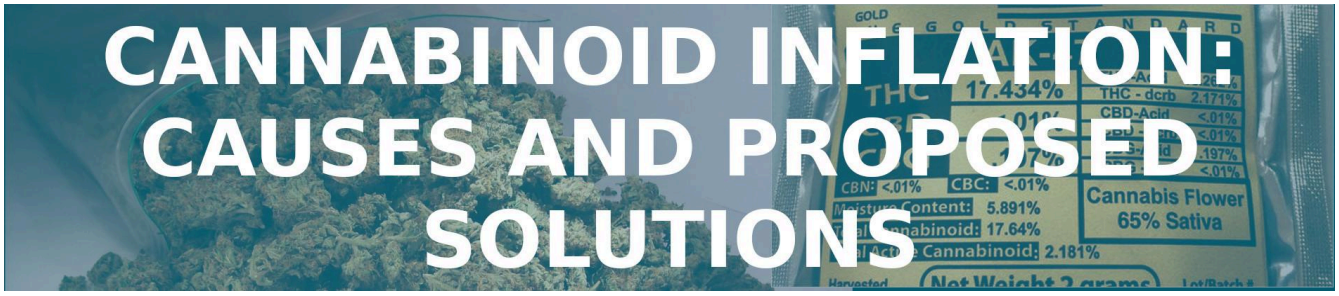

Abstract

The cannabis industry faces a pervasive challenge known as cannabinoid inflation, where testing laboratories provide inaccurately high cannabinoid concentrations to win business, threatening the existence of legitimate labs. Digamma Consulting, seasoned experts in cannabis chemistry, proposes practical, low-cost regulatory solutions to address this issue. Solutions include Suspect Product Checks, Chemical Analysis, Laboratory Audits, and Data Analysis Reports. These measures aim to ensure accurate testing standards, protect public safety, and enhance consumer confidence. This white paper outlines the urgency of resolving cannabinoid inflation for the development of a safe, fair, and thriving cannabis industry.

Introduction

The cannabis industry is at a pivotal juncture where manipulations of testing data threaten consumer safety, regulatory compliance, and market fairness. Amidst this landscape, Digamma Consulting, recognized as a seasoned and impartial expert in cannabis chemistry, endeavors to address a critical challenge plaguing the sector: cannabinoid inflation. This white paper serves as a comprehensive elucidation of the issue, coupled with solutions aimed at empowering government regulators to ensure transparency, impartiality, and legal defensibility in cannabis testing reporting and labeling.

Cannabinoid inflation, an unfortunately prevalent phenomenon, sees cannabis testing laboratories furnishing inaccurately high cannabinoid concentrations in a bid to secure business. This practice distorts market competition and poses a grave threat to legitimate testing facilities, which cannot compete with inflated results. As dispensaries gravitate

towards labs offering higher THC values, the industry witnesses a concerning trend of laboratory shopping, exacerbating the problem further.

For this white paper, Digamma Consulting draws from over twelve years of experience since establishing the nation's pioneer cannabis testing lab and through working with 48 labs in 16 states. Since 2011, Digamma has witnessed the escalation of the cannabinoid inflation issue across the United States. The repercussions extend beyond economic concerns, impinging upon public safety and consumer confidence. And the related issue of contamination deflation is equally concerning, as the same labs inflating cannabinoids may be under-reporting problems. Digamma advocates adherence to rigorous testing standards similar to those stipulated by the United States Environmental Protection Agency (USEPA), renowned for their stringency and legal defensibility, to counteract this alarming trend.

Cannabinoid inflation, left unchecked, not only jeopardizes the viability of conscientious labs but also poses a significant liability for medical patients reliant on accurate cannabinoid labeling for appropriate dosing. The imperative to address this challenge is underscored by its ramifications for developing a safe, fair, and thriving cannabis industry both domestically and internationally.

In response to this pressing issue, Digamma proffers three comprehensive solutions tailored for government regulators:

- **Solution A: Data Analysis Report:** Advocating for the adoption of data analysis reports, providing a firm basis for regulatory action.
- **Solution B: Suspect Product Checks (Secret Shopper):** Proposing a cost-effective mechanism for states to conduct sampling and testing of products at accredited reference laboratories to detect inflated cannabinoid values.
- **Solution C: Chemical Analysis Laboratory Audits:** Recommending audits by chemical analysis experts to regulate issues of cannabinoid inflation and ascertain the veracity of testing data.

Accompanying this white paper are appendices delving into the technical intricacies of cannabinoid inflation and Digamma's extensive experience in cannabis analysis. The ultimate goal of this endeavor is to bolster consumer safety and confidence, thereby fostering trust in cannabis and its regulatory framework. We invite further discussion and collaboration to address this critical issue and propel the cannabis industry toward a future characterized by integrity, transparency, and accountability.

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Solution A – Data Analysis Reports

Data analysis reports are a low-cost technique for state regulators to process existing data collected in their jurisdiction and to see patterns that indicate manipulation. The methodology is similar to what occurs on the final results reports for the Emerald PT Report, which shows the accuracy and precision of the participating labs for a given analysis.

Accuracy is typically shown against a known true value for a PT sample, but the same concept applies when Certified Reference Materials (CRM) are used for a round-robin style assessment of laboratory accuracy. It is generally shown as a percent recovery of the true value.

Precision is typically shown against the distribution of reported results for the same analyzed sample across participating labs. Through this method, the performance of laboratory precision is weighed relative to the group's performance as a whole and is typically represented as a Z-score value for each participant. Z-scores is the number of standard deviations a value is from the mean, indicating whether a laboratory is within the average or is an outlier.

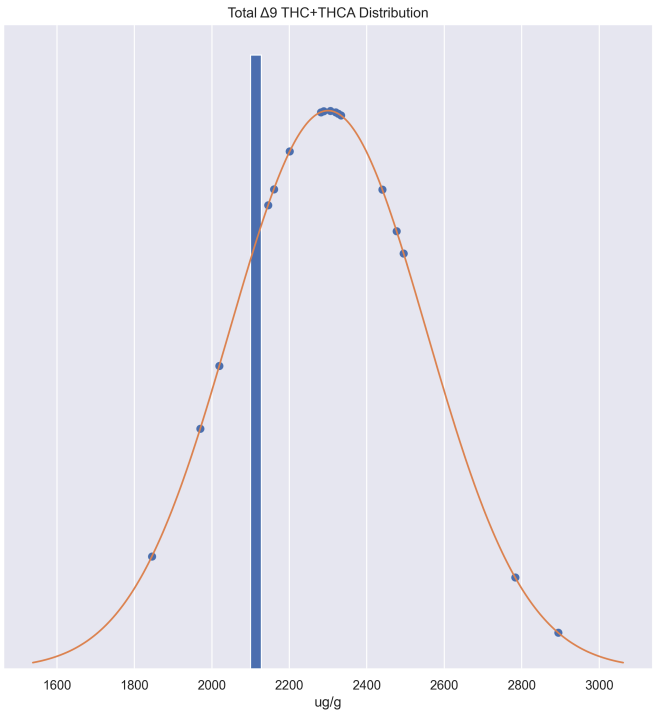

Chart 01 – This chart shows a sample of a normal distribution curve of total THC results for a PT round between cannabis testing labs. The blue line is the true value of the sample sent out for analysis, and the curve shows the distribution of reported results. It documents a median higher than the true value, which supports the hypothesis of cannabinoid inflation in reported results by testing labs. The chart is connected to Solution A.

When a combination of accuracy and precision is well illustrated for a large data set collected from a given jurisdiction, patterns such as cannabinoid inflation and contaminant suppression become visible on a larger scale. The push of THC numbers up above 20%, a significant selling point for cannabis products, becomes visible in the data distributions and can indicate an issue of laboratory data accuracy. This same trend is seen with contaminants, which show a high probability of data manipulation when reported values are just below an action level and are more common than the surrounding values.

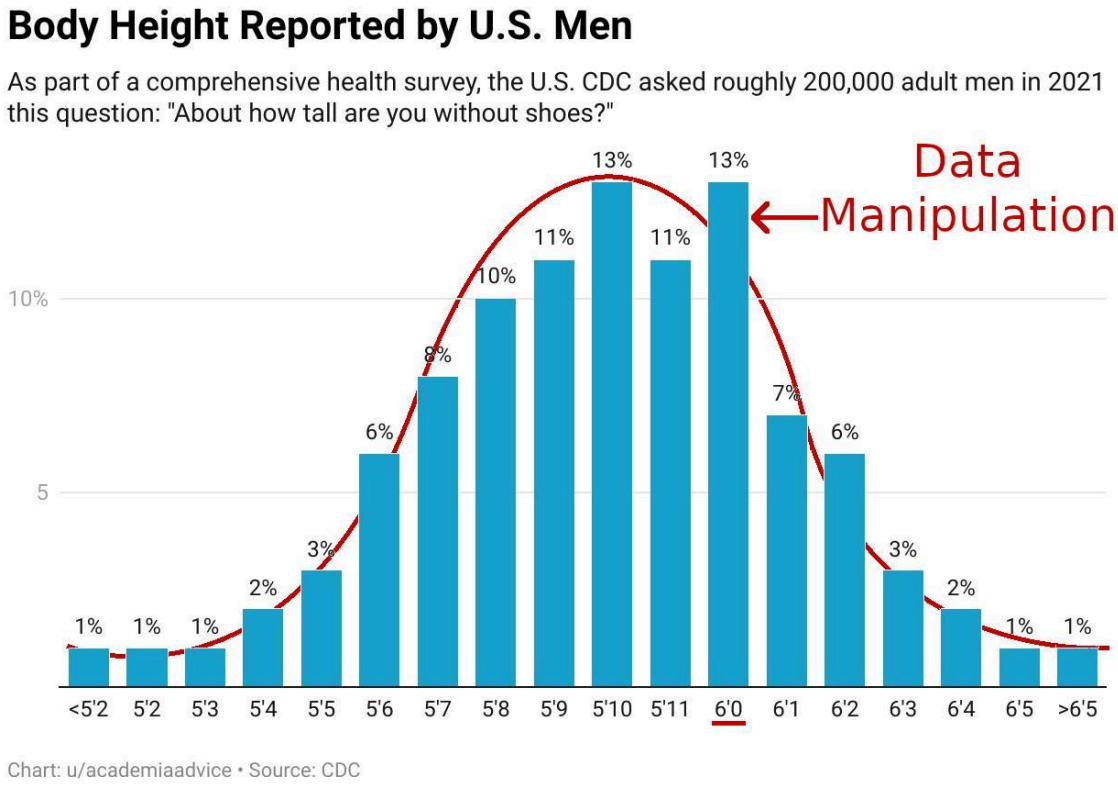

Chart 02 – This chart is a sample of a normal distribution curve of the total height of American men. This distribution shows the sampling bias that men who are 5’11 will often report that they are 6'0, creating a noticeable disruption from the normal distribution at 6 '0. This trend and its exceptions are outlined in red. This chart is connected with Solution A.

While Digamma believes this type of data analysis is the easiest, quickest, and lowest cost method to find data manipulation, it lacks some of the more systematic approaches outlined in Solutions 1 and 2 above. Some articles listed in Appendix 1 use this technique to help illustrate the problem of relying wholly on data analysis reports. This technique could be more effective in partnership with regulators with a larger data set size, giving state regulators valuable information as a basis for decisions and actions.

Solution B - Suspect Product Checks (Secret Shopper) Program

The essential element needed to prevent cannabinoid inflation is objective and reliable data that can be used to assess the claims of products on shelves in licensed dispensaries. With this data, the state regulators would have accurate and reliable information to use as a basis for enforcement actions.

The traditional method that many states have used to verify cannabis testing laboratory's competency has been ISO/IEC 17025:2017 accreditation. Although this accreditation is a strong indicator of competency of an analytical laboratory in many industries, ISO/IEC 17025:2017 does not prescribe measurement accuracy. This may be due to a lack of regulatory knowledge or the limited scope of ISO/IEC 17025:2017 assessments by accreditation bodies such as Perry Johnson Laboratory Association (PJLA), American Association for Laboratory Accreditation (A2LA), and ANSI National Accreditation Board (ANAB), three primary groups commonly used for cannabis laboratory accreditation. Regardless of the causes, the practical effect is that ISO/IEC 17025:2017 accreditation alone cannot verify laboratory accuracy in the cannabis industry.

Currently, the standard to determine competency for cannabis testing laboratories is ISO/IEC 17025:2017 accreditation. Although this accreditation is a strong indicator of reliable performance in many industries employing standardized methods, ISO/IEC 17025:2017 accreditation does not specify or prescribe precision for internally validated methods. Please reference ISO/IEC 17025:2017 Section 7.2 for validation requirements. Variability in results may be due to a lack of consensus methods for lot designation, sampling technique, subsampling and homogenization technique, test method specifications such as gravimetric vs volumetric dilutions. Furthermore, some states do not require that all methods/analytes/matrices are accredited. For example in New York the lab can be ISO/IEC 17025:2017 accredited for 'filth and foreign materials' and not even have cannabinoid quantification on the scope of their accreditation. Additionally a laboratory can list 'cannabis products' as the matrix which is

non-specific and creates gaps in the regulatory framework which can be used for data manipulation.

The next method to verify laboratory accuracy on cannabinoid results is proficiency testing (PT) programs. ISO 17025:2017 accreditation requires participation in a 3rd party PT program, in which a PT administrator sends a blind sample with a known concentration to all participating labs. In turn the labs test the sample and return their results to the administrator and are analyzed for accuracy. The results are compared to the known concentration and the labs are graded accordingly. The *Emerald PT Report* is one of the most extensive PT programs in the cannabis industry, which is a program that Emerald Scientific and Digamma operate in partnership.

PT program reports are ideal for catching inaccuracies in laboratory reporting that may not be intentional, such as inadequate contaminant testing (pesticides, metals, etc.). However, PT programs cannot demonstrate deliberate cannabinoid inflation because labs can provide the most accurate value when participating in a PT program and return to creating higher values when reporting client sample results. While the PT programs are ideal for demonstrating laboratory competence, they are poorly suited to catch intentional cannabinoid inflation.

Thus, a program is needed to collect data on cannabinoid inflation when performed intentionally. Digamma suggests a **Suspect Product Checks Program** where products on the shelves for consumer purchase are collected by secret shoppers and analyzed by a state reference lab. The reason a state reference lab is critical for the success of this program is because of the need for transparency and independence of the data being generated. Some states have attempted to use “Round Robin” style testing where they send a sample to many private laboratory licensees, and this practice is neither independent nor transparent and a poor basis for enforcement actions by regulators, as often a “Round Robin” style testing will show consistently inflated cannabinoid values across all participating laboratories. The values from this independent state analysis are compared with the label values, and this information is used to measure the amount of inflation. This procedure bypasses the issue in PT programs, where labs

intentionally inflating cannabinoid concentrations can evade detection. The program works because the comparison is done with samples of actual cannabis consumer goods and products without the lab's knowledge beforehand.

	Suspect Product Check (State Ref Lab)	**Laboratory Results** (Private Lab Licensee)	**Product Label** (Dispensary Off-The-Shelf)
Results	20 %Wt	30 %Wt	33 %Wt
Percent Recovery	100%	150%	165%

Chart 03 – This section describes how data will be collected from the producer and/or lab, and how it will be analyzed. The product's labeled value or the lab's test results are divided by Suspect Product Check results to create a percent recovery value. Findings of 100% represent an exact match with the Suspect Product Check value, and numbers over 100% show at least some degree of cannabinoid inflation.

MODEL SECRET SHOPPER PROGRAM: SAMPLE DATA (MASTER)

ID	Product		Producer			Laboratory			Dispensary		Cannabinoid Value %		
Item No.	Strain Name	Tracking	Licensee	Tracking	Harvest Date	Licensee	Tracking	Test Date	Licensee	Tracking	Label Claim	Ref Lab	Deviation
10000001	Girl Scout Cookies	9611823534	Cultivation A	6392722369	2023-10-19	Laboratory A	5782580048	2023-10-26	Dispensary A	9534612790	24.6	18.3	134.43%
10000002	Gorilla Glue#4	2902526966	Cultivation B	5173698149	2023-10-23	Laboratory B	8484312834	2023-10-30	Dispensary B	6132526878	30.9	23.8	129.83%
10000003	Kosher Kush	453878671	Cultivation C	869184210	2023-10-30	Laboratory C	1461999850	2023-11-06	Dispensary C	7465780042	22.6	21.0	107.62%
10000004	Pineapple Express	3569673124	Cultivation D	4018053641	2023-11-02	Laboratory A	9897256588	2023-11-09	Dispensary D	6287247087	25.6	18.9	135.45%
10000005	Bubba Kush	9194313205	Cultivation E	1267487049	2023-11-05	Laboratory C	8773395409	2023-11-12	Dispensary E	1533602850	17.1	17.2	99.42%
10000006	Strawberry Cough	8520341307	Cultivation F	948345584	2023-11-09	Laboratory A	2412781265	2023-11-16	Dispensary F	9057841562	23.1	17.3	133.53%
10000007	Super Lemon Haze	8979567936	Cultivation G	2580404151	2023-11-13	Laboratory B	2954793189	2023-11-20	Dispensary G	6928887923	21.6	19.2	112.50%
10000008	Vanilla Kush	7568298316	Cultivation H	2673905882	2023-11-17	Laboratory D	5747764217	2023-11-24	Dispensary H	8671825504	23.9	15.9	150.44%
10000009	Lemon Cookies	154715828	Cultivation A	2027593221	2023-11-22	Laboratory C	5263211502	2023-11-29	Dispensary A	705014519	22.1	20.9	105.74%
10000010	Sour Diesel	6727488980	Cultivation B	6124270972	2023-11-25	Laboratory D	6435701172	2023-12-02	Dispensary B	398207347	33.2	21.8	152.29%
10000011	Acapulco Gold	7851915805	Cultivation C	2435083626	2023-11-27	Laboratory B	4242183304	2023-12-04	Dispensary C	8493243699	25.0	20.9	119.62%
10000012	Pineapple Love Bomb	2172175085	Cultivation D	5361844329	2023-11-30	Laboratory C	8007588246	2023-12-07	Dispensary D	5024359848	25.0	22.9	109.17%
10000013	Jack Herrer	6302236166	Cultivation E	7407316304	2023-12-02	Laboratory D	7933222106	2023-12-09	Dispensary E	7440888906	32.0	20.2	158.42%
10000014	Cookie Monster	8831333112	Cultivation F	6609285559	2023-12-05	Laboratory A	1951891606	2023-12-12	Dispensary F	4506279111	28.2	20.9	134.93%
10000015	OG Kush	3032392685	Cultivation G	1774025462	2023-12-09	Laboratory B	7143040573	2023-12-16	Dispensary G	1688426893	25.0	19.9	125.63%

Legend	<+10%	<+20%	<+30%	>+30%

Chart 04 – This chart represents a sample data set showing the concepts outlined for Solution B – Suspect Product Check (Secret Shopper) Program. Data is shown as a master data list collected across the jurisdiction.

MODEL SECRET SHOPPER PROGRAM: SAMPLE DATA (BY LABORATORY)

Laboratory A

ID	Product		Producer			Laboratory			Dispensary		Cannabinoid Value %		
Item No.	Strain Name	Tracking	Licensee	Tracking	Harvest Date	Licensee	Tracking	Test Date	Licensee	Tracking	Label Claim	Ref Lab	Deviation
10000001	Girl Scout Cookies	9611823534	Cultivation A	6392722369	2023-10-19	Laboratory A	5782580048	2023-10-26	Dispensary A	9534612790	24.6	18.3	134.43%
10000004	Pineapple Express	3569673124	Cultivation D	4018053641	2023-11-02	Laboratory A	9897256588	2023-11-09	Dispensary D	6287247087	25.6	18.9	135.45%
10000006	Strawberry Cough	8520341307	Cultivation F	948345584.4	2023-11-09	Laboratory A	2412781265	2023-11-16	Dispensary F	9057841562	23.1	17.3	133.53%
10000014	Cookie Monster	8831333112	Cultivation F	6609285559	2023-12-05	Laboratory A	1951891606	2023-12-12	Dispensary F	4506279111	28.2	20.9	134.93%
												Laboratory A Average	134.58%

Laboratory B

ID	Product		Producer			Laboratory			Dispensary		Cannabinoid Value %		
10000002	Gorilla Glue#4	2902526966	Cultivation B	5173698149	2023-10-23	Laboratory B	8484312834	2023-10-30	Dispensary B	6132526878	30.9	23.8	129.83%
10000007	Super Lemon Haze	8979567936	Cultivation G	2580404151	2023-11-13	Laboratory B	2954793189	2023-11-20	Dispensary G	6928887923	21.6	19.2	112.50%
10000011	Acapulco Gold	7851915805	Cultivation C	2435083626	2023-11-27	Laboratory B	4242183304	2023-12-04	Dispensary C	8493243699	25.0	20.9	119.62%
10000015	OG Kush	3032392685	Cultivation G	1774025462	2023-12-09	Laboratory B	7143040573	2023-12-16	Dispensary G	1688426893	25.0	19.9	125.63%
												Laboratory B Average	121.89%

Laboratory C

ID	Product		Producer			Laboratory			Dispensary		Cannabinoid Value %		
10000003	Kosher Kush	453878670.7	Cultivation C	869184209.8	2023-10-30	Laboratory C	1461999850	2023-11-06	Dispensary C	7465780042	22.6	21.0	107.62%
10000005	Bubba Kush	9194313205	Cultivation E	1267487049	2023-11-05	Laboratory C	8773395409	2023-11-12	Dispensary E	1533602850	17.1	17.2	99.42%
10000009	Lemon Cookies	154715828.3	Cultivation A	2027593221	2023-11-22	Laboratory C	5263211502	2023-11-29	Dispensary A	705014518.7	22.1	20.9	105.74%
10000012	Pineapple Love Bomb	2172175085	Cultivation D	5361844329	2023-11-30	Laboratory C	8007588246	2023-12-07	Dispensary D	5024359848	25.0	22.9	109.17%
												Laboratory C Average	105.49%

Laboratory D

ID	Product		Producer			Laboratory			Dispensary		Cannabinoid Value %		
10000008	Vanilla Kush	7568298316	Cultivation H	2673905882	2023-11-17	Laboratory D	5747764217	2023-11-24	Dispensary H	8671825504	23.9	15.9	150.44%
10000010	Sour Diesel	6727488980	Cultivation B	6124270972	2023-11-25	Laboratory D	6435701172	2023-12-02	Dispensary B	398207346.5	33.2	21.8	152.29%
10000013	Jack Herrer	6302236166	Cultivation E	7407316304	2023-12-02	Laboratory D	7933222106	2023-12-09	Dispensary E	7440888906	32.0	20.2	158.42%
												Laboratory D Average	153.72%

Legend	<+10%	<+20%	<+30%	>+30%

Chart 05 – The chart represents a sample data set showing the concepts outlined for Solution B – Suspect Product Check (Secret Shopper) Program. It has been reformatted to show individual laboratory trends in deviation value for cannabinoid inflation.

See above for an example generated with model data for a hypothetical Suspect Product Checks Program. It models how the data would be collected and tracked to the cultivator, manufacturer or distributor, lab, and dispensary and compared to the reference laboratory concentrations on the product label. The report generates an accuracy percentage showing the inflation of THC or other cannabinoids in the examined samples. It can easily be organized by laboratories or any other party to see trends in inflation averages within this subset.

For a Suspect Product Check Program to have an objective value for comparison to label claims, an independent laboratory must perform the cannabinoid analysis for the state regulators. For the laboratory to be accurate enough for use by regulators, it must be validated not only to levels of the ISO 17025:2017 program but also to standards used in EPA and FDA analysis laboratories. This level of validation provides the legal defensibility of analytical data necessary for

use in state regulations and legal proceedings. This methodology can be accomplished with a validation of the analytical method that complies with standards outlined by federal regulatory agencies.

Additionally, the state's cost of such an analysis is relatively low. While many licensed cannabis testing labs spend about $2 million on their analytical equipment for a complete set of seven instruments, a state-associated cannabinoid analysis laboratory would only need one instrument to set the whole laboratory up for a much lower cost. Establishing a Suspect Product Check Program is a critical and necessary tool for state regulators to collect data at an affordable rate, especially when other costs, such as laboratory space and staff, can be merged with existing state laboratory resources.

Upon request, Digamma can outline cannabinoid testing equipment costs and the total costs of working together to establish and validate a functioning cannabinoid analysis lab.

Solution B2 – Legal Defensible Data For State Reference Lab

The critical variable in any regulatory or legal challenge is creating and maintaining defensible chemical analysis data to use as a basis for enforcement and to defend against outside parties. Diagrams outline Digamma’s validation style and its roots in EPA compliance for serious contaminants hazardous to public health in Solution C. It is worth noting that data from the accredited reference laboratory used by the state for Solution B, outlined below, is critical and necessary for any laboratory compliance program's success.

Expanded uncertainty is the critical variable that any laboratory needs for defensibility in the broadest sense. Expanded uncertainty is a value calculated using the variations of each measurement in a process, which gives a range of variation for the final reported results. Expanded uncertainty calculations must be pegged to traceability to the International System of Units for legal defensibility.

Other variables include scale calibration, scale verification, pipette calibration, pipette

verification, and quality logs relating to uncertainty measurements, including temperature, frequency, centrifugal force, and solvent/reagent purity verification. These variables must comply with the relevant chemical analysis standards. Thus, the essential elements of tracking expanded uncertainty have a downstream influence on direct calibration metrics, such as instrument calibration curves, linear dynamic ranges, extraction efficiency, and matrix interference, including ion suppression and amplification phenomena that may affect the accuracy of the final reported results. More information on Digamma's thoughts on legal defensibility and the general accuracy of cannabis analysis labs is in Appendix 3. This can help generate the most defensible data for the state.

Because the elements addressed here are technical, Digamma feels that sharing our complete validation reports with technical parties within your department may be the best way to communicate the methodologies we have adapted from the EPA for quality control and legal defensibility in cannabis testing laboratories. These documents include validations of every analytical method operated by a cannabis analysis laboratory in 16 U.S. states on every major instrument manufacturer (PerkinElmer, Agilent, Waters, Thermo, Shimadzu) since 2011.

Digamma would happily share this information with any Government regulator after signing a non-disclosure agreement (NDA). We ask that these documents not be published because they represent over a decade of scientific and regulatory development work, and their public release would be detrimental to our organization. Please let us know if your institution is interested in reviewing this information.

Solution C – laboratoryAudits

laboratory audits are essential to address the cannabinoid inflation enforcement problem. Even when a standardized method is enforced uniformly, such as those California's DCC required in 2023, the labs can still manipulate data to produce inflated results for their clients in ways that can only be detected by a direct audit.

In this environment, as in the environment-related industry, auditing laboratories are needed to ensure that regulated laboratories are not committing fraud. Even when the data packets shared with the state show all of the calculations, calibrations, and quality control samples (standard in most states for cannabis testing and mandatory for all EPA and FDA-licensed labs), other elements can be used to manipulate the results. Some of these are covered in the 2016 ACS article on cannabinoid inflation and its technical basis, found in Appendix 1. A thorough audit by experienced laboratory chemists, who are familiar with such manipulations, would be considerably deeper in scope, which Digamma has outlined in Appendix 2. Manipulations range from changes to calibration standards to modifications of data analysis and would not be evident from the data packets submitted to the state.

A thorough audit would ensure that all quality control data from the data packet is available, can be traced to the data source, and includes all components that may be used to alter the final reported data. These components include but are not limited to scale calibration, standard calibration procedure and frequency, instrument maintenance and frequency, sample prep extraction, data analysis, and final results reported calculations.

Digamma can develop a thorough quality management systems (QMS) auditing program to exclude the possibility of compliant testing labs performing these manipulations. This process allows enforcement to be applied equally throughout a given jurisdiction, with qualified audit staff to perform laboratory audits as needed. It can be organized with regulatory oversight in diverse formats, ranging from supporting the establishment and training of the current state personnel for conducting these audits to outsourcing the task to a proficient private firm capable of executing them. In Appendix 2, Digamma outlines the most critical variables affecting cannabinoid inflation audits. For more general details about the QMS program, see Appendix 3.

Charts 6 and 7 below contain a sample of the validation protocols based on EPA standards that Digamma has been using to help labs get licensed through proper method validation. It includes validation of accuracy, precision, detection limits, matrix extraction efficiency, known interferences, and independent reproducibility and robustness.

[redacted]

Validation of Cannabinoid Analysis by HPLC-UV in Cannabis species plants and their derivative products

Lab Director: [redacted]
Lab Technician:

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Reviewed and Approved:

_____ _____
[redacted] Date
Lab Director Signed

Chart 06 – This chart is an outline of sample validations of 14 cannabinoids in the state of Missouri in late 2022, with sections and chapters of the validation report indicated to show its breadth. It is connected to Solutions 1B and 2.

SUMMARY

1. SCOPE

A validation study was performed for the analysis of cannabinoids by High Performance Liquid Chromatography with UV detection (**HPLC-UV**). The analytical method was validated in three phases. In the first phase, **linearity and range**, method calibration R^2, LOD, and LOQ values were derived and compared with regulatory requirements. In the second phase, **matrix spike replicates** were performed for each class of matrix analyzed by the method and data was compared to regulatory requirements. In the third phase, **robustness**, an "unknown" sample was analyzed by different laboratory employees under varying external conditions and LQC results were compared with regulatory requirements. More details for each phase of the validation is demonstrated below.

This validation was performed with acceptance criteria based on the governing jurisdiction for analytical services, in this case the State of Missouri Department of Health and Senior Serives (19 CSR 30-95). The requirements are outlined in CSR laws and statutes, and have been summarized below:

- No less than 5 calibration points for generating calibration curves
- No less than 0.990 correlation coefficient (R^2) for each calibration curve
- Limits of Detection (LOD) and Limits of Quantification (LOQ) for each analyte must be experimentally derived with no less than 7 replicates
- Derived LOD and LOQ values must comply with CSR action levels for each analyte (1mg/g in sample)
- All Quality Control (QC) samples must comply with CSR specifications
  - $\pm$ 30% recovery on all matrix spike recovery QC samples
  - $\pm$ 30% on all continuing calibration verification (CCV) QC samples
  - $\leq$ 30% relative percent difference (RPD) on replicate QC samples
  - $\leq$ LOQ for all blank QC samples, including preparation blanks (PB) and calibration blanks (CB)

The most current version of this information can be found on the CSR website at:
https://health.mo.gov/safety/cannabis/

		CBDV	CBDA	CBGA	CBG	CBD	THCV	CBN	d9-THC	d8-THC	CBC	THCA
Calibration	More than 5 Calibration Points	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE
	Greater than 0.990 R2 value	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE
Replicates	7 or greater replicates	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE
	LOD and LOQ comply with regulations	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE
	Accuracy as measured by %recovery <30%	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE
	Precision as measured by %RPD <30%	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE
Matrix	Accuracy as measured by %recovery <30%	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE
	Precision as measured by %RPD <30%	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE
Robustness	LQC Passes Compliance Criteria for two or more laboratory staff	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE

Chart 07 - This is a report summary and outline of this sample validation of 14 cannabinoids in Missouri in late 2022, with sections and chapters of the validation report indicated to show the depth of focus for each validation component. It is critical to communicate the legal defensibility of the methodology, precisely as is used in

federally regulated testing, such as EPA and FDA. These ideas are connected to Solutions 1B and 2.

Digamma would happily share a copy of the entire validation document with a regulator or elected official upon request. The images in this section simply illustrate the data overview to show the validation's scope.

Additionally, Digamma would be happy to share documents on auditing cannabis analysis labs for more general audits with a broader scope. These may include concerns with **false negatives of severe contaminants** such as microbiology or pesticide analysis, whether due to error or manipulation. We believe that there is widespread under-reporting of contaminants in the cannabis supply chain at this time, based on our experience in the methodologies and practices of our extensive client list of laboratories analyzing cannabis. Although we believe the cannabinoid inflation issue is more pressing, due to its highly public nature and the effect it is having on consumer confidence in both the industry, supply chain safety, and regulatory framework, we believe the struggle to audit laboratories for proper reporting on contaminants to be a more important issue to pursue in the long run due to the serious health and safety implications it carries. Regardless of the deficiencies that currently exist in cannabis analysis laboratories, with proper education, monitoring, and enforcement **these problems can be easily solved**, to the benefit of the whole industry, with many of the solutions we are outlining. The more comprehensive audits may also include the scope of general laboratory accuracy and accountability with comparable standards in parallel analytical chemistry sectors and provide the state with more information on laboratory diligence and accuracy in reporting. This information can be found in Appendix 3.

Appendix 1: Media Articles Outlining Cannabinoid Inflation Issues

August 2016 - Variations in THC Reporting (From American Chemical Society 2016 Presentation by Digamma)
Part1 - http://growersnetwork.org/laboratories/variations-cannabinoid-reporting-part-one/

Part2 - http://growersnetwork.org/laboratories/variations-in-cannabinoid-reporting-part-two/

Part3 - http://growersnetwork.org/laboratories/variations-cannabinoid-reporting-part-three/

Part4 - http://growersnetwork.org/laboratories/variations-in-cannabinoid-reporting-part-four/

Part5 - http://growersnetwork.org/laboratories/variations-cannabinoid-reporting-part-five/

Part6 – http://growersnetwork.org/laboratories/variations-cannabinoid-reporting-part-six/

April 28th, 2017 - Leafly Investigation: Is Washington's Top Cannabis laboratory Inflating THC Numbers?
https://www.leafly.com/news/industry/leafly-investigation-washingtons-top-cannabis-lab-inflating-thc-numbers

February 1st, 2019 - Oregon marijuana regulators fail to meet even basic standards, state audit finds
https://www.oregonlive.com/news/2019/01/oregon-marijuana-regulators-fail-to-meet-even-basic-standards-state-audit-finds.html

January 27th, 2021 - Nevada cannabis testing lab targeted for passing tainted samples
https://mjbizdaily.com/nevada-cannabis-testing-lab-targeted-for-passing-tainted-samples/

June 29th, 2021 - America's Pot Labs Have A THC Problem
https://fivethirtyeight.com/features/americas-pot-labs-have-a-thc-problem/

September 15th, 2021 - HNHPC, INC. vs. THE DEPARTMENT OF CANNABIS CONTROL
https://mjbizdaily.com/wp-content/uploads/2021/09/Burner-distro-lawsuit.pdf

October 20th, 2021 - Study: Most Delta-8 THC Products Are Mislabeled—And Some Companies Are Faking Lab Results
https://www.forbes.com/sites/chrisroberts/2021/10/30/study-most-delta-8-thc-products-are-mislabeled-and-some-companies-are-faking-lab-results/?sh=4bd336dd7ec1

November 29th, 2021 - California rolls out plans to standardize cannabis testing statewide
https://mjbizdaily.com/california-rolls-out-plans-to-standardize-cannabis-testing-statewide/

June 16th, 2022 - Inaccurate strain names, poor labeling hinder marijuana industry, study shows
https://mjbizdaily.com/inaccurate-strain-names-poor-labeling-hinder-marijuana-industry/

July 1st, 2022 - DON PLUMLEE et al. v. STEEP HILL INC
https://mjbizdaily.com/wp-content/uploads/2022/07/Plumlee-v-Steep-Hill-Arkansas.pdf

July 25th, 2022 - 4 Arkansas marijuana companies hit with RICO suit over alleged THC inflation
https://mjbizdaily.com/4-arkansas-marijuana-companies-hit-with-rico-suit-over-alleged-thc-inflation/

July 28th, 2022 - The Inflated THC Crisis Plaguing California Cannabis
https://cannabisindustryjournal.com/feature_article/the-inflated-thc-crisis-plaguing-california-cannabis/

August 11th, 2022 - How cannabis testing labs help put undue focus on THC potency
https://mjbizdaily.com/how-cannabis-testing-labs-help-put-undue-focus-on-thc-potency/

August 17th, 2022 - Weed buyer beware: THC inflation is getting out of hand
https://www.leafly.com/news/science-tech/marijuana-thc-inflation-is-getting-out-of-hand

September 8th, 2022 - EXCLUSIVE: We tested top Calif. prerolls for potency inflation
https://www.weedweek.com/stories/exclusive-we-tested-top-calif-prerolls-for-potency-inflation/

October 17th, 2022 - Nevada marijuana lab disciplinary hearing further highlights industry's testing woes
https://mjbizdaily.com/nevada-marijuana-lab-disciplinary-hearing-further-highlights-industrys-testing-woes/

October 10th, 2022 - JASPER CENENO et al vs. DREAMFIELDS BRANDS INC. et al
https://www.dovel.com/wp-content/uploads/2022/10/Jeeter-complaint-FINAL.pdf

October 25th, 2022 - Marijuana company sued for not making customers high enough
https://www.cbsnews.com/news/cannabis-marijuana-dreamfields-jeeter-lawsuit-california-thc-high/

October 26th, 2022 - A California marijuana company is being sued over the potency of its joints
https://www.cnn.com/2022/10/26/business/california-marijuana-lawsuit-thc-trnd/index.html

October 31st, 2022 - Customers Sue California Marijuana Company For Overstating THC Potency In Its Joints
https://www.forbes.com/sites/dariosabaghi/2022/10/31/customers-sue-california-marijuana-company-for-overstating-thc-potency-in-its-joints/?sh=152309a93030

December 1st, 2022 - Dovel & Luner Sues V O Leasing Corp for Mislabeled THC Content
https://www.dovel.com/news/dovel-luner-sues-v-o-leasing-corp-for-mislabeled-thc-conent/

December 12th, 2022 - Valley Greens Retail Outlet, Inc et al. v. Savage Enterprises, et al.
https://www.insurancejournal.com/news/west/2022/12/08/698377.htm

January 13th, 2023 - More changes needed to address inflated THC levels

https://stratcann.com/insight/more-changes-needed-to-address-inflated-thc-levels/

March 21st, 2023 - Canadian cannabis industry reckons with inflated THC label claims
https://mjbizdaily.com/canadian-cannabis-industry-reckons-with-inflated-thc-label-claims/

April 12th, 2023 - Uncomfortably high: Testing reveals inflated THC potency on retail Cannabis labels
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0282396

July 14th, 2023 - Organigram blames lower sales on THC inflation and no longer being able to sell “ingestible extracts”
https://stratcann.com/news/organigram-blames-lower-sales-on-thc-inflation-and-no-longer-being-able-to-sell-ingestible-extracts/

July 18th, 2023 - Organigram Blames ‘THC Inflation’ For Growing Losses and Falling Revenues in Q3
https://businessofcannabis.com/organigram-blames-thc-inflation-for-growing-losses-and-falling-revenues-in-q3/

August 2nd, 2023 - California Falls Short on Tracking Illegal Cannabis, Appellate Court Says
https://www.law.com/therecorder/2023/08/02/california-falls-short-on-tracking-illegal-cannabis-appellate-court-says/?slreturn=20231107172558

September 14th, 2023 - Valley Greens Retail Outlet, Inc et al v. Savage Enterprises, et al
https://www.scribd.com/document/678516992/37-2023-00041548-CU-BT-CTL-ROA-1-09-14-23-Complaint-1697654340880

September 20th, 2023 - NEW CALIFORNIA LAW AUTHORIZES LAWSUITS BY LICENSED CANNABIS BUSINESSES AGAINST UNLICENSED CANNABIS OPERATORS
https://www.omarfigueroa.com/new-california-law-authorizes-lawsuits-by-licensed-cannabis-businesses-against-unlicensed-cannabis-operators/

September 25th, 2023 - Legal cannabis labels inflate THC potency contained in products, executives say
https://www.theglobeandmail.com/business/article-dried-cannabis-labels-thc-content/

September 28th, 2023 - Accusations of Inflated THC Potency Surface in Canada
https://cannatechtoday.com/accusations-of-inflated-thc-potency-surface-in-canada/

October 26th, 2023 - Washington state suspends marijuana testing laboratory’s certification
https://mjbizdaily.com/washington-state-suspends-marijuana-testing-laboratorys-certification/

November 30th, 2023 - Marijuana lab-testing analysis finds routine THC inflation, data manipulation
https://mjbizdaily.com/marijuana-lab-testing-analysis-finds-routine-thc-inflation-data-manipulation/

December 1st, 2023 - Challenges and Considerations in OCS Addressing THC Inflation
https://www.linkedin.com/pulse/challenges-considerations-ocs-addressing-thc-inflation-jazz-samra-zmirc/?trk=public_post

December 5th, 2023 (date of access) - OrganiGram
https://inflated-thc.com/

December 20th, 2023 State cannabis regulators still one step behind questionable THC lab data
https://mjbizdaily.com/state-cannabis-regulators-still-one-step-behind-questionable-thc-lab-data/

Appendix 2: Outline of Cannabinoid Analysis laboratory Audit

A comprehensive laboratory audit protocol must be developed to establish uniform auditing standards across laboratories. This protocol is essential to guarantee the entire spectrum of cannabinoid analysis practices is addressed before conducting an audit of a licensed laboratory. Laboratory audits can exist on co-existing and overlapping levels, such as the prescriptive AOAC assessment which is overlapping with the ISO 17025:2017 assessment, as well as audits by local and state regulatory authorities that are typical for cannabis labs at this time.

Digamma has provided insights into key components utilized in the cannabinoid inflation industry. These crucial elements should be incorporated into any audit protocol designed to investigate this phenomenon in suspected laboratories. These components have been organized into specific topics, and Digamma has concisely described the practices to be scrutinized during an audit. The resulting information will contribute to an audit report delivered to the state, presenting comprehensive findings on the observed practices. Many states currently require provision of the ISO/IEC 17025:2017 assessment report by the laboratory to the regulator which may provide valuable insight.

Calibration / Reference Standard Manipulation

Audit Deliverable Purpose: To investigate the manipulation of calibration standards through degradation, improper dilution, and sourcing of less-than-reputable concentration standards.

Recommended Audit Actions: Audit calibration standard storage and handling procedure to ensure a lack of degradation. An audit of calibration curve standard preparation from the stock material purchased by the lab. A review of sources of calibration standards and their reliability for use as reference standards. Analysis of unopened, stored, and diluted calibration standards for quantitative comparison of concentrations used by the laboratory (can be done by the lab's equipment, by the state reference lab, or by portable devices brought on-site by auditors, e.g. spectrophotometer, IMS)

Note: ISO/IEC 17025:2017 already requires the use of accredited CRM when possible and requires verifications. However the acceptance criteria (related to continued use after opening or expiry) is determined by the laboratory's internally developed method and could be prescribed by a regulator.

Calibration Curve Manipulation

Audit Deliverable Purpose: To investigate manipulations of calibration curves, through extrapolated calibration curves, improper dilution steps in sample prep, and manipulations of the calibration curve.

Recommended Audit Actions: Audit of procedure for quantifying unknown samples using the validated method is declared Linear Dynamic Range (LDR). Derivation of LDR, calibration curve standard concentrations, LOQ and LOD values, and matrix recovery values will be reviewed and assessed for compliance and accuracy. Audit of sample prep process to evaluate for extraction efficiency, dilution procedure, and compliance with the method's declared LDR.

Sampling

Audit Deliverable Purpose: To investigate sampling procedure, including biased sampling of the batch or the laboratory representative sample, mis-weighing or mis-voluming in sample prep steps, or contamination of samples during prep.

Recommended Audit Actions: Audit of procedure outlining the sampling of batches, storing and transporting samples, sub-sampling batch samples in the laboratory, sample weighing and calibration, pipette use and calibration, inventory record keeping, and cross-contamination and adulteration prevention policies and practices. Inventory record keeping would demonstrate that labs may be prepping their samples with more than the mass listed in their calculations, giving higher values without further manipulating the data. Conducting an audit of product inventory tracking is essential to gather evidence of this practice. The only documented proof of this manipulation is consistently reflected in lower-than-listed inventory values, primarily observed in

the case of cannabis flower during testing.

Note: Sampling varies a lot between laboratories and even states. True random sampling of homogenous lots would be the 'most representative". Implementation consistently may pose an issue for established client-laboratory relationships which would have to be monitored by state regulators and this would be very hard to distinguish *during* any audit/assessment/direct observation, unless the regulator has & watches 'routine' surveillance.

Note: Calibration under ISO 17025:2017 for pipette balance 'inventory' is required. However, acceptance criteria for ongoing use & calibration schedule determine by laboratory is not under the 'ISO/IEC 17025:2017 clause' which would address an audit of product inventory. It is possible that balance or pipette has loose acceptance critera, which would have a destabilizing effect on the final uncertainty of the reported value. It is also possible that gravimetric versus volumetric dilutions may also trigger similar issues with data accuracy and provide opportunities for data manipulation.

Sampling Size, Homogenization, and Replication

Audit Deliverable Purpose: To investigate biased sub-sampling sizes, the use of replicates in a method that allows for reporting of the highest observed value, and any homogenization practice that would manipulate the final reported result, including contamination with target compounds.

Recommended Audit Actions: Audit of procedures outlining homogenization and sub-sampling of representative samples of the production batch performed in the analytical laboratory. The process includes examining the sub-sampling mass size, the policy and practice surrounding replicate analysis and its effect on reporting, and the homogenization procedure used in the laboratory. An audit of sampling size and its impact on replicate testing of the same batch of material would be used to indicate precision and repeatability. A significant variance combined with a policy of replicate testing by selecting a single or sub-section of results can easily give a higher-than-average reported value.

Note: Moisture is also largely an internally developed/validated which can have any MU - different laboratories employ different moisture technique/instrument with varying considerations for contributions to uncertainty leading to some labs using different temperatures. Many laboratories do not consider loss on volatiles such as terpenes which will have a negative effect on reported data accuracy.

Correction Factors - Mass

Audit Deliverable Purpose: To investigate the manipulation of mass-based correction factors, such as stem removal and moisture, and ensure that all correction factors are used accurately and uniformly and are not a source of errors or manipulation of reported results.

Recommended Audit Actions: Conduct an audit of procedures for sample preparation and reporting, emphasizing the selective removal of plant tissue, such as stems, and examining the correction factors employed by mass for moisture content. If a moisture content correction is performed in the method's reporting procedure, the moisture value can be a source of manipulation of cannabinoid results if it is not accurately derived. Excessive heating of samples for moisture content poses a risk of oxidation or carbonization, leading to inaccurately high moisture content values. Consequently, this can result in inflated cannabinoid content values after dry-weight correction. A thorough investigation of the moisture content derivation procedure is essential to address this issue. It entails auditing the process and scrutinizing all quality and validation data associated with deriving and reporting this value.

Correction Factors - Decarboxylation

Audit Deliverable Purpose: To investigate improper use of molecular mass conversions, such as those between THCA and THC and other cannabinoids and their corresponding acid forms. It would also review the manipulation of reported results by improper summation of values such as unrelated or antagonistic cannabinoids such as THC and CBD.

Recommended Audit Actions: An audit involves scrutinizing procedures for reporting final results,

focusing on calculated correction factors like cannabinoid acid decarboxylation and equivalent concentrations post-conversion.

Derivation of exact mass conversion factors used, either from regulations or scientific literature, and review of the policy of reporting combined, total, or potential cannabinoid concentrations are necessary to assess these conversion factors thoroughly.

Chromatographic Co-Elution

Audit Deliverable Purpose: To investigate the mis-integration of non-target compounds by the analytical method, including other cannabinoids and UV active compounds such as waxes that are common in the cannabis plant. It includes intentional allowance of target compound carry-over from one sample analysis to the next in the same instrument, inflated the final reported value relative to the amount present in the sample.

Recommended Audit Actions: Conduct an audit of chromatograms for target compounds to assess potential co-elution of other targets or matrix interferences that may affect the measured quantity of the target compound. It involves reviewing chromatograms, assessing column length and maximum resolution, evaluating instrument flush time and addressing carry-over contamination, and conducting a comprehensive matrix interference assessment.

Much of the audited procedures will be reviewed and compared to the declared values and procedures outlined in the method's validation report. Digamma has noted laboratories employing very short columns, approximately 50mm long, enabling co-eluting compounds to increase their reported values in matrix samples artificially. Strikingly, this manipulation does not impact solvent standard calibrations, often yielding compliant quality control sample data and proficient proficiency testing (PT) results for the lab. However, it results in consistently higher reported values for matrix-based samples. This discrepancy can be examined by scrutinizing the data declared in the validation report on matrix interference studies and conducting an audit of routine quality samples that pertain to these components, including matrix blanks and spike replicates.

Detector Manipulation

Audit Deliverable Purpose: To investigate the manipulation of detector settings, which may allow interfering compounds to be mis-integrated as target compounds.

Recommended Audit Actions: Audit instrument detector settings, emphasizing UV or visible light frequency, the quantitation versus qualifier detector channels, and any qualifying channel ratios derived from analytical standards. This audit will focus on known interferences declared in the analytical method's validation report and the probability of these interferences having a substantive impact on the final reported result of the target compound.

Data Analysis Manipulation

Audit Deliverable Purpose: To investigate the manipulation of data analysis procedure, emphasizing the mis-integration of target compounds, mis-integration, and manipulation of calibration standard integration.

Recommended Audit Actions: Conduct an audit of instrument chromatogram integration procedures, policies, and practices involving a comprehensive review of all manually integrated peaks from a randomly selected analytical batch conducted by the laboratory. The investigation will collect data on the amount and frequency of manual integrations versus auto-integrations per analytical batch for baseline consistency from peak to peak and the relationship of integration technique between calibration, quality, and client samples.

Physical Instrument Parameter Manipulation

Audit Deliverable Purpose: To investigate the alteration of physical parameters on the analytical instrument, which could be altered from the values on the analytical method's validation report and the method as performed during a Proficiency Testing (PT) round, by tracking the logs that would show a lack of manipulation of these physical variables, the presence of alterations suggesting manipulation, or missing segments of data that may or may not coincide with periods of high reported values by the laboratory.

Recommended Audit Actions: Audit all instrument logs that verify the invariance of physical variable settings that impact the final reported value. These include injector volumes, flow rates, temperature settings, vacuum pressures, electrovoltaic parameters, and electromagnetic parameters (mass spec methodologies only). Traceability practices showing the physical parameters of the analytical method printed into each data packet by each analytical batch would make a step of the audit performable with document and data review only. If the laboratory in question does not adhere to standard traceability practices, on-site audits of current and established procedures will be essential to validate the uniformity of these physical instrument parameters.

Appendix 3: Outline of General QMS Analysis Laboratory Audit Elements

We have outlined general guidelines for method validation and QMS data management for cannabis analysis laboratories to show the legal defensibility of all reported data and maintain the quality logs that help support and prove these assertions.

We have outlined the stages here below:

	Criteria			
	Required		**Ideal**	
1. **Linearity and LOQ derivation**				
1.A Calibration 1-n	R^2>0.99, >5 Cal Points		>7 Cal Points	
1.B Replicate Injections (7+)	LOQ < Action Level		LOQ < AL/5	
2. **Matrix Spike Recovery Replicates**	Accuracy	Precision	Accuracy	Precision
2.A Flower	±30%	±0.30	±20%	±0.15
2.B Concentrate	±30%	±0.30	±20%	±0.15
2.C Edibles01	±30%	±0.30	±20%	±0.15
2.D Edibles02 (if applicable)	±30%	±0.30	±20%	±0.15
3. **Robustness and LQC**				
Matrix QC:				
PB and MB	<LOQ		<LOD	
LCS	70-130% Recovery		80-120% Rec.	

LRS	<30% RPD	<30% RPD
ICV	70-130% Recovery	80-120% Rec.
Matrix CRM	70-130% Recovery	80-120% Rec.
CCV	70-130% Recovery	80-120% Rec.
CCB	<LOQ	<LOD

Matrix-Specific Sample Classes for Validation and Per-Batch Sample Prep

Flower – Cannabis flower or proxy (hemp bud, hops bud, etc)

Concentrate – Organic hemp oil

Edibles01 Hydrophilic – Gummy bears

Edibles02 Hydrophobic – Chocolate bars

QMS On-Going Per-Batch Requirements

ICV	Independent Calibration Verification	±30% recovery
PB	Prep Blank	<LOQ
MB	Matrix Blank	<LOQ
MS	Matrix Spike	±30% recovery
SD	Sample Duplicate	<30% RPD
CRM	Matrix CRM “Unknown”	±30% recovery
CCV	Continuing Calibration Verification	±30% recovery
CCB	Continuing Calibration Blank	<LOQ

SINGLE CALIBRATION		
Sample Text	**Matrix**	**QC**
Calibration 01	Solvent	Calibration
Calibration 02	Solvent	Calibration
Calibration 03	Solvent	Calibration
Calibration 04	Solvent	Calibration
Calibration 05	Solvent	Calibration
Calibration 06	Solvent	Calibration
Calibration 07	Solvent	Calibration
Calibration 08	Solvent	Calibration
Internal Calibration Verification	Solvent	ICV
Prep Blank	Solvent	PB
Matrix Blank	Flower	MB
Matrix Spike	Flower	LCS or MS
Sample Duplicate	Flower	SD or MR
Flower Samples	Flower	S01-S10
Continuing Calibration Verification	Solvent	CCV
Continuing Calibration Blank	Solvent	CCB
Matrix Blank	Concentrate	MB
Matrix Spike	Concentrate	LCS or MS
Sample Duplicate	Concentrate	SD or MR
Flower Samples	Concentrate	S11-S20
Continuing Calibration Verification	Solvent	CCV
Continuing Calibration Blank	Solvent	CCB
Matrix Blank	Other	MB
Matrix Spike	Other	LCS or MS
Sample Duplicate	Other	SD or MR
Flower Samples	Other	S21-S30
Continuing Calibration Verification	Solvent	CCV
Continuing Calibration Blank	Solvent	CCB

TOTAL RUNS SINGLE CAL ^	**28**
TOTAL RUNS MATRIX CAL >	**48**

LEGEND

Solvent	
Flower Samples	
Concentrate	
Other	

MATRIX CALIBRATION		
Sample Text	**Matrix**	**QC**
Calibration 01	Flower	Calibration
Calibration 02	Flower	Calibration
Calibration 03	Flower	Calibration
Calibration 04	Flower	Calibration
Calibration 05	Flower	Calibration
Calibration 06	Flower	Calibration
Calibration 07	Flower	Calibration
Calibration 08	Flower	Calibration
Internal Calibration Verification	Flower	ICV
Prep Blank	Flower	PB
Matrix Blank	Flower	MB
Matrix Spike	Flower	LCS or MS
Sample Duplicate	Flower	SD or MR
Flower Samples	Flower	S01-S10
Continuing Calibration Verification	Flower	CCV
Continuing Calibration Blank	Flower	CCB
Calibration 01	Concentrate	Calibration
Calibration 02	Concentrate	Calibration
Calibration 03	Concentrate	Calibration
Calibration 04	Concentrate	Calibration
Calibration 05	Concentrate	Calibration
Calibration 06	Concentrate	Calibration
Calibration 07	Concentrate	Calibration
Calibration 08	Concentrate	Calibration
Internal Calibration Verification	Concentrate	ICV
Prep Blank	Concentrate	PB
Matrix Blank	Concentrate	MB
Matrix Spike	Concentrate	LCS or MS
Sample Duplicate	Concentrate	SD or MR
Flower Samples	Concentrate	S01-S10
Continuing Calibration Verification	Concentrate	CCV
Continuing Calibration Blank	Concentrate	CCB
Calibration 01	Other	Calibration
Calibration 02	Other	Calibration
Calibration 03	Other	Calibration
Calibration 04	Other	Calibration
Calibration 05	Other	Calibration
Calibration 06	Other	Calibration
Calibration 07	Other	Calibration
Calibration 08	Other	Calibration
Internal Calibration Verification	Other	ICV
Prep Blank	Other	PB
Matrix Blank	Other	MB
Matrix Spike	Other	LCS or MS
Sample Duplicate	Other	SD or MR
Flower Samples	Other	S01-S10
Continuing Calibration Verification	Other	CCV
Continuing Calibration Blank	Other	CCB

Chart 08: Matrix-matched LQC v. Matrix-matched calibration and batch preparation. All LQCs are indicated with the acronym used in the preceding section.

The below image, **Chart08** line, illustrates each analysis performed by the laboratory for a

full-compliance suite of testing for a state-regulated COA. Water activity, foreign matter, and moisture are required but not shown.

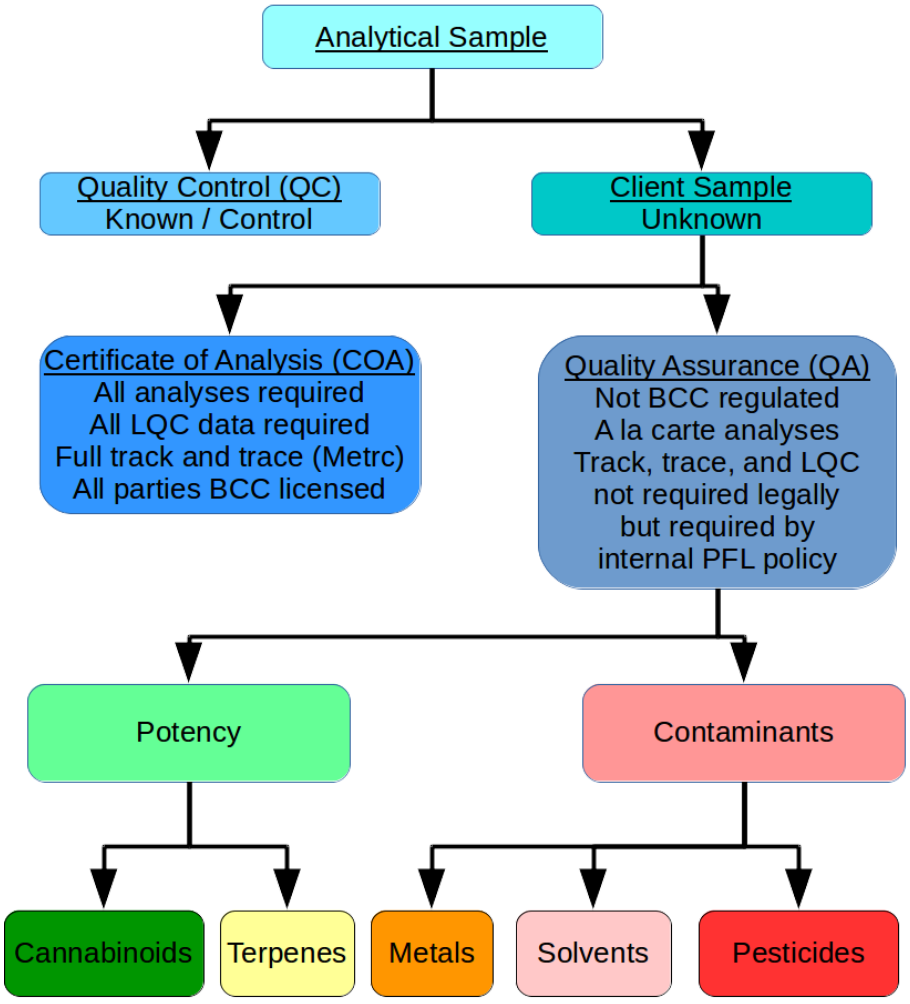


Chart 09: Flow Diagram of Analytical Samples that may be submitted to the lab. Colors match the instrument color-coded diagrams and labels.

As shown in **Chart 08** and **Chart 09**, the LQC samples associated with a batch of client samples must pass their criteria for the client sample data to be considered valid. It will be imperative if regulators or accreditation under ISO perform an audit or if a former client attempts legal action against the lab. The LQC data associated with the client data is the main form of

defense that will be at the lab's disposal.

Standard LQC Set (per each matrix class)		
ACRONYM	**Full LQC Name**	**Criteria**
PB	Prep Blank	<LOQ
MB	Matrix Blank	<LOQ
LCS	Lab Control Standard	70-130%
LRS	Lab Replicate Sample	<30% RPD
ICV	Independent Cal Verification	70-130%
CCV	Continuing Calibration Verification	70-130%
CCB	Continuing Calibration Blank	<LOQ

Chart 10: Chart summarizing the LQC requirements of the cannabinoid analysis method. Except for microbiology, moisture content, water activity, and foreign matter analysis, all other analyses will have the same LQC criteria.

The logical flow of the LQC samples and the logical tests that their status as “PASS” or “FAIL” prove (or disprove) can best be summarized in a flow chart with critical decision points in the protocol or process done by the analyst outlined in a simple binary yes/no schematic. This flow chart is essentially a reproduction or is redundant with the SOP of the analytical method, especially the LQC section of the protocol. When the flow chart is followed correctly, the laboratory will generate and record all necessary LQC for compliance and legal protection of the lab. Following this chart will ensure that all necessary LQC samples are prepared and run at the instrument by the preparation technician in the laboratory. This flow chart does not address how to analyze the data generated by the LQC samples to qualify the accuracy of the client samples. That topic is addressed in the following paragraphs.

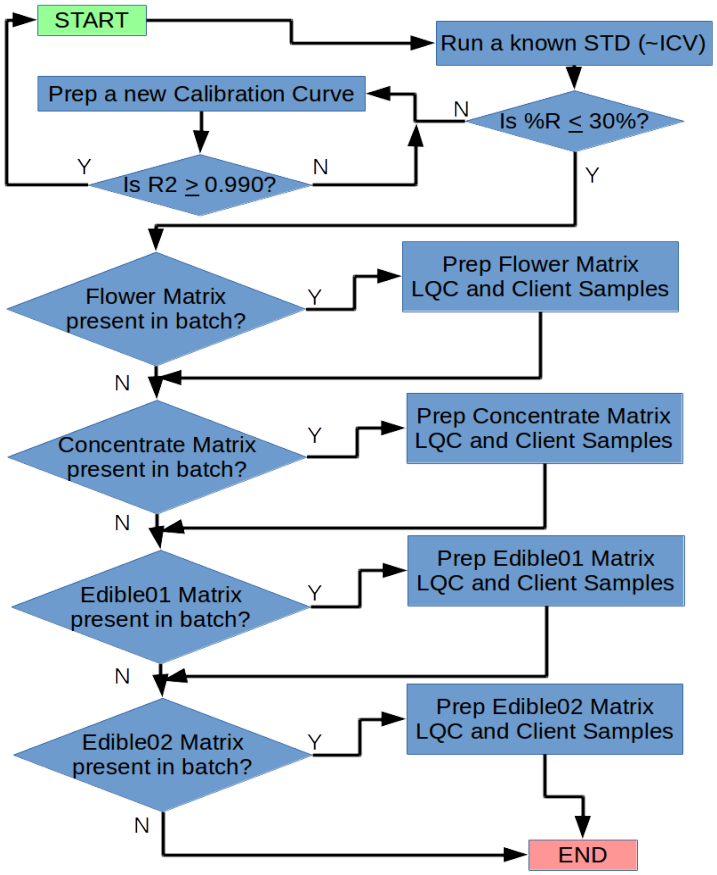


Chart 11: Flow chart of decisions of LQC samples. The diagram is designed to be started on the top left in the green box labeled “START” and flows through a series of yes/no decision points labeled Y and N for yes and no, respectively. The flowchart ends with the red box in the lower right corner labeled “END.” Diamond-shaped boxes represent binary decision points (yes/no), and rectangles represent steps or procedures to be carried out.

Below is a series of sample LQC batch data summarized as either “PASS” or “FAIL” and color-coded appropriately (with green and red, respectively).

Contaminated Consumables		
PB	Prep Blank	FAIL
MB	Matrix Blank	FAIL
LCS	Lab Control Standard	PASS
LRS	Lab Replicate Sample	PASS
ICV	Independent Cal Verification	PASS
CCV	Continuing Calibration Verification	PASS
CCB	Continuing Calibration Blank	FAIL

Chart 12: Sample LQC Data and Associated Possible Diagnosis - Contaminated Consumables

If multiple blanks show contamination, then it is likely that some component in the sample prep process is contaminating all of the samples (or many of them) in the analytical batch. Positive controls, such as the LCS, may have larger expected values, so the contamination may not be visible or shown in the available statistics.

Contaminated Matrix Proxy (Minor)		
PB	Prep Blank	PASS
MB	Matrix Blank	FAIL
LCS	Lab Control Standard	PASS
LRS	Lab Replicate Sample	PASS
ICV	Independent Cal Verification	PASS
CCV	Continuing Calibration Verification	PASS
CCB	Continuing Calibration Blank	PASS

Chart 13: Sample LQC Data and Associated Possible Diagnosis – Contaminated Matrix Proxy (Minor)

If only one blank fails, and it is the Matrix Blank (MB), the matrix proxy used to prepare the LQC may either be contaminated or exhibiting an interference-based false positive. Switching the MB to a new material as a diagnostic tool in identifying the source of contamination is a natural next step.

Contaminated Matrix Proxy (Major)		
PB	Prep Blank	PASS
MB	Matrix Blank	FAIL
LCS	Lab Control Standard	FAIL
LRS	Lab Replicate Sample	PASS
ICV	Independent Cal Verification	PASS
CCV	Continuing Calibration Verification	PASS
CCB	Continuing Calibration Blank	PASS

Chart 14: Sample LQC Data and Associated Possible Diagnosis – Contaminated Matrix Proxy (Major)

If both the Matrix Blank (MB) fails and laboratory Control STD (LCS) fails, the matrix proxy

may be so contaminated that it is interfering with %R of the LCS. It is a sign of more significant contamination than what was outlined in .

Instrument Carry-Over		
PB	Prep Blank	FAIL
MB	Matrix Blank	FAIL
LCS	Lab Control Standard	PASS
LRS	Lab Replicate Sample	PASS
ICV	Independent Cal Verification	PASS
CCV	Continuing Calibration Verification	PASS
CCB	Continuing Calibration Blank	FAIL

Chart 15: Sample LQC Data and Associated Possible Diagnosis – Instrument Carry-Over

If all blanks fail, but all positive controls pass, the contamination may not be from sample prep and consumables but from instrument carry-over between runs. It means the method needs to be modified to allow for a more thorough purging of analytes between analytical sample runs. It can be verified with a null injection (tray position = -1), which performs an analytical run without injecting a volume of the analytical sample from the vial. If the null injection is contaminated, then that confirms that the instrument carry-over is the issue causing the LQC failures.

Instrument Mis-Calibration		
PB	Prep Blank	PASS
MB	Matrix Blank	PASS
LCS	Lab Control Standard	FAIL
LRS	Lab Replicate Sample	PASS
ICV	Independent Cal Verification	FAIL
CCV	Continuing Calibration Verification	FAIL
CCB	Continuing Calibration Blank	PASS

Chart 16: Sample LQC Data and Associated Possible Diagnosis – Instrument Mis-Calibration

If the blanks are all passing, and the LRS is passing, but all other positive controls are failing, then the issue is miscalibration. It can be fixed by re-running existing calibration dilutions, and if the problem persists, preparing a fresh calibration curve from a stock solution will cure it. Check the R^2 of the calibration curves after re-running the calibration dilutions to verify the calibration is BCC or equivalent state regulator compliant.

Instrument Drift (Detector Stability) [Major]		
PB	Prep Blank	PASS
MB	Matrix Blank	PASS
LCS	Lab Control Standard	FAIL
LRS	Lab Replicate Sample	FAIL
ICV	Independent Cal Verification	FAIL
CCV	Continuing Calibration Verification	FAIL
CCB	Continuing Calibration Blank	PASS

Chart 17: Sample LQC Data and Associated Possible Diagnosis – Instrument Drift (Detector Stability) [Major]

If blanks pass but all positives, including CCVs, are failing, then it is likely that in addition to a possible miscalibration, there may also be instrument drift. The sole distinction between these concepts lies in their continuity: a miscalibration could be a consistent and replicable process that is not accurately centered on the most precise result. Conversely, a detector drift might initiate with a perfect calibration at the commencement of the analytical batch but drift so rapidly in response that subsequent samples in the batch fall outside the acceptance window of compliance criteria.

Instrument Drift (Detector Stability) [Minor]		
PB	Prep Blank	PASS
MB	Matrix Blank	PASS
LCS	Lab Control Standard	PASS
LRS	Lab Replicate Sample	FAIL
ICV	Independent Cal Verification	PASS
CCV	Continuing Calibration Verification	FAIL
CCB	Continuing Calibration Blank	PASS

Chart 18: Sample LQC Data and Associated Possible Diagnosis - Instrument Drift (Detector Stability) [Minor]

Sometimes, the instrument drift is very subtle and does not cause all positive controls (such as the LCS) to fall outside of the acceptance criteria. However, it is still essential to diagnose instrument detector drift as it is one of the primary causes of batch failure, particularly late or end-of-batch CCVs. The LRS can sometimes detect drift the earliest because it analyzes two identical injections and measures their deviation. If this number is very high, even if all other LQCs pass, there is still significant instrument drift.

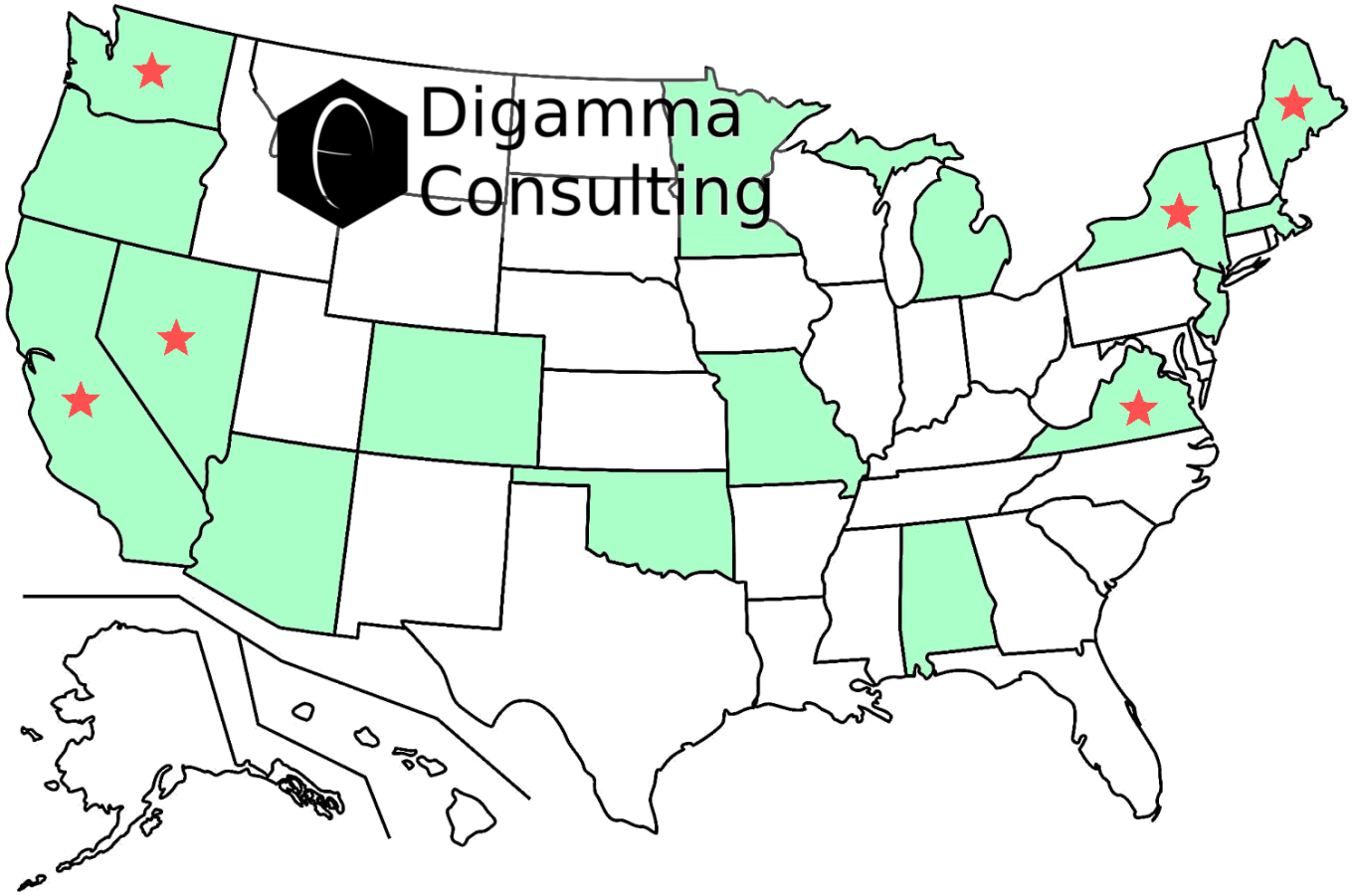
Expired Standards (CAL or ICV or both)		
PB	Prep Blank	PASS
MB	Matrix Blank	PASS
LCS	Lab Control Standard	PASS
LRS	Lab Replicate Sample	PASS
ICV	Independent Cal Verification	FAIL
CCV	Continuing Calibration Verification	PASS
CCB	Continuing Calibration Blank	PASS

Chart 19: Sample LQC Data and Associated Possible Diagnosis – Expired Standards (CAL or ICV or both)

If all LQCs pass except for the ICV, then the issue may be that the standards the analyst is working with are expired and no longer valid. Even if the standard is not expired, improper storage conditions, which may not be visible or detected by the analyst using the standard, could also cause the accuracy of the calibration to falter. If this issue occurs, re-prepping all calibration and ICV standards from fresh stock solutions generally resolves the problem. If time and resources permit, a small diagnostic experiment can be performed to track the source of the error, allowing it to be noted in the lab's QMS error logs and allowing future edits and changes to methodologies to avoid or minimize those errors.

Appendix 4: Digamma Company *Cirriculum Vitae* and Experience

Digamma's typical clients include start-up cannabis analysis labs in 16 states and 4 countries, including New Zealand, Germany, Pakistan, and the United States. We have shown a map representing our licensed clients below:



An outline of the consulting projects successfully performed by Digamma Consulting, totaling over 45 laboratories. Digamma Consulting performs validations on chemical processes and drafts, edits, and submits laboratory validation reports (analytical) or applications (manufacturing) to regulatory bodies needed for state license application. If other services were performed they are indicated below.

ACTION	COMPANY	LOCATION	START	END	TASK
Founding	Digamma	Oakland, CA	2013/12/01	Present	Creating Initial Company Names, Data Systems, Marketing Material, Etc
Product Development	Flow Kana	Oakland, CA	2014/03/15	2014/03/16	Consulting for regulations in the cannabis industry
Analytical Laboratory Installation	Cannabinology	San Rafael, CA	2016/12/05	2018/03/26	Installation of Analytical Laboratory: Cannabinoids, Terpenes, Solvents, Pesticides, Metals
Incorporation	Digamma	Oakland, CA	2017/01/01	Present	Creating Initial Bank Account, Fictitious Name State, Filing Incorporation and Tax Documents
Analytical Laboratory Installation	Guild Extracts	Oakland, CA	2017/04/03	2018/12/05	Consulting for THC product start up
Analytical Laboratory Installation	Bel Costa Labs	Long Beach, CA	2017/06/16	2019/10/07	Installation of Analytical Laboratory: Cannabinoids, Terpenes, Pesticides, Metals
Analytical Laboratory Installation	Forensic Analytical Laboratories	Hayward, CA	2017/07/03	2018/08/14	Installation of Analytical Laboratory: Solvents
Product Development	Bend Solutions Group	Bend, OR	2017/07/27	2017/08/08	Consulting for CBD product start up
Product Development	CB Therapeutics	San Diego, CA	2017/08/09	2018/01/30	Consulting for synthetic cannabinoid synthesis start up
Product Development	Arya	Denver, CO	2017/08/09	2017/09/08	Consulting for CBD product start up
Product Development	TruCBD	Bend, OR	2017/08/11	2017/09/18	Consulting for CBD product start up
Product Development	Phil Borghuis	Corte Madre, CA	2017/10/19	2017/10/24	Consulting for CBD product start up
Product Development	Purple Queen Production	Las Vegas, NV	2017/10/20	2017/10/24	Consulting for CBD product start up
Application Consultation	Higher Yields Consulting	Denver, CO	2017/11/08	2019/09/28	Consulting for cannabis state licensing applications
Product Development	Divine Alchemy	San Francisco, CA	2017/11/12	2017/12/28	Consulting for vape start up
Product Development	Flowerpilot	Berlin, Germany	2017/11/17	2018/08/06	Consulting for novel instrument development
Analytical Laboratory Installation	Pure Analytics	Santa Rosa, CA	2017/12/18	2018/01/21	Installation of Analytical Laboratory: Pesticides
Product Development	Kin Slips	Oakland, CA	2018/02/26	2018/10/12	Consulting for THC product start up
Analytical Laboratory Installation	Encore Labs	Pasadena, CA	2018/03/03	2018/04/27	Installation of Analytical Laboratory: Pesticides

ACTION	COMPANY	LOCATION	START	END	TASK
Product Development	Om Edibles	Berkeley, CA	2018/03/04	2018/06/08	Consulting for THC product start up
Analytical Laboratory Installation	Health Liberty Products	Nelson, New Zealand	2018/04/29	2019/06/19	Installation of Analytical Laboratory: Cannabinoids
Data Consulting	Emerald Scientific	San Luis Obispo, CA	2018/04/29	2020/10/19	Consulting for data analysis and data reporting
Analytical Laboratory Installation	BioCann Labs	Irvine, CA	2018/09/25	2020/05/04	Installation of Analytical Laboratory: Cannabinoids, Terpenes, Solvents
Analytical Laboratory Installation	Movad Labs	Los Angeles, CA	2018/10/05	2020/04/26	Installation of Analytical Laboratory: Cannabinoids, Terpenes, Solvents, Pesticides, Metals
Court Witness	Michael Cindrich	San Diego, CA	2019/01/03	2020/03/01	Consulting as scientific expert witness for legal trials
Methodology Documents	Green Country Scientific	Tulsa, OK	2019/01/24	2019/04/05	Licensing of Analytical Methodology Procedure Documentation
Analytical Laboratory Installation	Evio	Berkeley, CA	2019/02/11	2019/02/25	Installation of Analytical Laboratory: Pesticides
Methodology Documents	Apricot Analytics	Oakland, CA	2019/05/16	2019/06/19	Licensing of Analytical Methodology Procedure Documentation
Analytical Laboratory Installation	EcoGen Labs	Grand Junction, CO	2019/06/11	2019/06/14	Installation of Analytical Laboratory: Cannabinoids
Analytical Laboratory Installation	NatureSafe Labs	San Diego, CA	2019/09/02	2020/09/02	Installation of Analytical Laboratory: Cannabinoids, Terpenes, Solvents, Pesticides, Metals
Analytical Laboratory Installation	Verity Analytics	San Diego, CA	2019/09/10	2020/01/08	Installation of Analytical Laboratory: Cannabinoids, Terpenes, Solvents, Pesticides, Metals
Analytical Laboratory Installation	ACT Labs	Lansing, MI	2020/01/07	2020/02/25	Installation of Analytical Laboratory: Solvents, Pesticides
Analytical Laboratory Installation	ProForma Labs	Salinas, CA	2020/06/08	2021/02/22	Installation of Analytical Laboratory: Cannabinoids, Terpenes, Solvents, Pesticides, Metals
Analytical Laboratory Installation	Cloud TEN	Saint Louis, MO	2021/02/05	2021/08/31	Installation of Analytical Laboratory: Cannabinoids, Terpenes, Solvents, Pesticides, Metals
Analytical Laboratory Installation	Green Precision Anaytics	Kansas City, MO	2021/04/26	2021/09/14	Installation of Analytical Laboratory: Solvents

ACTION	COMPANY	LOCATION	START	END	TASK
Manufacturing Facility SOPs and application	LexiCann NJ	Jersey City, NJ	2021/11/07	2021/12/14	Authoring of Quality and Operations Manual
Manufacturing Facility SOPs and application	Harvest Works Farms	Molmdel, NJ	2021/10/26	2021/12/14	Authoring of Quality and Operations Manual
Legislative Consultation	Oneida Indian Nation	Oneida, NY	2022/03/04	2022/03/25	Consulting on Legislation for a Sovereign Indian Nation acting as a State Government
Analytical Laboratory Installation	ATC Labs	Scarsdale, AZ	2022/04/13	2022/06/21	Installation of Analytical Laboratory: Solvents, Pesticides, Terpenes
Analytical Laboratory Installation	Steadfast Lab	Hazel Park, MI	2022/05/13	2022/05/16	Authoring of Standard Operating Procedures for Pesticides
Analytical Laboratory Installation	Bloomfield Hills, MI	Warren, MI	2022/04/13	2022/06/21	Authoring of Standard Operating Procedures for Solvents
Analytical Laboratory Installation	CATLAB	Kittery, ME	2022/06/06	2022/06/22	Installation of Analytical Laboratory: Solvents
Analytical Laboratory Installation	Green Precision Anaytics	Kansas City, MO	2022/07/25	2022/08/05	Installation of Analytical Laboratory: Cannabinoids and Terpenes
Analytical Laboratory Installation	Green Precision Anaytics	Kansas City, MO	22/10/09	2022/11/04	Installation of Analytical Laboratory: Pesticides
Manufacturing Facility SOPs and application	Evexia	Tuscaloosa, AL	11/07/22	12/20/22	Authoring of Quality and Operations Manual
Analytical Laboratory Installation	Phyto-Farma Labs	Warwick, NY	03/03/23	04/04/23	Installation of Analytical Laboratory: Microbiology
Analytical Laboratory Installation	Mille Lacs Corporate Ventures	Onamia, MN	03/07/23	04/12/23	Installation of Analytical Laboratory: Lab-Wide Cost Benefit Analysis