Buyer Beware: Cannabinoid Analysis in Cannabis Products

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Disclosures and Disclaimers

• Disclosure
  • I work for and own a portion of ChemaTox Laboratory, Inc.

• Disclaimer
  • I have no affiliation or interest in any of the other companies, brands, groups, or organizations mentioned in this presentation.
  • All information is provided for educational purposes only.
Me, then Lunch

Today and tomorrow, I am all that stands between you and your lunch break!
Once Upon a Time ...

There was the state of Colorado and marijuana was not legal
Then everything changed

• 2000 – Colorado passes Amendment 20: Medical use of marijuana for persons suffering from debilitating medical conditions
  • CO Constitution art. 18, §14(2)(b)

• 2007 Judge’s ruling causes a change in caregiver/patient status allowing unlimited patients per caregiver

• January 2009 Obama takes office
  • October 2009 the U.S. Deputy Attorney General David Ogden issues guidelines for prosecutors
The rise in numbers

• 2009 to 2010 – Medical Marijuana (MMJ) registrations rise from less than 10,000 to over 100,000
  • Marijuana dispensary numbers skyrocket
    • 2009: 0 to ~250
    • Mid 2010: ~900
  • Popular press claims
    • More dispensaries then Starbucks in Denver
    • 15 Colorado Doctors Make 75 Percent of Medical Pot Recommendations

• 2012 – Nov. 6th Amendment 64 passes allowing recreational use
  • Ratified in Dec. 2012
• 2013 – Permissible Inference at 5 ng/mL THC in whole blood passes
• 2014 – Jan. 1st The first recreational marijuana stores open
Amendment 64 Vote – Green = Yes, Red = No
http://en.wikipedia.org/wiki/File:Colorado_Amendment_64_map.svg
Dispensaries (16) vs. Starbucks (8)

www.weedmaps.com

www.starbucks.com
Definitions

• “Industrial Hemp” means a plant of the genus Cannabis and any part of the plant, whether growing or not, containing a delta-9 tetrahydrocannabinol (THC) concentration of no more than three-tenths of one percent (0.3%) on a dry weight basis.

• "Edible Medical Marijuana - Infused Product" means any Medical Marijuana - Infused Product that is intended to be consumed orally, including but not limited to, any type of food, drink, or pill.
• "Proficiency Testing Samples" means performing the same analyses on the same Samples and comparing results to ensure the Samples are homogenous and stable, and also that the set of Samples analyzed are appropriate to test and display similarities and differences in results.

• "Sample" means anything collected from a Medical Marijuana Business that is provided for testing to a Medical Marijuana Testing Facility or a Retail Marijuana Testing Facility in accordance with Rule M 701 – Vendor Registration and Occupational License for Medical Marijuana Testing and Research.

• “Cannabinoid” means any of the chemical compounds that are the active principles of marijuana.

• "THC" means tetrahydrocannabinol

• "THCA" means tetrahydrocannabinolic acid (not THC-COOH)
Testing
Testing of THC Products

• Testing potency
  • Required THC, THCA, CBD, CBDA and CBN.
    • Any cannabinoid potency can be on a label if tested
  • 100 mg of THC limit on edibles
  • Dried and cured flowers must be tested
  • Products must be homogenous
    • If 10% of the product contains 20% or more of the THC it fails

• Other drugs are not on the list
• Acceptable methods are not fully defined
• www.colorado.gov/revenue/med
Facilities

- Number of Licensed Retail Marijuana Businesses as of November 2, 2015
  - 394 Stores
  - 505 Cultivations
  - 152 Product Manufacturers
  - 17 Testing Facilities
Mandatory Testing

• Testing Areas
  • Residual solvents
  • Poisons or Toxins
  • Harmful Chemicals
  • Dangerous Molds, Mildew or Filth
  • Harmful Microbials, such as E. Coli or Salmonella
  • Pesticides
  • THC and other Cannabinoid potency
    • Homogeneity Testing
• Rules: M 700 Series – Medical Marijuana Testing Facilities
  • Language modified from DUI/D Lab Rules and Regs
THC & other Cannabinoid Potency

- Who does the testing
- How do they do the testing
- What can go wrong
- Why are there are issues
State Certified Labs

• Standards of performance include but are not limited to:
  • personnel qualifications
  • standard operating procedure manual
  • analytical processes
  • proficiency testing
  • quality control & quality assurance
  • security, chain of custody
  • specimen retention
  • results reporting
State Certified Labs

• Labs have to be inspected by Colorado Department of Public Health and Environment (CDPHE)
• Must do proficiency testing

• List is maintained by the State
• [https://www.colorado.gov/pacific/enforcement/med-licensed-facilities](https://www.colorado.gov/pacific/enforcement/med-licensed-facilities)
Major Steps - Potency

• Product goes to licensed lab and they:
  • Extract THC from product
  • Use quantitative methods for testing
    • GC/MS & LC-MS/MS is common
    • Calculate THC%
  • Report results to Client so they can release batch
    • Enter data into state tracking system
The Issues

• Product goes to licensed lab
  • Sampling

• Extract THC from product
  • Non standard methods
  • Extraction efficiency

• Use calibrators and controls to make curve
  • Lack of matrix matched cals and controls

• Compare unknown to known
  • How known is the known really?
Sampling

- Inherently not evenly distributed
- Edibles
- Storage
  - Moisture
  - Heat
- Representative of batch
Extract THC

- Many different matrix options = Many SOPs
  - Candy
  - Baked goods
  - Drinks
  - Dabs
  - Plant
  - Tinctures
  - Infused oils
- One method for all cannabinoids in one lab?
- Every lab has a different method
Extraction Recovery

• % Recovery is critical for many methods

• Matrix matched controls
  • Many matrix options
  • Spiking after the fact - no

• Extracting from food

• Source of Control material

• Reference lab - none yet

• Standard addition methods
Accuracy and Precision

• Variation between tests and labs large

• For CBD only (hemp) strains
  • THC must be less then 0.3%
  • Need low limit of detection
  • High accuracy and precision

• Calibrators, controls, and standards are traceable to National Institute of Standards of Technology (“NIST”)
  • How??
Proficiencies

• First Round - December 7, 2015

• DOR will determine the options for obtaining appropriate marijuana from growers/retail for use in PT samples

• Following the end of the PT event, a panel of experts may be convened to determine the maximum permissible error
Major Road Block
U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

AUG 18 2011

Dear Registrant:

This letter is being sent to every Drug Enforcement Administration (DEA) registered analytical laboratory. DEA has recently received questions from analytical laboratories regarding from whom they may receive samples of controlled substances to conduct analytical testing for potency and contaminants. The purpose of this letter is to reiterate existing federal regulations on this matter.

The Controlled Substances Act (CSA) and its implementing regulations established a closed system of distribution so that controlled substances are at all times under the legal authority of an entity registered by DEA, or specifically exempted from registration. 21 U.S.C. § 822(a)(2) and 21 C.F.R. § 1301.11(a). All DEA registrants are required to carry out their activities involving controlled substances in conformity with the CSA and its implementing regulations.

DEA regulations govern any movement of controlled substances between these registered entities, thus the closed system facilitates an accurate accountability of all controlled substances from manufacturing through dispensing to ultimate users. A DEA registered analytical laboratory is only authorized to receive controlled substances for analysis from another DEA registrant, or an entity that is specifically exempted from registration pursuant to 21 C.F.R. § 1301.23 or 21 C.F.R. § 1301.24. Therefore, analytical laboratories are not authorized to accept controlled substances from individuals that are not registered, or are not specifically exempt from registration, with the DEA.

Questions regarding this correspondence may be directed to DEA’s Liaison and Policy Section, Office of Diversion Control, at (202) 307-4654.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator/
Deputy Chief of Operations
Office of Diversion Control

No Marijuana Testing
Source of THC Materials

- DEA
  - Closed system
  - Can only receive from and report to other registered or exempt agencies

- Cannot get from out of state
  - Illegal to mail and transport
What we are seeing

• Mandated testing before testing available
• Inconsistencies
  • Testing methods
  • Source material
• Results
  • Split testing results are getting better
  • 10% - 20% variation normal
• Making the rules as we go along
  • There have been hiccups
  • 2011 lab shut down pre Current MED
Slow Process

- It is a moving target
  - Legislatively set dates

- Pushing dates back
  - Homogeneity

- Many unknowns

- Limited resources
  - New territory
Standardization via CDPHE

• HB15-1283 signed June 2015
Creating a reference lab by December 31, 2015

The reference library is responsible for:
  proficiency testing
  remediating problems with licensed laboratories

This library must contain a catalog of methodologies for marijuana testing areas of potency, homogeneity, contaminants, and solvents

Addressing Proficiency Testing
Other Testing Notes
Residual solvents

• 6 Labs
• Butane Hash Oil (BHO)

• Solvent - Based Retail Marijuana Concentrate
• Only the following solvents are allowed:
  • butane, propane, CO2, ethanol, isopropanol, acetone, and heptane

• Moving to closed loop systems
Pesticides

- Governor - 2015
  - Directing state agencies to address threats to public safety posed by marijuana contaminated by pesticide

- Until scientific assessment establishes which additional pesticides can be safely applied to marijuana, marijuana contaminated by and Off-Label Pesticide shall constitute a threat to the public safety.
Contaminants

• Investigation of edibles making people sick
  • Too much THC or something else

• Metals: Arsenic, Cadmium, Lead and Mercury
• Bugs or bug parts
• Mold
• Shiga-toxin producing Escherichia coli (STEC)
• Salmonella
• Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger - Fungus
Now What

- On going work under HB15-1283
- National changes?
- Time and resources
- Reactions to new problems
Time for Lunch!

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References

   http://www.mcgeorge.edu/Documents/Publications/07_Kamin_EIC_FINAL.pdf
2. Marijuana Enforcement Division, Medical Marijuana Statistics
   http://www.colorado.gov/cs/Satellite/CDPHE-CHEIS/CBON/1251593017044
3. Marijuana Enforcement Division, News and Information, (4/18/2014)
12. www.colorado.gov/marijuana
References

6. Vote No on HB 13-1114, the 5 nanogram limit for THC driving http://www.change.org/petitions/coloradolegislature-vote-no-on-hb-13-1114-the-5-nanogram-limit-for-thc-driving