TESTING IN THE CBD INDUSTRY

How to Build Consumer Trust and

Avoid 6 Types of Testing Errors

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A Checklist For Your Company

To Execute Best Practices

OPEN BOOK EXTRACTS

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INTRODUCTION

The CBD industry is currently at risk of losing credibility with consumers due to inaccurate product labeling. Doctors suggested regulatory intervention in 2017, after a study **found that 70% of CBD products sold online did not contain the amount of advertised CBD**. A recent FDA report in March of 2020 shared that many CBD products "were found to not contain the levels of CBD they claimed," demonstrates that this issue has not been adequately addressed yet. Companies that continue to sell products with too much or too little CBD will erode customer trust and possibly risk consumer health.

Mislabelled CBD products may be the result of inconsistent testing practices. After all, companies cannot accurately tell consumers how much CBD a product contains if they themselves do not know. Because the CBD industry has no specific industry standards regarding potency testing for cannabinoids, test results vary between the many parties testing CBD products. This lack of regulatory standards has allowed companies and laboratories to use a range of testing methods that may all yield different outcomes for identical materials.

In this paper, we will explain why current testing produces such a high degree of variance, and what companies can do to increase testing reliability. We will also explain how OBX uses internal and external testing to ensure product accuracy. Finally, we will offer a testing checklist for both processors and brands to use to remain proactive with your QA/QC testing practices.

TEST RESULT VARIATIONS

In order to assess and demonstrate the variability in cannabinoid testing, OBX sent samples of identical material to five different third party labs. The following table reveals the labs' results for the percentage of CBD and two minor cannabinoids present in the distillate samples:

LAB	CBD MASS %	MINOR CANNABINOID 1 MASS %	MINOR CANNABINOID 2 MASS %
A	96.10	2.19	0.78
B	96.57	2.16	0.68
C	84.43	2.99	not detected
D	90.11	1.88	0.56
E	96.95	2.35	0.48

Table 1: Potency data from five different third party labs showing results for CBD and two minor cannabinoids in a distillate sample

Even though the given samples were identical, the labs reported vastly different levels of cannabinoids. Lab E, for example, reported a CBD mass percentage of 13.8% greater than Lab C. On average, the sample was said to contain a mass of 92.8% CBD. However, the standard deviation amongst samples was 5.5%. This means that on average, these labs may report a 5.5% difference of CBD mass in identical samples.

The results of minor cannabinoid testing revealed even greater differences. Lab D, for example, reported a minor cannabinoid one mass of 1.88%, whereas lab C reported 2.99%, revealing an overall mass percentage difference of 45.59%. The testing mass percent difference of minor cannabinoid 2 was even higher at 47.62%. In order to understand the causes and significance of these variable results, it is necessary to understand the testing methods that produce them.

CAUSES OF TEST ERROR

There are many contributing factors for the variance in potency data amongst testing labs. Some, but not all, of the reasons are described below.

1. Sample Preparation

Testing labs use a variety of methods to prepare different types of samples. Different products– including crude extracts, distillates, isolates and finished goods– are often handled in different ways. For example, flower material may be tested after being heat-dried, air dried, or not dried at all. These different preparation methods would all yield different tested potencies.

For flower material, each method of sample preparation has its own unique benefits and drawbacks. For example, heat-drying samples is a good way to remove excess moisture, but excessive heat can change the cannabinoid profile and potentially alter the content of other low-volatility compounds). On the other hand, choosing not to dry samples eliminates the risk of changing the cannabinoid content, but makes it harder to obtain consistently accurate results. Air-dried flower samples take longer to prepare but likely produce more accurate results.

We recommend that labs test air-dried flower samples. However, other methods of sample preparation are acceptable, so long as labs consistently use the same method.

2. Sample Homogeneity

The cannabinoid content found in a cross-section of some material does not always accurately reflect the potency of the whole sample. Some high CBD concentration distillates crystallize when resting at ambient temperature. If these samples are not homogenized before analysis, the uneven distribution of CBD in them can produce inaccurate results.

Ensuring sample homogeneity is a great way to improve test results accuracy. In order to make sure that samples are evenly mixed, labs will often have to invest in the time and infrastructure for achieving a representative sample. We recommend that tests should only be run on effectively homogenized samples.

3. Instrumentation and Testing Technique

A variety of instruments are used throughout the process of potency testing. HPLC (High Performance Liquid Chromatography) and UPLC (Ultra Performance Liquid Chromatography) systems use many different methods and columns to separate cannabinoids during testing. If cannabinoids are not effectively separated, test results may be inaccurate. Labs also use balances, pipettes, and glassware during sample preparation, which all introduce opportunities for user error. In particular, inconsistent pipetting technique amongst lab technicians may cause erratic results.

In order to minimize these kinds of errors, labs should use precision instruments. Proper training of lab personnel should also be a top priority. With effective instrumentation and testing techniques, labs can improve sample preparation and analytical instrumentation operations, leading to more accurate and consistent results.

4. Human Error

Human error can compound the challenges of potency testing. In our experience, third party labs have occasionally provided "false positives" by reporting the existence of cannabinoids that were not present in the given samples. Some labs also produce "false negatives." This can occur when cannabinoid concentration falls below the LOQ (Limit of Quantitation).

Well trained employees and properly calibrated systems can go a long way towards improving test accuracy. We recommend that testing personnel are properly trained to ensure that mistakes due to reporting or inaccurate interpretation of data are minimized. When in doubt, it can be helpful to prioritize ISO certified labs, as these labs must be deemed technically competent by third-party accreditors.

5. Reliance on Software

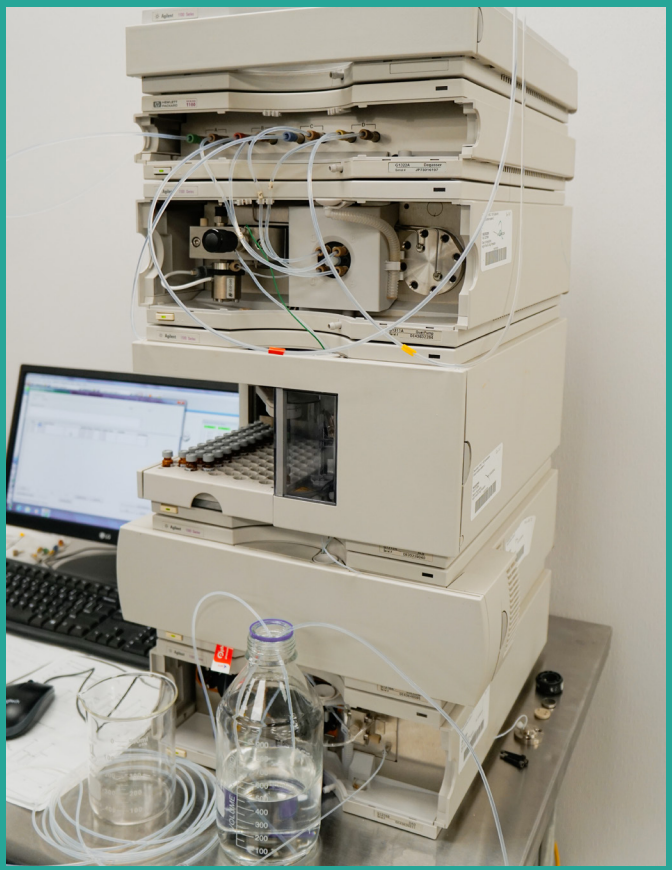
Complete reliance on software can also cause difficulties in data analysis. Chromatography systems have many different components that must work together to provide sound, high-quality data. One dysfunctional component may affect the entire system and potentially affect data integrity. Software is also prone to malfunctions and may result in the generation of misleading results.

It is extremely important to have well-trained analytical personnel who can identify instrument errors and recognize inconsistent data due to software glitches. We also recommend that system software and data collection protocols are routinely reviewed to ensure quality data capture and analysis.

6. Cannabinoid Standard Sourcing and Preparation

Test labs must use reference material to calibrate their instrumentation and testing methods. Despite the illicit status of THC, reference standards are now routinely provided to analytical labs by a handful of DEA-exempt suppliers. These certified reference materials are needed to generate calibration curves and accurate potency testing data.

Accurate calibration curves are absolutely essential to accurate test results. In order to ensure proper calibration, we recommend that labs calibrate systems with certified reference material and subsequently monitor their systems for calibration deviations.



THIRD PARTY TESTING & INTERNAL TESTING

In order to consistently produce or procure quality CBD products, multiple rounds of potency and quality testing are often needed. It is possible to test the cannabinoid concentration of hemp plants, finished cannabinoid products, or anything in between. It may also be beneficial to internally and externally test the same sample to verify results. In short, decisions around how, when, and with whom to test cannabinoids can impact results.

Internal testing helps cannabinoid producers churn out consistent products. If the CBD production process can be reduced to a series of reliable steps, internal testing can be used to ensure that those steps are indeed producing consistent results.

For example, if producers can process hemp into crude oil and crude oil into distillate in consistent and predictable ways, then the known cannabinoid content of hemp can be used to predict the cannabinoid content of its distillate. This becomes very important during the process of formulating products with specific cannabinoid profiles. Here, accurate internal and external testing can ensure that consumers get correctly labeled products.

External testing may also be used to validate internal testing and cultivate trust amongst consumers. Third-party labs have no incentive to report higher or lower cannabinoid numbers, so their results are often considered more trustworthy. Further, given the previously described inconsistencies in cannabinoid testing, it is helpful to have multiple corroborating tests on one sample.

Testing CBD products multiple times–as well as internally and externally–may be well worth the effort for wholesalers and retailers. Consistent processing methods and internal testing can improve internal efficiency and improve the quality of product labeling. Meanwhile, third party testing can increase consumer trust.

CONCLUSION

Over the past few years, academic studies and FDA reports have suggested that many CBD products are inaccurately labeled. Some of this mislabeling can be chalked up to inaccurate testing. When OBX sent identical samples to five different third-party labs for cannabinoid concentration testing, each lab came back with different results; there was a wide variation in the reported results.

These discrepancies can be explained by variations in sample preparation, sample homogeneity, instrumentation, testing techniques, human error, software error, and troubles with cannabinoid sourcing and calibration. Because of the relative inaccuracy of current cannabinoid testing methods, we believe that a combination of internal and external testing are currently necessary to ensure product quality and consumer safety.

In the future, standardized practices or regulatory oversight could improve the reliability of cannabinoid testing. We are hopeful that the industry will move towards the standardization of testing procedures and protocols. Standardization of industry test methods and requirements will improve the quality of labeling and ultimately result in higher consumer confidence. For now, CBD suppliers and retailers share a responsibility to understand the current state of testing procedures and hone their methodology to deliver quality products to consumers. A strong focus on reliable and accurate cannabinoid testing should increase consumer safety and trust, and strengthen the CBD industry as a whole.

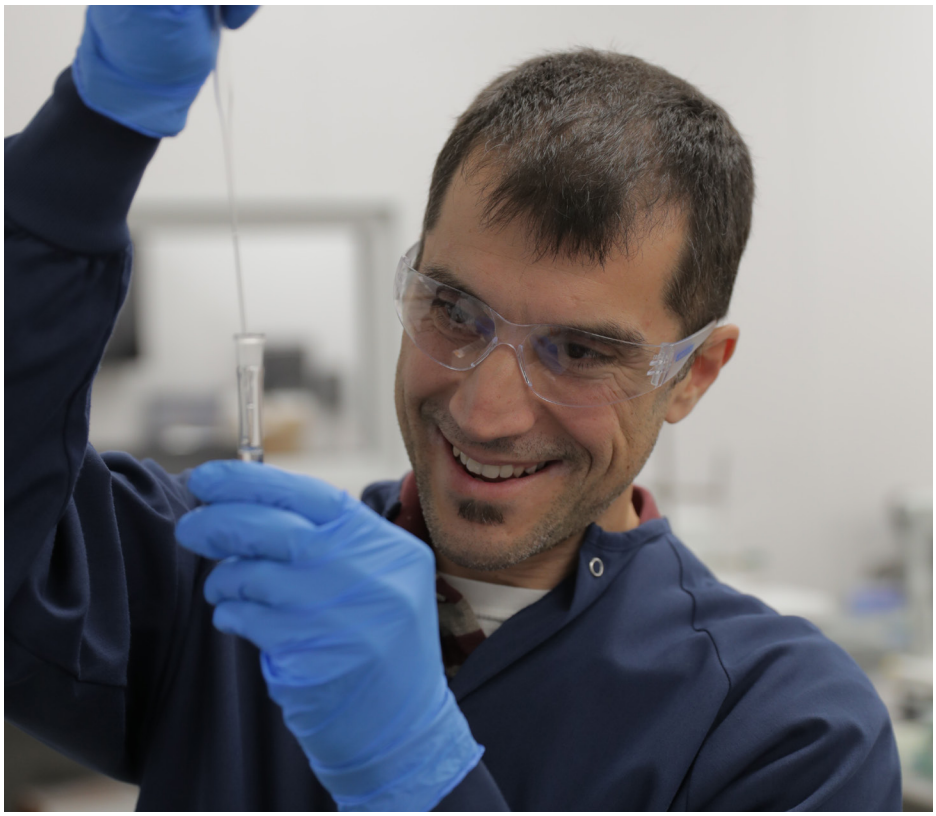
PROCESSORS & MANUFACTURERS
TESTING CHECKLIST

- [ ] Establish an internal protocol to test samples and improve process and product quality
  - [ ] Ensure your testing equipment is well-maintained
  - [ ] Test samples are always prepared in the same way following SOPs
  - [ ] Tests are recorded using proper software with the capability to pull proper batch reports, identify data inconsistencies & variation, and support your QA team with drawing conclusions to improve product quality
  - [ ] Software analysis is overseen by properly trained personnel
  - [ ] Establish a process for identifying root cause and corrective action for testing variation
  - [ ] Utilize external testing results to continually have a system of checks and balances until industry wide testing standards are adopted
  - [ ] Lab periodically monitors system suitability and calibration
- [ ] Test your samples with numerous third party labs to ensure the quality of tests ran from third party
- [ ] Use certified reference materials in your test lab

BRANDS & CPG COMPANIES
TESTING CHECKLIST

- [ ] Ensure your ingredients and finished products are tested thoroughly with your supply chain partners
  - [ ] Track ingredient COAs and test results from your ingredient supplier
  - [ ] Test samples are always prepared in the same way following SOPs
  - [ ] Ensure you're receiving consistent product quality from your supply chain partner
- [ ] Verify your test results from your ingredient and finished product supplier with third party lab testing
- [ ] Educate your consumers on the extent to which you test your products and how to properly interpret COAs

INSIGHTS & RECOMMENDATIONS
PROVIDED BY:



David Temelkoff

Quality Control Manager

Analytical chemist with extensive quality control, instrumentation, and R&D background during his 15 year career at GlaxoSmithKline. Expert in analytical techniques using NMR spectrometry, GCMS, HPLC, LCMS, IR, TLC, et al.

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317 Lucy Garrett Road
Roxboro, NC 27574
info@openbookextracts.com