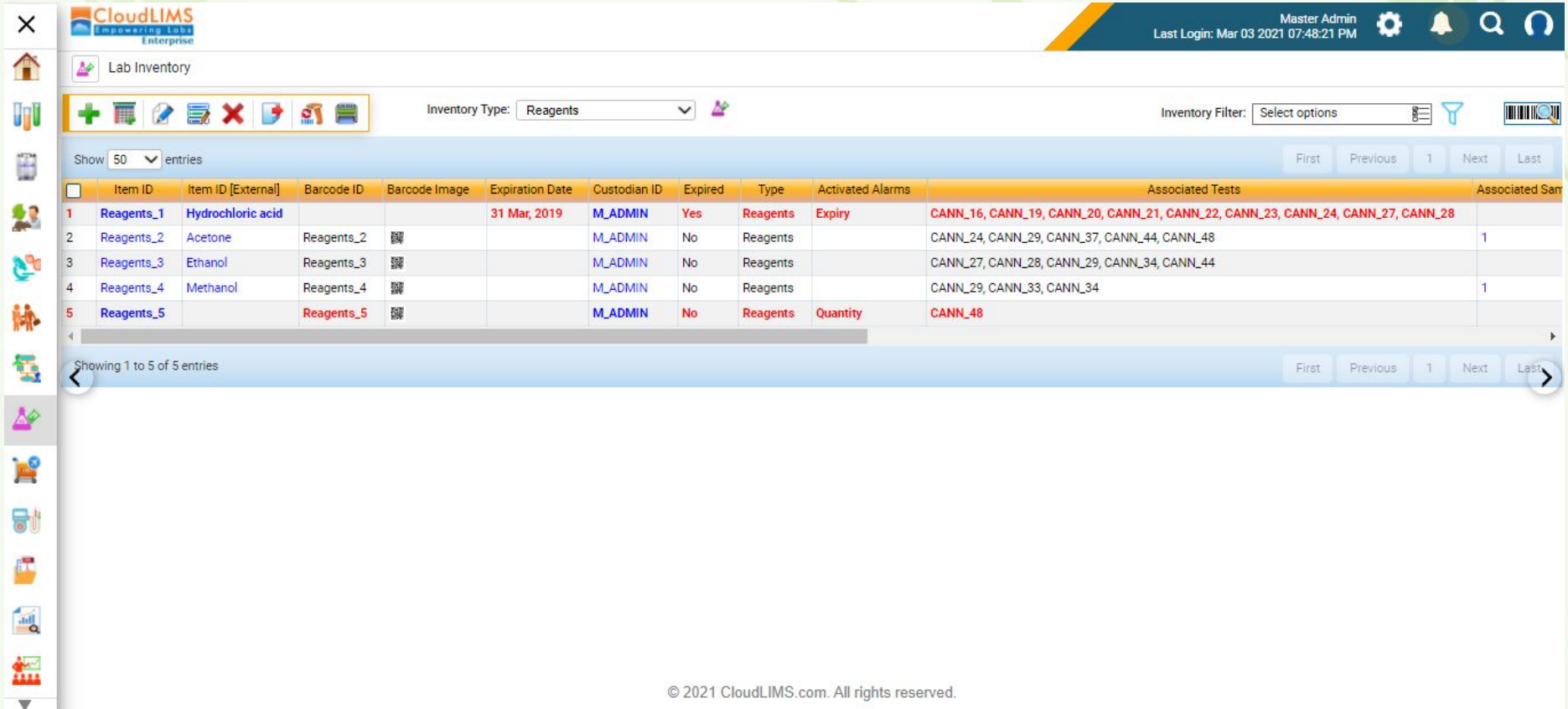
Externally Provided Products & Services

Accurate barcode labeling of reagents and maintaining their stocks



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How? ISO/IEC 17025 Process Requirements

Review of Requests, Tenders, & Contracts

✔ Clause 7.1

Validation of Methods

✔ Clause 7.2.2

Accurate Reporting of Results

✔ Clause 7.8

Manage QC Samples & Their Results

✔ Clause 7.7.1

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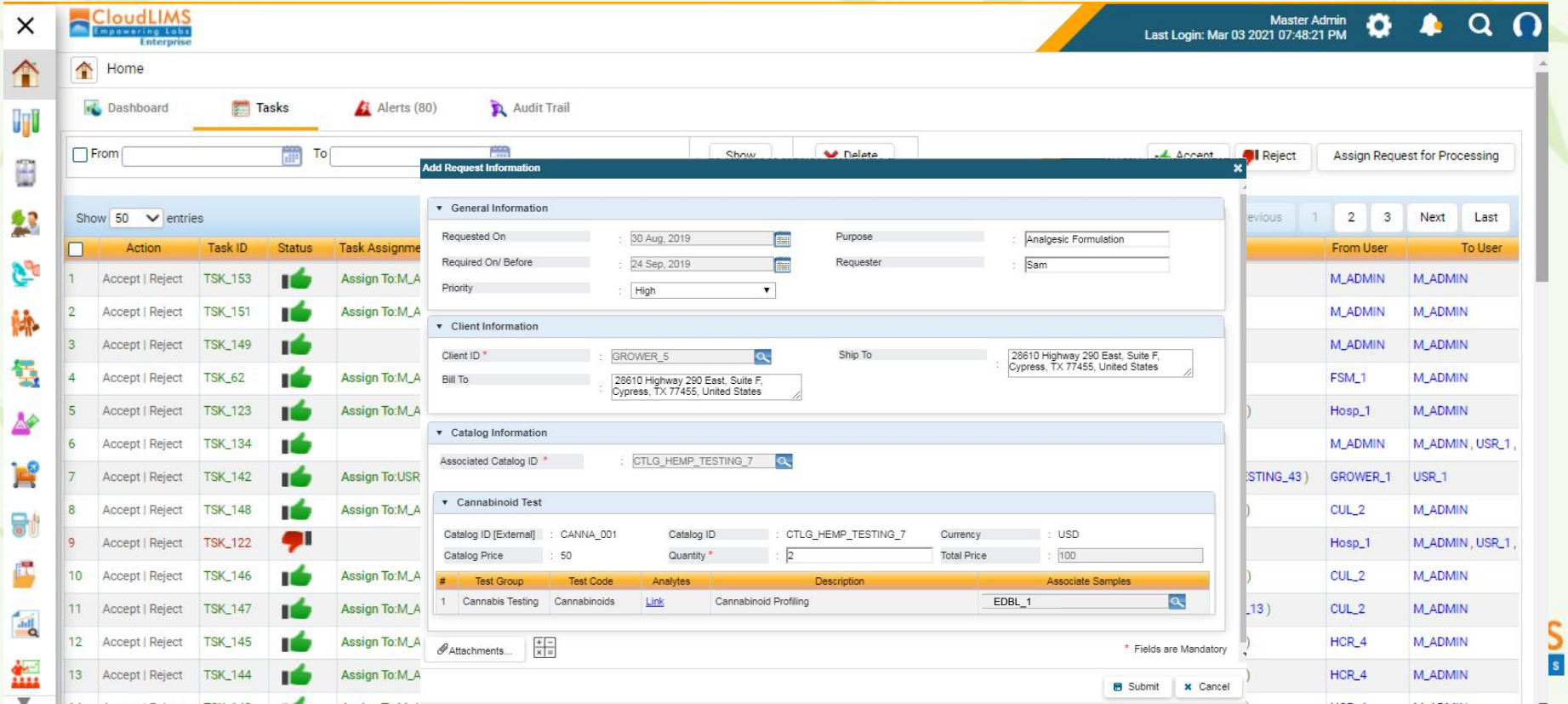
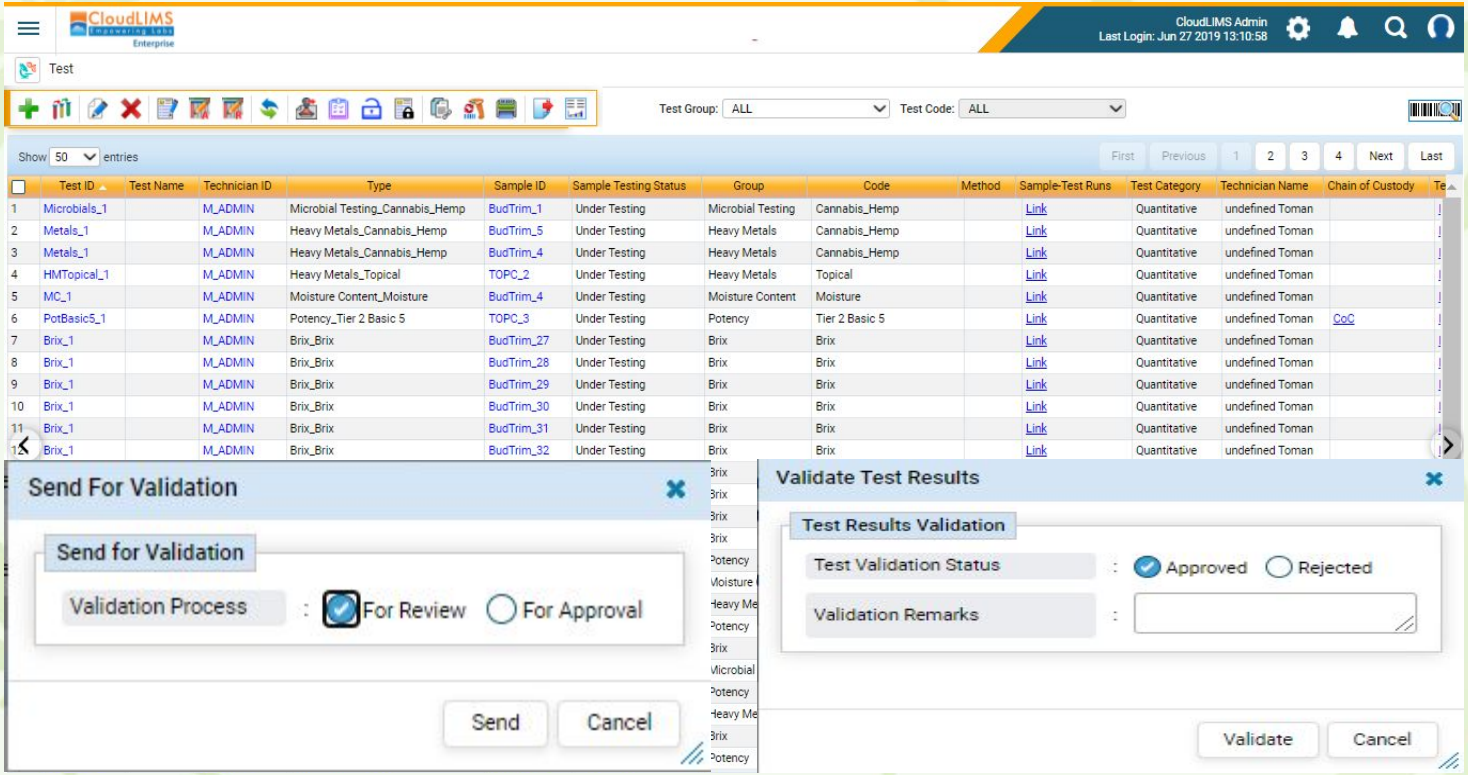
Review of Requests

The lab manager can view analytical tests requested by clients and can accept, reject and assign tasks to staff pertaining to the service requests



Validate Test Results

Manage multiple tests, send multiple results for validation, track the validation status, thereby assuring the validity of final test results



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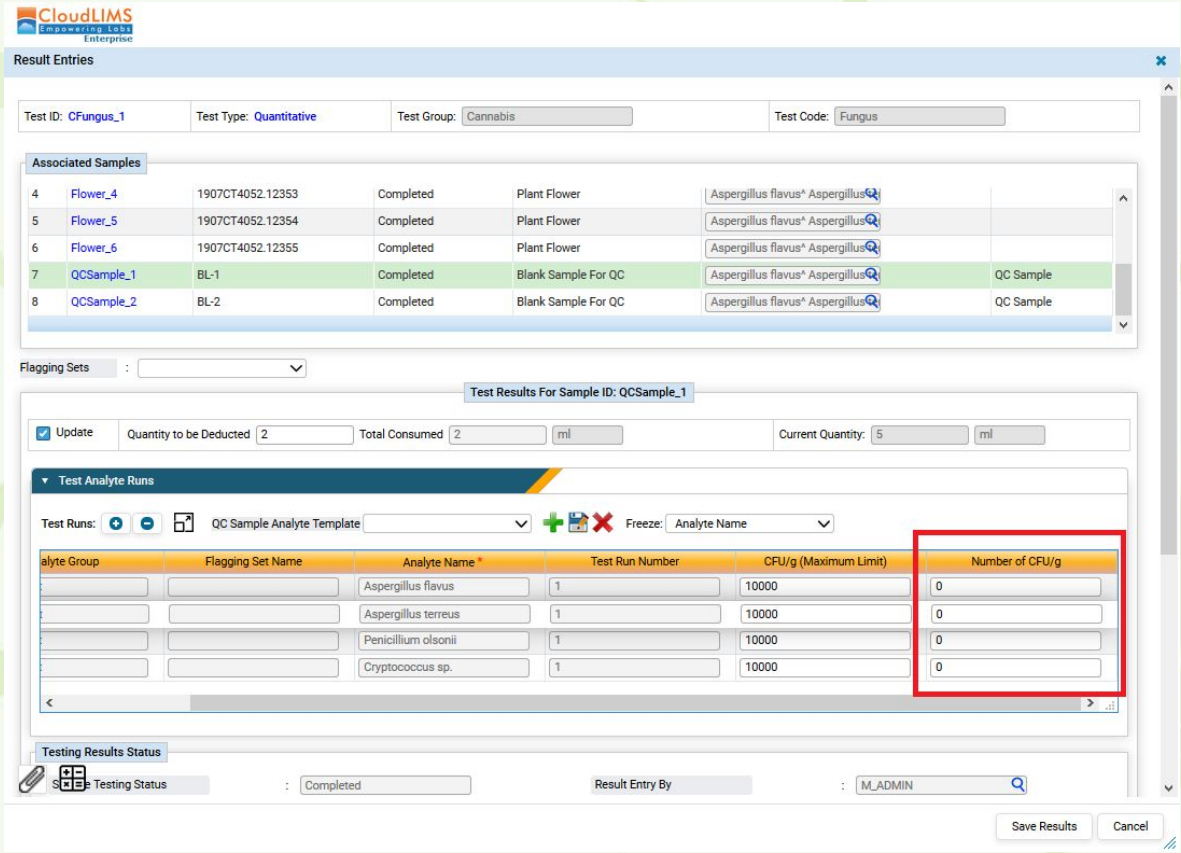
Manage QC Samples & Their Test Results

Manage quality control samples and monitor their results to detect anomalies



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Generate Custom CoAs

California Compliant CoA

ABCL_170 page 1 of 1

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:

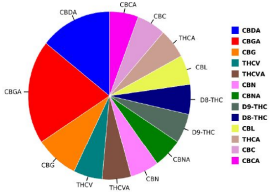
*NOTHC - Cannabinoid Profile Analysis

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%	>=999%
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			4.386	43.86
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
>LOL 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

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Maryland Compliant CoA

CBD Canna Labs

Office: 802-908-8142 | Fax: 802-908-8142
18 HERCULES DR, COLCHESTER, VT 05446

Certificate of Analysis

Company:	RPS2 213 Interstate Dr, Somersworth, NH 03878	**Sample ID:**	FLD_001	**Report Date:**	2021-09-02
		Lot:	A	**Date Analysed:**	2021-08-26
Customer ID:	C10054	**Matrix:**	Flower Dry	**Analyst:**	Henry Barone
Grower License#:	NA	**Date Sampled:**	2021-08-26	**Report ID:**	
		Date Received:	2021-08-26		

Cannabinoid Summary

Cannabinoid Profile	LOQ (mg/g)	Concentration (mg/g)	Weight (%)	Flag
CBDVA	0.000	<LOQ	<LOQ	
CBDV	0.001	<LOQ	<LOQ	
CBDA	0.001	0.0020	0.0002	
CBGA	0.001	<LOQ	<LOQ	
CBG	0.002	<LOQ	<LOQ	
CBD	0.002	0.0003	0.00003	<LoQ
THCV	0.002	0.0020	0.0002	<LoQ
CBN	0.001	<LOQ	<LOQ	
D9 THC	0.002	0.0003	0.00003	<LoQ
D8 THC	0.002	<LOQ	<LOQ	
THCA	0.003	0.0003	0.00003	<LoQ
CBC	0.002	<LOQ	<LOQ	
Total THC		0.0005631	0.00005631	
Total CBD		0.002054	0.0002054	
Total Cannabinoids		0.0049	0.00049	

0.0005631 Total THC	0.002054 Total CBD
0.00049 Total Cannabinoids	0.0003 D9-THC
0.19% Percent Moisture	3.65 : 1.00 THC : CBD Ratio

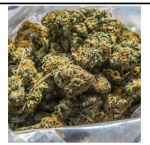
Cannabinoids Methodology: High Performance Liquid Chromatography(HPLC) using PerkinElmer FLEXAR™ with Photo Diode Array Detector (PDA).

Total CBD and total THC are calculated values, to account for assumed decarboxylation from the acid form (THCA or CBDA) to the neutral form, causing weight loss of the acid group.

These values are calculated as follows:

Total THC = (THCA x 0.877) + D9-THC
Ratio of Total CBD: Total THC
Total CBD = (CBDA x 0.877) + CBD
Reagent Blanks <LOQs for all analytes

LOQ = The lowest quantity that this method can reliably detect. Any cannabinoid that was not detected is assumed to be less than the stated LOQ (<LOQ).
All results reflect dry weight of material, based on % moisture of the sample.



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(802) 140-0148 laboratory@cbdcannalabs.com

Colorado Compliant CoA

Quality Testing Labs

1

Certificate Of Analysis

Potency

Client Information

First Name:	Elijah	**Last Name:**	Patch	**Email:**	qtl@gmail.com
Phone No. :	(303) 937-9484	**Address:**	7935 E US Hwy 50		
City:	Boone	**State:**	CO	**Zip**	81025

Sample Information

Sample ID:	CNEX_50	**Sample ID (External):**	CBN Isolate
Type:	Concentrates N Extracts	**RFID/METRC Tag:**	1A4000B000370DD000000168
Entry Date:	2021-08-25	**Incoming Package Notes:**	
Class:	Hemp	**Date Analyzed:**	2021-08-25 - 2021-08-26

Cannabinoid Profile: HPLC-PDA: Potency/ Tier 2 Basic 5

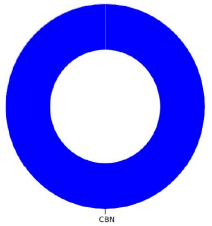
Analyte Name	Result (%)	Result (mg/g)
CBDa	0.000	
CBD	0.000	
CBN	100.000	
d9 THC	0.000	
THCa	0.000	
Other Cannabinoids	0.000	

Total THC	**0.000**	
Total CBD	**0.000**	

LOQ = 0.827

Note:
Formula for calculating Total THC and Total CBD are:
Total THC = (THCa x 0.877) + THC
Total CBD = (CBDa x 0.877) + CBD

Relative Cannabinoid Concentration



Other Information

Analysis Comment	Remark

Prepared by: Noah Toman
2021-08-26

Approved by: Oliver Griffin
2021-08-26 17:11:31.0

Report contains results for only those items submitted to the laboratory. Sampling not performed by Quality Testing Labs. Results applied to the samples as received. This report shall not be reproduced except in full without approval from Quality Testing Labs.

How? ISO/IEC 17025 Resource Requirements

Pertain to the operation and effectiveness of the quality management system within a laboratory

Control of Records

✔ **Clause 8.4**

Document Control

✔ **Clause 8.3**

Internal Audits

✔ **Clause 8.8**

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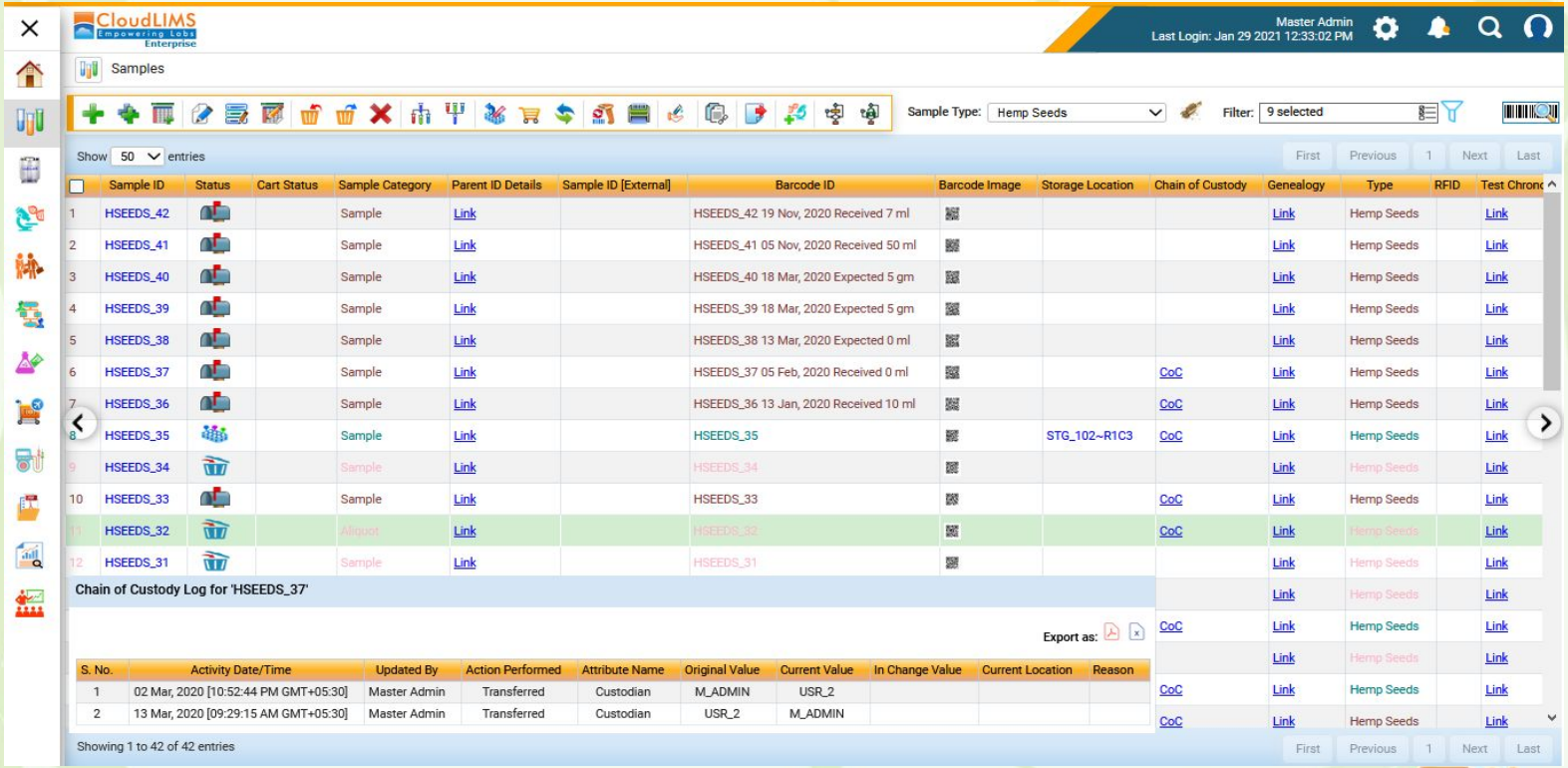
Control of Records: Maintain a Chain of Custody

Maintain a chain of custody of all samples throughout their lifecycle



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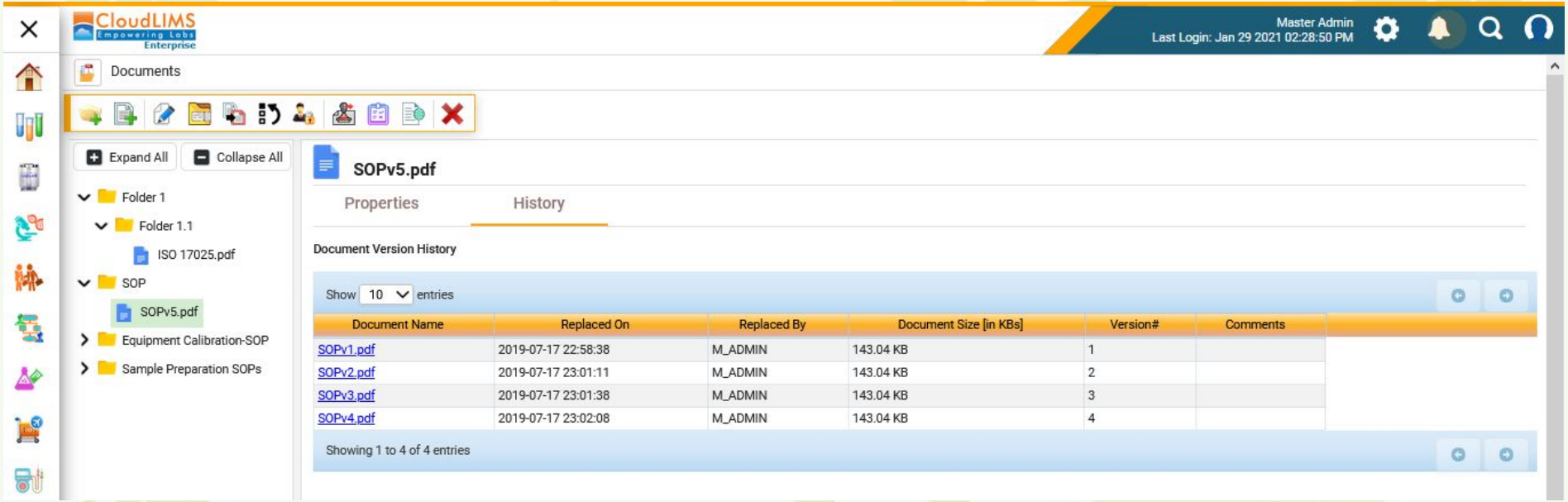
Document Control

Manage SOPs and confidential documents and provide access to all authorized users while tracking the full version history of the folders, subfolders and each document within them



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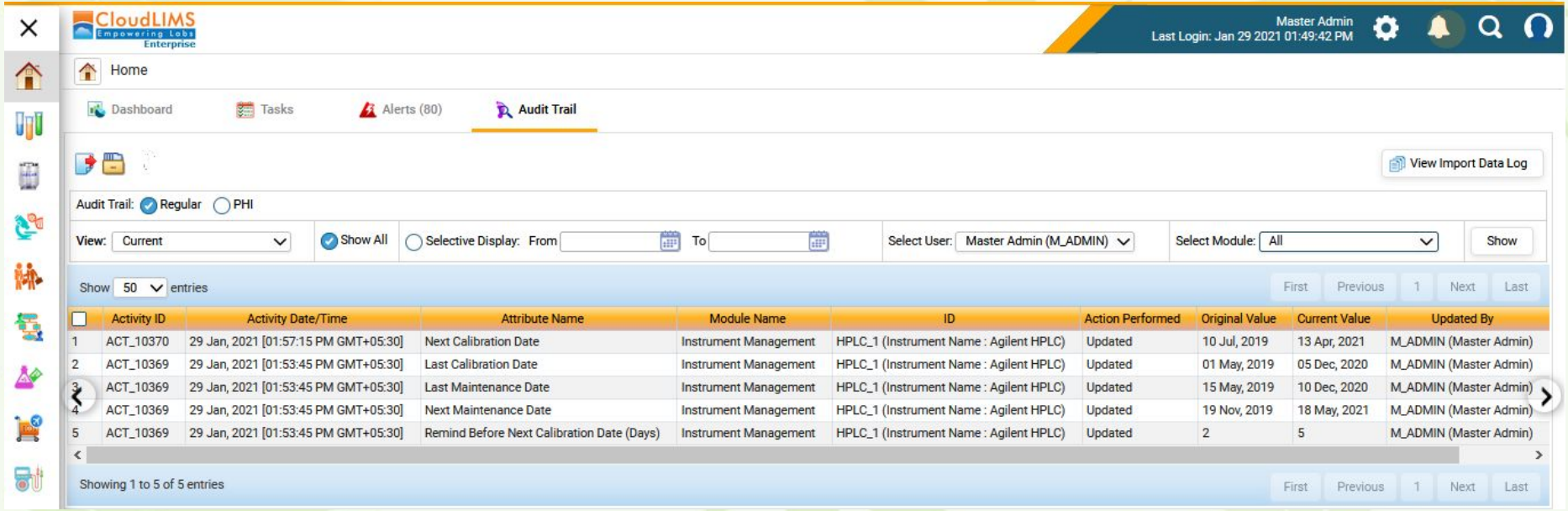
Internal Audits: Audit Trail

Maintain a read-only audit trail of each activity along with a date & time stamp



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Benefits of Deploying a Cannabis LIMS

TEST RESULT ACCURACY

PRODUCTIVITY

QUALITY

LOWER COSTS

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Action Plan To Get ISO 17025 Accredited

Plan, Document, Execute!

- Select an ISO 17025 compliant LIMS
- Select an accreditation body
- Apply for accreditation
- Get accredited
- Maintain Accreditation

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The Process: ISO/IEC 17025:2017 Accreditation

Some of the specific factors used to assess technical competency include:

- Quality assessments of equipment
- Procedures used for performing calibration and testing
- Proper sampling practices
- Traceability of measurements to national standards
- Accurate recording and reporting procedures
- Personnel qualifications
- Suitable testing facilities

Steps to Accreditation

File Application
▼
Receive Quote
▼
Enter Contract
▼
Prepare for Accreditation
▼
Document Review
▼
Preliminary Assessment (Optional)
▼
Opening Meeting (Entry Briefing)
▼
Accreditation Assessment
▼
Closing Meeting (Exit Briefing)
▼
Corrective Action
▼
Executive Committee's Decision
▼
Accreditation Certificate
▼
Surveillance Assessments

Life After Initial Accreditation

- Maintain accreditation
- Re-assessment and evaluation
- Participate in relevant proficiency testing programs between reassessments
  – To further demonstrate technical competence
- Audits
- Continuous improvement
- Scope expansion

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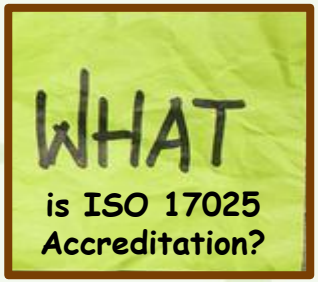
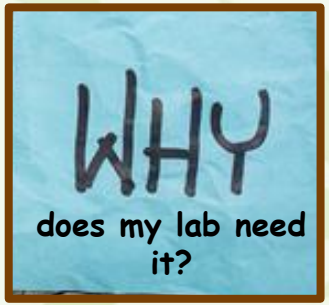
In Conclusion...



Most Important Regulatory Compliance



Legal, Credible, Competitive

Deploy a LIMS

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Thank You For Your Attention!

www.cloudlims.com
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support@cloudlims.com

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