

*in this issue*

**ANALYTICAL**  
Beer's Law:  
Demystifying  
Absorptivity

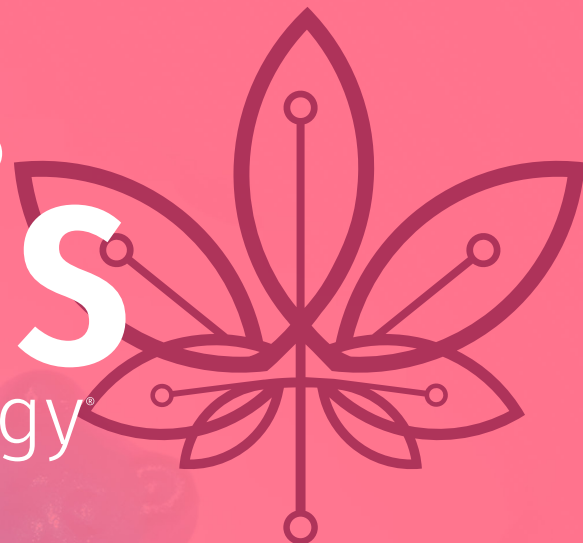
**CULTIVATION**  
LED Lights Lead  
the Way

**EXTRACTION**  
Fundamentals  
of Supercritical  
Fluid Extraction

may 2022 | vol 5 • no 4

# cannabis

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## Note from the CEO

### Cannabis Education Moves the Cannabis Industry Forward

**WELCOME TO THE** latest issue of *Cannabis Science and Technology*®! Currently, we are ramping up for the Cannabis Science Conference (CSC) West taking place in Long Beach, California at the Long Beach Convention Center from May 18–20. This exciting event will include cannabis industry experts, testing laboratories, medical practitioners, instrument manufacturers, research scientists, policy makers, and interested novices all pulled together to learn, share ideas with one another, and help the cannabis industry move forward. We are looking forward to seeing our readers as well as speakers such as Montel Williams and Richard van Breenman and other attendees at this year's Cannabis Science Conference West show. Gathering at the Cannabis Science Conference West provides a great platform for cannabis education. With the stigma on the industry and federal decriminalization still trying to prevent cannabis from moving forward, it is crucial to continue showing the medicinal benefits and scientific properties of the cannabis plant to promote change and advocate for it.

Just like the Cannabis Science Conference program, it is also *Cannabis Science and Technology*®'s main goal to explore the science of cannabis and hemp by supporting the educational research performed on these tremendous plants. Here, our latest issue explores a variety of topics seen in the cannabis industry. In this month's "Cannabis Analysis" column, Brian Smith ventures into Part III of his discussion on Beer's Law and why absorptivity is important along with some of its advantages and limitations. For our featured articles, Erin McEvoy talks with Abbey Roubush, Director of Government Affairs for Americans for Safe Access (ASA), about the goals of ASA and the topics mentioned at their annual State of the States report. In "Tech Innovations," David Hodes examines and reviews various extraction processes, new products, and new equipment being used for better and safer extractions. In "Cultivation Classroom," Madeline Colli interviews David Cohen, CEO of Fluence, and discusses the popularity in LED lighting methods and how it is the preferred product used in the industry. These are just some of the highlights found within these pages.

Enjoy the May 2022 issue of *Cannabis Science and Technology*®!

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## Beer's Law, Part III: *Demystifying the Absorptivity*

By **Brian C. Smith**

In my previous two columns I introduced you to Beer's Law. In the first column (1), we examined the Beer's Law equation and how it relates light absorbance to concentration, and how to use Beer's Law to determine cannabinoid and terpene amounts in cannabis samples. In the second Beer's Law column (2), I introduced the idea of totally inelastic collisions between photons and molecules and used that picture to derive Beer's Law mathematically. We then discussed the limitations of Beer's Law. Here in part III, we will finally come clean about what the absorptivity truly is, and how it impacts how we can use Beer's Law.

### Review Beer's Law

Beer's Law allows spectroscopy to be quantitative because it relates the amount of light absorbed by a sample to the concentration of chemical species in that sample (1,2). Beer's Law has the following form:

$$A = \epsilon LC \quad [1]$$

where  $A$  is the absorbance;  $\epsilon$  is the absorptivity;  $L$  is the pathlength; and  $C$  is the concentration.

By rearranging Beer's Law, we can see how to solve for the concentration of an analyte in an unknown sample as such:

$$C_{\text{unk}} = A/\epsilon L \quad [2]$$

where  $C_{\text{unk}}$  is the concentration of analyte in an unknown sample.

Thus, measuring a concentration in a sample using Beer's Law is a matter of measuring the absorbance of the sample, and knowing the product of the absorptivity and pathlength,  $\epsilon L$ . This product is obtained via the calibration process. Beer's Law has the same form as the equation for a straight line as such (3):

$$A = \epsilon LC$$
$$Y = mx + b \quad [3]$$

where  $Y$  is the  $y$ -axis data value;  $m$  is the slope of a line;  $x$  is the  $x$ -axis data value; and  $b$  is the  $y$ -intercept.

To obtain a Beer's Law calibration, the absorbances of standard samples containing known amounts of the analyte are measured. Then, the measured absorbances for the standards are plotted on the  $y$ -axis, and the known analyte concentrations on the  $x$ -axis. If the sample system being analyzed obeys Beer's Law, this plot will be a straight line whose slope is  $\epsilon L$ , the quantity we need to use along with Equation 2 to determine concentrations of analyte in unknown samples.

### The Absorptivity

Recall (1,2) that the absorptivity is the proportionality constant between absorbance and concentration. It is a fundamental physical constant for a pure molecule at a given wavenumber of absorbance, temperature, and pressure. For example, the absorptivity of pure liquid water at 1 atmosphere of pressure,

25 °C, and at 1630  $\text{cm}^{-1}$  is a fundamental physical constant of the water molecule. The absorptivity changes from wavenumber to wavenumber for a given molecule. Thus, the absorptivity of water at 1630  $\text{cm}^{-1}$  is different than at 1000  $\text{cm}^{-1}$ . Different molecules typically have different absorptivities at the same wavenumber. For example, the absorptivity of water and acetone at 1630  $\text{cm}^{-1}$  are different. Lastly, in general, different molecules have different absorptivities at different wavenumbers. Thus, the absorptivity of water at 1630  $\text{cm}^{-1}$  is different than that of acetone at 1715  $\text{cm}^{-1}$ .

### Beer's Law Units

Since the absorbance is a unitless quantity, when the units of the absorptivity, pathlength, and concentration are multiplied together they must cancel out. How does this happen? The units of concentration are in moles/volume. Remember that volume has units of width  $\times$  height  $\times$  length, which is length cubed, or  $L^3$ . Which means the units of concentration are moles/ $L^3$ . The units of the pathlength are simply length or  $L$ . When we multiply the units out in Beer's Law the results are seen in Equation 4.

$$A = (L^2/\text{mole})(L)(\text{mole}/L^3) \quad [4]$$

For the absorbance to be a unitless quantity the absorptivity must have units of  $L^2/\text{mole}$ . These units may seem physically counterintuitive. Length<sup>2</sup> is an area, and a mole measures number

of molecules. How can a collection of molecules have an area? As promised previously (1,2), all will now be revealed about the mysterious absorptivity.

### Absorptivity: The Rest of the Story

Recall from the last column (2) that the absorbance process is the result of what are called *totally inelastic* collisions between photons and molecules. In a totally inelastic collision, all the energy in the photon is deposited into the molecule, and the photon ceases to exist. The resultant decrease in light intensity as measured by a spectrometer gives rise to an absorbance peak in the sample's spectrum. When we derived Beer's Law (2) we calculated the total number of collisions as being

$$I C dL \quad [5]$$

where  $I$  is the light intensity in slab dL;  $C$  is the concentration; dL is an infinitesimally thin slab of sample and where  $I$  represents the number of photons in dL, and  $C$  represents the number of molecules in dL.

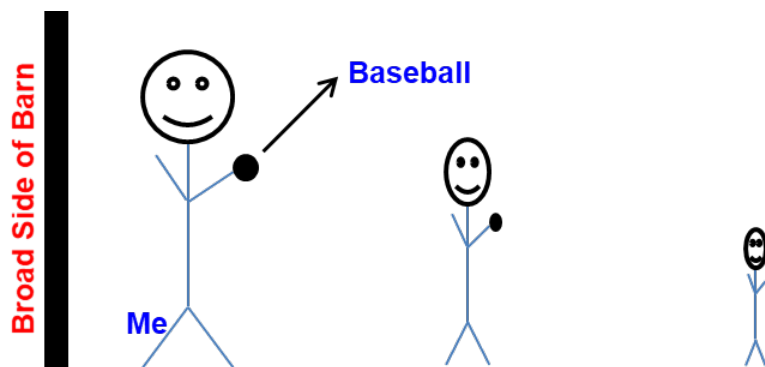
Now, only a fraction of collisions will be of the totally inelastic variety. As I said previously (2), the absorptivity represents the fraction of all collisions that are totally inelastic.

To summarize this is what we know about the absorptivity:

1. It is the proportionality constant between absorbance and concentration.
2. It is a fundamental physical constant of a pure molecule at a given wavenumber, temperature, and pressure.
3. It has units of  $\text{length}^2/\text{mole}$ .
4. It represents the fraction of photon molecule collisions that are totally inelastic.

I could have added a fifth thing to this list, which would be the quantum mechanical definition of the absorptivity

**Figure 1:** Your esteemed author attempting to hit the broad side of a barn with a baseball.



derived from things such as energy levels, wavefunctions, and wavefunction overlap (4). However, I am feeling merciful and will spare you the math behind that. How on earth can one simple physical constant have so many aspects to it? That's what we are here to talk about.

### Throwing Baseballs at Barns

How can something with units of  $\text{length}^2/\text{mole}$  represent a fraction of totally inelastic collisions? As it turns out, characterizing collisions between microscopic particles is something physicists have been studying for a long time. For example, if you have heard about atom smashers and particle accelerators, this is what I am talking about (5). As it turns out, photon-molecule collisions are simply a subset of the types of collisions that physicists already understand.

One thing particle physicists are interested in is the probability that two particles will collide when they encounter each other. A unit that physicists use to describe the probability of two particles colliding is called the *barn*, which is defined as  $1 \times 10^{-24} \text{ cm}^2$  (6). What on earth does this unit mean? Did you ever hear a baseball pitcher described as “not being able to hit the broad side of a barn?” Well, that is where the unit is derived

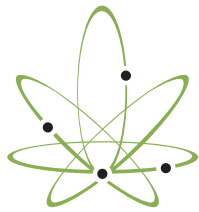
from. I can relate to not being able to hit the broad side of a barn since my statistics from my Little League career as a starting pitcher are 1 1/3 innings pitched with 1 strikeout, 2 walks, 3 hits, and 4 earned runs. Needless to say, I was transferred back to right field after that performance.

At any rate, **Figure 1** shows me trying to hit the broad side of a barn with a baseball.

Note that when I stand close to the barn, as seen to the left in the figure, the barn appears large in area to me, and the probability of my hitting it is large. If I step back several paces, the side of the barn appears smaller to me than before and the probability of hitting it goes down. If I step back a long distance, as seen to the right in the figure, the area of the barn appears quite small to me, and my probability of hitting it is very low. Now, the units of area are  $\text{length}^2$ . So, the probability of my hitting the barn is determined by the apparent area of the barn from where I am standing. Thus, this is how probability has units of area.

Now, remember from above that the units of the absorptivity are  $\text{length}^2/\text{mole}$ , or in other words probability/mole. Now, not to belabor the point, but a mole contains Avogadro's number, or  $6.02 \times 10^{23}$ , molecules (Avogadro constant [7]), or





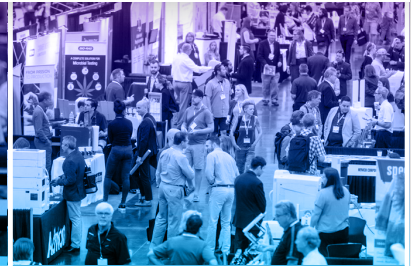
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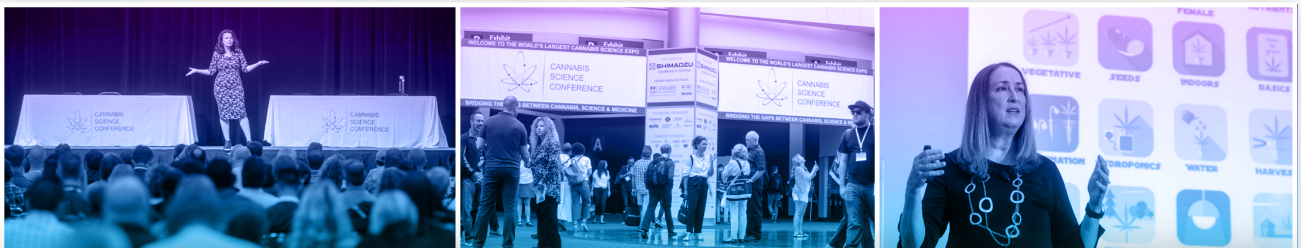
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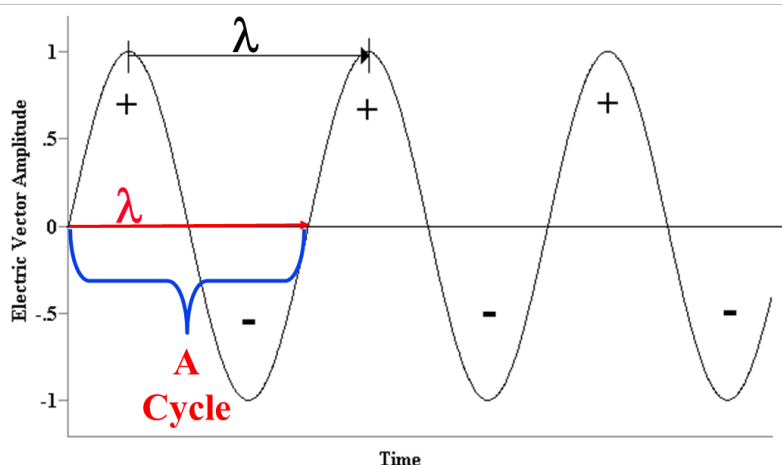
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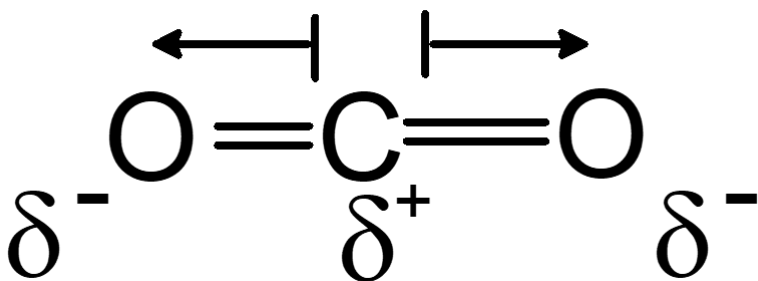
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**Figure 2:** An illustration of how the amplitude and polarity of the electric vector of light varies over time.



**Figure 3:** The electronic structure of carbon dioxide. The  $\delta^+$  symbol denotes a partial positive charge, and the  $\delta^-$  symbol denotes a partial negative charge.



$6.02 \times 10^{23}$  molecules/mole. If we divide the absorptivity in units of  $\text{length}^2/\text{mole}$  by Avogadro's number in units of molecules/mole, we obtain a quantity that is in units  $\text{length}^2/\text{molecule}$  or probability/molecule. We obtain a quantity I will call the *molecular absorptivity*.

What the molecular absorptivity measures is the apparent area of a molecule from the point of view of a photon. If the molecule looks large to the photon, the probability of a totally inelastic collision will be high, and the absorptivity will be large. On the other hand, if the molecule looks small to the photon, the probability of a totally inelastic collision and hence the absorptivity will be small.

We stated above that the absorptivity describes the fraction of all collisions that are totally inelastic. How is this a probability? Let's assume the fraction of totally inelastic collisions is  $1/5$  or 20%. This means that 20% of all collisions, or 1 in 5, are totally inelastic. This also means the odds of a collision occurring are 1 in 5, and that, folks, is a probability. So, our idea of the absorptivity describing the fraction of totally inelastic collisions is consistent with the units of the absorptivity being a probability.

### Variables that Effect the Absorptivity

If the absorptivity describes how big a molecule looks from the point of view

of a photon, what things will affect this quantity? Remember that light contains an electric vector (2) whose polarity varies over time from positive to negative to positive as illustrated in **Figure 2**.

The *electronic structure* of a molecule is simply a description of where the electrons and nuclei are located most of the time. The electronic structure of carbon dioxide is seen in **Figure 3**.

Because of the electronegativity differences between oxygen and carbon, the electrons in the carbon-oxygen bonds spend most of their time near the oxygen. This results in a partial positive charge,  $\delta^+$ , forming on the carbon atom, and a partial negative charge,  $\delta^-$ , forming on the oxygen atoms.

To tie this all together, it is the interaction between the electric vector and the electronic structure of the molecule that causes absorbance to take place. If the interaction is strong the molecule will appear “large” to the photon, the probability of a totally inelastic collision will be large, and hence the absorptivity will be large. Alternatively, if the interaction between the electric vector and the electronic structure of the molecule is weak, the molecule will appear “small” to the photon and hence the probability of a totally inelastic collision will be small as will be the absorptivity.

What variables then affect a molecule's electronic structure and hence its absorptivity? One thing is intermolecular interactions; the strength of the interactions between a molecule and its neighboring molecules. An example of intermolecular interactions, the hydrogen bonding between water molecules, is seen in **Figure 4**.

In **Figure 4** the electronegativity difference between oxygen and hydrogen means the O-H bonds are polar and contain partial positive and negative charges. The positive hydrogen on one water molecule will coordinate with the negative oxygen on a neighboring

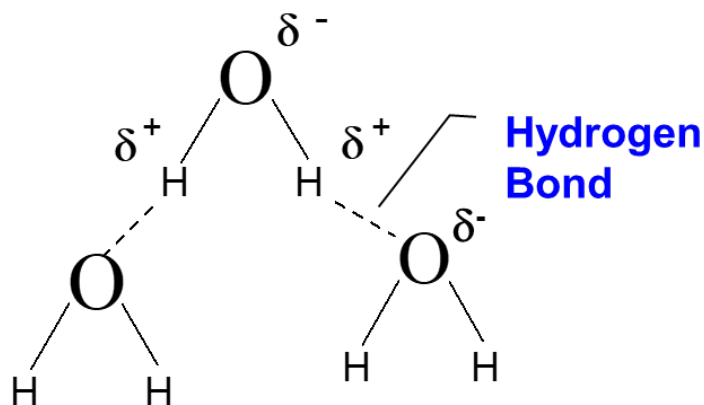
molecule forming a strong intermolecular interaction called a *hydrogen bond*.

What variables then affect intermolecular interactions and hence the absorptivity?

**1. Pressure:** Imagine a sample of water vapor. At low pressure the water molecules are relatively far apart, and the intermolecular interactions will be weak. At higher pressure the molecules are forced closer together, the intermolecular interactions are stronger, and hence the absorptivity will change.

**2. Temperature:** Again consider a sample of water vapor. Temperature is a measure of the average kinetic energy of a collection of molecules (3). When molecules collide,

**Figure 4:** An example of molecular interactions, in this case the hydrogen bonding in a sample of water molecules.

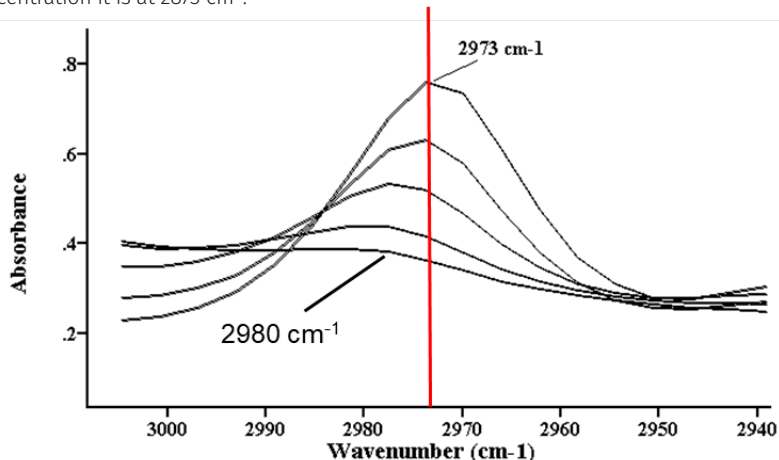


their electronic structures are scrambled by the impact. At low

temperature the water molecules will be moving slowly, and their



**Figure 5:** The mid-infrared absorbance spectra of a series of IPA in water samples. Note at the lowest concentration the peak maximum is at  $2980\text{ cm}^{-1}$ , whereas at the highest concentration it is at  $2973\text{ cm}^{-1}$ .



collisions will be few and weak. At higher temperatures the collisions will be many and strong, which is why temperature affects the absorptivity.

**3. Concentration:** Imagine a solution of isopropyl (rubbing) alcohol (IPA) in water. In pure IPA the nature of the intermolecular interactions will be different than in say, a solution of 10% IPA in water. This is illustrated in **Figure 5**, which shows the mid-infrared absorbance spectra of a series of five IPA in water samples, with the IPA concentration varying from 10% to 70%. These same spectra were seen in a previous column when we talked about calibration with Beer's Law (1). Note that at the lowest concentration, where the peak is smallest, the peak top is at  $2980\text{ cm}^{-1}$ . However, at the highest concentration, where the peak is largest, the peak top is at  $2973\text{ cm}^{-1}$ . This change in the position of the peak top is due to the absorptivity of IPA changing with concentration. We have seen previously that this data yielded an excellent calibration (1). Thus, if the change in absorptivity with concentration is small, Beer's Law can still work.

**4. Composition:** Imagine a solution

of 50% IPA in water, and a 50% solution of IPA in vinegar, which contains acetic acid. As you may know, pH is a measure of acidity and basicity, where 7 is neutral and lower numbers mean more acidic (8). The pH of the IPA/water solution is going to be right around neutral or 7. The pH of the IPA/vinegar solution will be acidic and about 3. In both these cases, the concentration of IPA is the same, but the chemical composition of these two samples is different. The intermolecular interactions between IPA and the water molecules will be different than between IPA and the acetic acid molecules. This means the absorptivity of IPA in these two different solutions will be different, and its spectra will be different. This means composition affects the absorptivity, and since pH determines molecular composition, it too affects the absorptivity.

To summarize then, the variables of pressure, temperature, concentration, composition, and pH all affect intermolecular interactions, and hence electronic structure. This in turn will affect how light interacts with a molecule, hence the absorptivity. The dependence

of the absorptivity on these variables is why when we say that the absorptivity is a constant for a pure substance, temperature, pressure, and other conditions must be specified.

Analytical chemists sometimes define a sample's *matrix* as its physical and chemical condition, including things like temperature, pressure, concentration, composition, and pH. Another way of summarizing the bullet points above is that the absorptivity is matrix sensitive, which means Beer's Law calibrations are matrix sensitive. Therefore, spectrometers can only be used to analyze things for which they have been calibrated (which is true of all analytical instruments). In my career with Big Sur Scientific, where we sell mid-infrared-based cannabis analyzers (9) I have had people complain about their analyzer because they used it to analyze pizza and yet it gave a total tetrahydrocannabinol (THC) reading. This is because the instrument can only accurately analyze sample types for which it has been calibrated, and if you use it to analyze samples for which it is not calibrated you will get nonsensical results. The matrix sensitivity of Beer's Law is also why when you use a spectroscopy-based cannabis analyzer there are specific sample type choices such as cannabis, hemp, medium-chain triglyceride (MCT) oil tinctures, and so forth. It is up to the user to make sure the sample type chosen in the software matches the sample type actually being analyzed so that the correct calibrations are applied, and accurate results are obtained. Again, if the sample type chosen in the software does not match the sample type analyzed, inaccurate results will be obtained.

So, there you are, the rest of the story on the absorptivity. I bet you never guessed so there was so much science behind such a simple proportionality constant.

## Conclusions

We reviewed Beer's Law and how it is used to determine concentrations of molecules in unknown samples. We then reviewed what we knew about the absorptivity, including that it has units of length<sup>2</sup>/area. Using the example of me trying to throw a baseball at a barn, we showed that the idea of the absorptivity describing the probability of totally inelastic photon-molecule collisions makes sense. Then, using the concepts of the electric vector of light, molecular electronic structure, and intermolecular interactions we found that the absorptivity is affected by the variables of pressure, temperature, concentration, composition, and pH. This means that the absorptivity is matrix sensitive, which means we can only use spectros-

copy to quantitate sample types for which we have a calibration.

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## ABOUT THE COLUMNIST

**BRIAN C. SMITH, PhD**, is Founder, CEO, and Chief Technical Officer of Big Sur Scientific. He is the inventor of the BSS series of patented mid-infrared based cannabis analyzers. Dr. Smith has done pioneering research and published numerous peer-reviewed papers on the application of mid-infrared spectroscopy to cannabis analysis, and sits on the editorial board of *Cannabis Science and Technology*®. He has worked as a laboratory director for a cannabis extractor, as an analytical chemist for Waters Associates and PerkinElmer, and as an analytical instrument salesperson. He has more than 30 years of experience in chemical analysis and has written three books on the subject. Dr. Smith earned his PhD on physical chemistry from Dartmouth College. Direct correspondence to: [brian@bigsurscientific.com](mailto:brian@bigsurscientific.com)

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# LED Lights Lead the Way in Cannabis Cultivation

By **Madeline Colli**

*When it comes to cannabis cultivation, growers have their own methods on how to get the best products from their plants. Through using different soils, irrigation practices, lighting, and other approaches, each item plays an important role in how the plant matures. In this interview, David Cohen, CEO of Fluence, discusses the rise in LED lighting methods and how it can be the best tool for the industry.*

**Q:** How did you get interested in the cannabis industry?

**A:** **David Cohen:** Well, I think the cannabis industry became more interested in me before I was interested in it, and I can explain that. I've been in LED lighting to various degrees for about 20 years, really since the first LED lighting fixtures came out. I was in Europe for five years, running a couple of different companies there.

I had Osram as a customer and when Osram bought Fluence in 2018, they wanted to hire a CEO to drive the business because the founders were going to exit. So, they reached out to me and said, "You want to come take a look at this company in Austin, Texas?" and one thing led to another, and that's how I took the job.

It wasn't like I was seeking it out. It kind of found me. But once it found me, it's been a really great relationship. The cannabis industry for my company and for myself has been a spectacular experience.

A lot of people set out as a mission to go get into cannabis. And it's not that I didn't want to, I just really never had thought about it back in 2018. But what they wanted to do with the company was very intriguing. And when I took a look at the market and the growth potential, I was hooked and then I really started learning about growing cannabis and what the different customer needs were and all that.

**Q:** Can you tell us a little bit about Fluence?

**A:** **Cohen:** Fluence was founded by three gentlemen in Austin, Texas in 2015. They had an idea that they could make a kind of superior grow light and bring it to market. And by about 2016 or 2017, they had not only come up with a great

set of products—a small portfolio of products—but they were also taking advantage of what was going on in cannabis at the time because a lot of the big players in lighting were quite hesitant to get into this space because of their boards of directors, their ethical policies, and whatnot. There were a lot of companies that wouldn't touch it.

Fluence came up with a great product at just the right time when really Canada and Colorado were taking off and got the lion's share of the market by bringing really superior products with a ton of research behind it, and that really just put the company on an unbelievable growth trajectory.

By late 2017 or early 2018, they realized that in order to keep growing at the pace that they were growing, which is essentially doubling revenues every year, that they would need to go find either some outside money to fuel the growth or sell the business. So, they elected to sell it, which obviously opened up a great opportunity for me. I took over in 2018 and from 2018 to 2021, with the exception of 2020 (the COVID year), we've continued on roughly 100% top line growth. It's grown very quickly and very large in a short amount of time, at least to my experience of growing companies.

**Q:** What is the best type of light for cannabis cultivation?

**A:** **Cohen:** It really depends on how you're going to grow cannabis. There are a couple of different schools of thought out there. Number one is the traditionalists that you grow cannabis with the sun and as the sun goes, the plants go. And that's one way to do it.

Then when you go inside and you want to grow it using artificial light, you can do it in a greenhouse, which is a big open glass structure flat. All the plants are on the same level and



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you're using a mixture of sunlight and artificial lighting, usually LED lights.

And then there's another way that's becoming very popular now, which is vertical growing cannabis. Instead of going out left to right, you go straight up, and you could have two, three, four, or five levels of these big, huge racks. The lighting for the racks and the lighting for the greenhouse are very different because of the proximity of the light to the plant.

In a greenhouse, the light is much, much higher up in the air. By default, that is extremely powerful. The rack growing, the lights are right on top of the plant, usually six or seven inches, maybe even a little bit less. The intensity can't be as much because it would kill the plant.

It's difficult to answer that question, what's the best type of light. I would say the best type of light generally is an LED light. You can get a lot more control with LEDs. You can change spectrums. You can manipulate the plant quite a bit more than you can with traditional light sources like high-pressure sodium (HPS). I would just say generally, an LED light, but then you get into the specific type of growing that you're doing.

**Q:** What kind of spectrum do LED lights use?

**A:** **Cohen:** You can come up with whatever spectrum you want. At Fluence, what we've done is we've pioneered the broad spectrum, which is a spectrum that exactly mimics the sun. And that was one of the things that Fluence really changed the game on.

Growing plants inside had historically been done with either high-pressure sodium (HPS) lights, which are very yellowish in tint or LED lights that are kind of a mixture of blue, purple, and red. And those blue-purple-red lights are very difficult to work under. It's extremely taxing on your eyes.

You can't see without some kind of glasses like real close-up views of the plant if there's bugs or mites or infestations or mold, and it's just really difficult to work under. So, what Fluence did after a couple years of research has showed that the best way to grow this plant is by using broad spectrum, which looks white with some kind of red and green dots in it.

But if you look at the spectrum on a piece of paper, it's almost exactly the spectrum of the sun. And what we found is that's the most successful. We led the market with that in 2016 and 2017, and now virtually, every single lighting company out there is using broad spectrum.

I don't know what the exact percentages are, but I would guess more than 75% of the people selling LED lights to grow cannabis are selling lights that are broad spectrum.

**Q:** How did you research LED grow lights in the cannabis industry? What other research is your company working on related to cannabis cultivation?

**A:** **Cohen:** We do a ton of research, but basically, because we're in Texas and we don't have a license to grow cannabis, we're highly dependent on partners. We have a wonderful working relationship with Texas Original Compassionate Cultivation, which is one of the three licensed cannabis growers in the state of Texas for medicinal.

We have a huge space in their grow where we are doing research around the clock on all types of spectrum and form factors and light intensities. And we also do this with a lot of our customers in states where it's legal, such as in California, Michigan, and Massachusetts.

Even in Canada, we have R&D grow rooms at our customers' sites that we run, but we're running it under their license because we can't run the product in Austin. We're working with these

customers to understand what the difference between different cannabis cultivars are and how light intensity impacts the growth of those cultivars.

[Note: It's not legal to grow cannabis in Texas without a medical license. Fluence's research team has partnered with one of the three licensed cannabis producers in Texas to study best practices in growing cannabis.]

For example, put it in vegetable terms, you have cherry tomatoes, beefsteak tomatoes, and Roma tomatoes. Those are just three types. Inside of those types, there's hundreds of different cultivars. What we're trying to do is find out how we can use our lights and change or manipulate the spectrum to impact specific events in a plant of a specific cultivar.

You're really getting down into the subset of, now we have this one strain cultivar, how do I get this plant to grow either faster or more flower or higher THC, different cannabinoid profile? There's a lot of things that you can manipulate in the plant by using lighting, but it really depends on what cultivar you're using.

When you ask the question, what other research are we doing, we're constantly researching the effect of various different types of spectrums on various different types of cultivars and trying to build a database of relationships between these. For example, let's say 20 cultivars are most similar, they grow generally the same, but these 20 grow better. And that's a metric where you have to decide what does grow better mean? Bigger, faster, more flower, higher THC under a different light spectrum? We're finding that different spectrums affect different cultivars quite substantially.

If we have a customer that's going to bring up a grow, let's say, a million square feet of cannabis plants, which is a lot of plants. And we know what cultivars they're going to be growing, specifically what strains, we can prescribe



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a lighting recipe that will maximize either their cycle times to grow, the plant biomass or, like I said, the different THC and cannabinoid profiles.

This is the part for me when I started to understand what type of research we were doing when I came to the company, I was fascinated. We're doing the same thing in commercial agriculture, not just cannabis. It's very similar to figuring out how do I get this basil plant to grow fuller, but also to last longer on the shelf by two or three days?

Because if the basil grower—cannabis is a little bit different in this regard, but I'll use this as an example because it's a very good one—if the basil grower can guarantee the supermarket that you're going to get four more days of shelf life off my product before it starts to wilt, they can get a higher price. Consequently, if the cannabis grower is growing the same strain as everybody else around them, but we can teach them how to get the THC 20% higher, or we can reduce 20% of the time it takes to grow, we can help them make more money. There's a lot that goes into it, and it all starts, and it is driven by lighting, which kind of surprised me when I came in here.

**Q:** Why are LED lights becoming the industry's "go-to" in horticultural growing?

**A:** Cohen: There's a number of different reasons. I have it from my perspective and there's certainly the grower's perspective, which is going to be a little bit different. Ultimately, you can control what you're doing much more accurately using LED lights because you can tune them.

You can dim them, they can go higher intensity, lower intensity, you can have different spectrums. The traditional way to grow cannabis inside with HPS lights, there's one light, it's one color, it is what it is, and you grow what you grow. But also with HPS lights, really

good growers will wind up changing the bulbs out because high-pressure sodium bulbs deteriorate very quickly.

Then you're swapping bulbs out two or three times a year. What do you do with those bulbs? You throw them in the trash. They're going to a landfill. LED lighting lasts 50,000 hours before it really starts to degrade, and that's about 11 years. We have not yet gotten to the point where the lights that we've sold into the market are even close to being needed to be upgraded.

But what we can do when that time comes is we can save the light, take out the LED part of it, recycle that, and then put another LED in. You have a sustainability component; you have a control of your grow component. LED lighting has proven, by far over the last two or three years, to grow healthier, fuller, higher THC plants than HPS.

And then lastly, you have electricity. And this is now becoming a bigger and bigger issue. We really struggled at the beginning to make the return on investment based on electricity, even though the LED lights consume about 40% less energy than a high-pressure sodium light does.

You're literally saving 70% on your electric bill. But when this all started, electricity rates in the United States and Canada were very, very low, four or five cents a kilowatt hour. You needed a lot of kilowatt hours to make that back. But what's happening now with the kind of global supply chain shortage and the price of oil going up and the price of electricity going up, that is now becoming a much bigger factor. So much so that we have customers that are growing under traditional HPS lights that have stopped growing because their electricity bills are killing their profits. And now they're really stuck. Do they go out and spend the money on LED lighting to get a lower electricity bill or do they wait for the cost of electricity to come down? I would say there's three

big things that make kind of LED lighting the go-to: control, sustainability, and electric consumption.

**Q:** Can you tell us about some of the results you found in the *Cannabis Business Times* "2021 'State of the Cannabis Lighting Market'" report?

**A:** Cohen: I think the most important takeaway for us is that LED adoption is on the rise. We've modeled this thing. We do it every year. We sit down and do a lot of market modeling around the world, and we still can't believe that these adoption numbers are as high as they are.

We had it about 20% less. LED usage for cannabis cultivation is up more than 45% for all stages of plant growth since the first report in 2016. A majority, about 60%, of those growers that we speak to that aren't using LEDs during flowering are considering doing it in the next six months.

That data says this is still growing very quickly and very closely emulates what we're seeing from a customer count revenue and overall growth of the company. It's really great to see that it's being adopted so much. When I first came in 2018, there were a lot of concerns about the reliability of LED lighting. And the experience that people had in the past was buying cheaper LED lights or stuff that was made in Asia. Then there were problems with the power, and a lot of fixtures catch on fire if you don't build these things right. LED lighting got a real bad reputation in growing plants for a long time.

With that, I think it's just about gone. In 2018 and 2019, the tide kind of came in on LED lighting and from 2019 to now, it's what people talk about when they build to grow. Can I afford to use LED lights or not? Because the important part is that a high-pressure sodium light is about \$250 where an LED light is like \$800 or \$900.

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You have a pretty staggering difference in cost, but the electricity difference alone is a huge number. And then if you talk about LED lightings are more efficient and you can grow one more full cycle of plants in a year. I mean, if you're pulling down a 10,000-plant crop and you can grow 10,000 more plants in a year, that's a direct hit to your bottom line. It's really what growers are paying attention to.

I would use the word astronomical. I can't believe it is taking on so quickly and so much. And because you also have a lot of these growers, that most of them were growing illicitly for a long time. They have small grows in either their house, their basement, or their backyard.

You get into a large-scale commercial grow with 10,000 plants, there's not very many people in the world who have 5- or 10-years' experience with that. And having a reduction in the amount of variability is always going to be better when you're taking on something that big. That's exactly what LED lighting does. It allows you to control the variables a lot easier.

**Q:** What is the difference between the three different types of lighting?

**A:** Cohen: So, we're talking about differences between LED, HPS, and metal-halide lighting. The primary difference is that an LED light is a solid-state electronic circuit. It's as much a computer as anything else. LEDs are simply diodes. And diodes are in computers, and they heat up and there's a treatment of either phosphorus or something on top of the LED that makes the heat transfer into this phosphor and generates the color.

HPS lights and metal-halide are your typical light bulb type of light. You plug it in, it works for a certain amount of time. The energy that the light creates only about 30-40% of it goes to

the plant, the rest of it comes off in wasted heat, so it's a very inefficient source and you can't control them, you can't dim them, you can't tune them, you only turn them on. The one good thing about them is they're extremely predictable and reliable, and they're very cheap. But there's a lot of countries in the world that are moving to ban this type of lighting because once the lighting is done, you can't dispose of these bulbs in a safe manner. It goes into the ground. Metal-halide bulbs, some of them have mercury in them; high-pressure sodium, the bulbs filter sodium, and you don't want that stuff in a landfill. That would be, in my view, the three different types of lighting.

**Q:** What is high lighting intensity?

**A:** Cohen: When we talk about high lighting intensity, we're talking about increasing the number of photons that come out of the light and hit the plant. In every area of LED or any kind of lighting, when you're talking about lighting up areas or rooms or streets or roads, you talk about lumens and the intensity of the light and how bright it is.

Plants don't know brightness or intensity necessarily. They know photons. When we talk about high intensity lighting, what we're referring to is a much higher photon producing light and that is bigger, better LEDs, more LEDs. And there's a wide range of how many photons you can make come out of a light.

There are 1000 photons, 1500, we call it PPFD, which is photosynthetic photon flux density (PPFD). The acronym PPFD is an indicator of how many photons are coming out of the light being delivered to a crop, which enables photosynthesis. And on high intensity lighting, what we're trying to do is hit the cannabis plant with as much light as it can possibly take and see what the breaking point is.

So, what our research over the last year or two has found is that you can go a lot higher in photons that are hitting the plant lighting intensity than anybody ever believed. You have to feed the plants differently. You have to water them differently. You have to care for them differently. But you can actually grow them much more efficiently with a higher number of photons coming up.

**Q:** What advice do you have for beginner and more experienced growers that are looking for the right lighting and growing methods?

**A:** Cohen: My personal advice, I'm not a grower, but what I've seen over the last three years is start small. Come up with what your endgame is for your grow, whether it's 5 plants, 50 plants, 5000 plants, 50,000 plants, and try to recreate a very small replica of what you think you're going to do, and then scale that slowly.

Almost every grow that we've seen, where they start, where they try to go from zero to 1000 right away is we see lots and lots of problems in scaling. Everything from disease on the plants to different temperatures in different rooms that affect the output. My advice for beginners, it would be, good for you. If you want to grow cannabis, that's great. Start slow, start small, and really learn what the different variables are that affect the plant. Even for more experienced growers, I would say the same thing. If you go too fast too soon without proving it out, the cost is really bad to lose a crop or to lose a cycle of plants. My advice, and I think all of our growers that we have on staff would agree, is to start small, prove out the concept, and then scale it slowly.

And remember, plants are living things. If the plants have some underlying disease or defect in them and you

put that one plant in a room of a thousand other plants, you're going to have a thousand plants that are infected in the same way. And you don't know it until the plants grow and you've put in all the time and energy into it, and then you go to harvest it and you realize you have a mess on your hands.

The most successful growers I've seen have taken whatever they want to do, done it at like a 10% scale, then a 30% scale, then maybe 50%, and just keep slowly expanding. Even though there's a lot of pressure to grow the plants because the cannabis is \$2000, \$3000, \$4000, or \$5000 a pound, so you think "I can make all this money." I believe you've got to go slow. That's my advice.

**Q:** Do you see any other kinds of lights or growing methods looking to become more popular than LED lights?

**A:** Cohen: I see different growing methodologies starting to come into the market, like growing in containers or growing in pods, but all of these use LED lights. If I was just to strictly stick to the delivery of photons to the plant, I don't know that there's any better way to do it right now.

If you can't do it with the sun and you don't live in Humboldt County in California, LED lighting is the best way to go. And so far, I haven't seen any other technology that is poised to change that in the near future.

*Editor's note: This interview was conducted in November 2021 and published prior to the announcement in December 2021 that ams OSRAM has entered into a definitive agreement to sell Fluence to Signify. Per the release, the acquisition is expected to close in the first half of 2022, subject to standard regulatory approvals and other conditions.*

*This interview was also edited for length and clarity. To read the full interview with David Cohen, please visit: <https://www.cannabissciencetech.com/view/led-lights-lead-the-way-in-cannabis-cultivation>.*

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# In the Cannabis Lab with Josh Smith from Telic Labs

*An inside look at the cannabis testing lab, including challenges and opportunities, the current regulatory requirement landscape, and what labs should be thinking about to prepare for the future.*



**Josh Smith**  
President, CSO  
Telic Labs

**CST: What drew you to cannabis science?**

**SMITH:** I took a roundabout route. My graduate degree is in clinical microbiology, and I spent time at the University of Wisconsin Biotech Center setting up a gene-chip facility using reverse-transcription, real-time polymerase chain reaction (PCR)—although quantitative PCR (qPCR) is shorter, faster, and easier. Then I moved around a bit and got into pharmaceutical R&D for 10 years. Then, through a separate project, I ended up talking to my partners and setting up a hemp and CBD lab based out of Madison, WI. Now we've expanded into purchasing a lab in Michigan, as well, to do adult-use and medical-marijuana testing.

**CST: How well do you think the cannabis science space is doing when it comes to the data coming out of labs?**

**SMITH:** The short answer is we have some work to do, and it's getting better. When we first started in 2018 it was ridiculous, piecemealed—all the methods were different. No one could agree on one potency or sample-preparation method, even a drying method was hard. And no one would share any of their information, tests, or how they did anything. Everyone was trying to keep their little piece of the pie sheltered, which was completely backward from what I had experienced after being in tightly controlled laboratories. But it's come a long way, and it is on the right path, but there's a lot of work that needs to be done and places such as AOAC International and ASTM International are helping with that.

**CST: Given where we are now, where do you see the biggest lab testing changes or challenges in the next couple of years?**

**SMITH:** The biggest changes will be microbiology and stability testing. Once FDA steps in, they're going to require expiration dates on everything, and the sticker shock of what that testing costs is going to cause a lot of people to be very angry. Also, most states only require the testing of toxins that produce E. coli and salmonella species as well as aspergillus. There are some tests for total coliforms, some that test total yeast and mold, and others that test for total aerobic. But once they have to test for full foodborne panels, again, people are going to have issues.

**CST: Compared to the industries you have worked in before, how tough are the problems facing cannabis testing labs?**

**SMITH:** From the science side, they're not. Every method the cannabis industry uses has been designed, built, and validated in another industry. We've been testing agricultural products for pesticides for decades, for example, so the testing methods are a small thing for the industry. The problem with the industry, though, is getting those standardized across all 50 states and beyond, in addition to getting non-lab folks in the industry to buy-in. There's still a huge black-market problem. So, these are the two biggest problems.

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**CST: What, in your opinion, is the biggest change we should be making in our approach to cannabis testing for consumer safety?**

**SMITH:** The big one is consolidating across the 50 states, standardizing methods and validation techniques. We've made progress, but it's going to take a little bit of time. One of the biggest changes will come from the legislators. This is a new cash cow and new money for everyone's district, but places like California have decided to take that overboard and charge 50% taxes for dispensaries in Oakland or San Francisco. So that's keeping people from wanting to buy into the system and buy into getting things tested. They have to pull their hand back from the cookie jar a little bit, otherwise, people are just going to say screw it.

**CST: What is your lab doing to help move the industry forward?**

**SMITH:** Myself and our lab director from Madison are on various ASTM and AOAC committees to help set methods standards. We've presented at various conferences, trying to help educate as much as possible. I am also on the shortlist for the Scientific Advisory Panel in Michigan to help write the guidelines in addition to serving as an expert witness for a couple of court legal cases

The key is education, especially for hemp and CBD farmers. I come from Northwestern Pennsylvania in the foothills of Appalachia, and if my dad didn't have hay fever, I would've been seventh generation on the same dairy farm. You get to know all those people after a while, and they're just looking to make money. I mean corn prices suck, soybean prices suck, dairy's gone to hell—they're just looking to put food on the table for themselves and their family, and this is supposed to be a way to do it. But their background is in more standardized crops—you know exactly how many days from planting to harvest, fertilizer ratios that each strain needs, etc., and they think that's the way this is, and a lot of them have lost their shirts over it, especially in the crash in 2019 harvest season for CBD. We're all here together in the industry, and we want it to succeed—it's just trying to make sure that everybody's playing by the same rules.

**CST: What kind of information or studies should cannabis scientists/labs be working on in the next five years?**

**SMITH:** Sample preparation methods because it is still back and forth. I would love to see what organisms are on cannabis that we should be testing for. For example, there are fungal species in California that we don't have to worry about up in Michigan or Wisconsin while Wisconsin has an issue with blastomycosis in the ground, but it tends to not be anywhere else. So, there's going to be a range of things that should be reviewed by region, but until somebody sits down and does those surveys, we're not going to be able to make that call.

There are going to be lists of things that we should be testing for in products. For example, pesticides are a pain to validate, run, etc., but if you're growing indoors, there shouldn't be any pesticides. We've been picking up myclobutanil, and that seems to carry over from clones when people are cutting them across—it's little things that you see over the years and what kind of compounds mask your potency results. For example, some orange dyes can mask the potency of CBD or other cannabinoids, so they come out low. I've seen strawberry flavoring change the potency by half—whenever I've run a beverage or a gummy that's been strawberry flavored, there seems to be an issue with that food dye.

Genetics is another aspect of cannabis testing—anyone who claims they have genetics on this thing is lying to you. No one has a clue, and it's going to take multiple years of people doing full genome sequencing and comparisons to figure that out.





# Taking a Measure of Evolving Extraction Technology

By **David Hodes**

*Different extraction processes, new products, and new equipment combine to create the perfect storm of better, safer extractions.*

Extraction technology is one of the faster changing parts of the cannabis science business. More concentrates and products are coming out all the time. But there is always a search, more of a scientific yearning, for a better, cheaper, or safer process than the current methods.

It's all about what you want to extract, then essentially working backward from there. There are new processes being invented all the time, and ideas generated by other industries to review and incorporate, as extractions and the products made from extractions becomes more popular.

It's time for a reboot about what extraction means, where it's being used, and why it's not the chemist's mystery that some believe it to be.

This "Tech Innovations" column will quote top thought leaders in extraction developments and find out what's being developed now, what's coming next, and how extractions are better and safer than ever before.

## Taking the Mystery Out of Extraction

Cannabis extraction should not be viewed as a "black art," but a quantifiable scientific process, according to Markus Roggen, president and chief science officer of Delic Labs, who describes himself as just the chemist who counts molecules and not the guy who does the medical studies.

"An artist says that they will always make a masterpiece because it cannot be ignored and cannot be used as a consumer packaged good," he said. "The businesspeople at Coca Cola know exactly how much it will cost them to make their product. It should not be a surprise. And so therefore, optimization is important."

Roggen is now employing machine learning (1) to the extraction process. He explained why he is doing that, and how he is getting there. "Extraction has the goal of removing the compounds of interest, such as cannabinoids, terpenes, and maybe other parts, from the whole plant matrix, and separating them from all of the unwanted compounds like waxes and sugars."

The cannabis plant is rich in compounds, he said, and different extraction processes had to be developed for them—solvent, solventless, CO<sub>2</sub>, and other new and familiar methods (2). How extraction usually works is that the extraction operator would step up to one machine, look at the machine, look at the cannabis they have, and then from experience or from a more structured optimization process, would dial into the machine the extraction process until he got what he wanted. "That's how we normally did it," he said.

But there are a limited number of experiments to do in finding the right optimization process just because of

the time of day, the number of materials, the cost, and the operating hours. "So, you might be doing two experiments to maybe 20 experiments to find the right setting for you," said Roggen.

The operator must consider that there are cannabinoids, terpenes, sugar, waxes, water content, then different strains of cultivars, and different sizes and different instruments, but also different concentrate products to be made, he added. "We might want something solid, or powder or edible," he said. "We might want to have a very high terpene oil for one product, and we want to have just cannabinoids for another product. So now if we want to optimize for all these various factors and outcomes, it becomes impossible to do experiments for it, because we have to do too many experiments to figure that out. That was our problem and why we considered machine learning."

## Introducing Machine Learning Methodology

The intended goal of machine learning is to understand the process, Roggen explained. "That's so that the operator makes the right product in the most efficient way, but also so that the business side of the company understands all the costs, is able to reduce the costs as much as possible and produce the most reliable and consistent product they can," he said.

Extraction is an old technique for the food processing industry (3). It appears

that there should be no reason to re-invent the process for the cannabis industry. But there are many variables with cannabis—the most difficult being that cannabis is illegal—so the mechanical and agricultural techniques that have been researched for decades for other food products don't exist for cannabis, Roggen explained. “We have a lot to catch up to. Cannabis by itself is a very complex plant. And we are interested in such a variety of compounds that a classic way of separation or extraction that you might see in the perfume industry doesn't work anymore,” he said.

Enter the beginning of machine learning. “With cannabis, we don't have a big data project. We don't have enough data. All machine learning is based on the idea that we take the existing data we can find, develop a basic understanding of how extraction works based on the data, and obviously some scientific principles, and then use a machine learning algorithm that is constantly improving,” he said. “So, it takes the existing data, makes a best guess about the process, then takes the learnings from that experiment to the next experiment into improving its algorithm. So, if we compare our current machine learning to an existing operator, we can improve the operations by 50% easily, then maybe 20% the next time.”

Roggen is also working on extractions with psilocybin (4) since the Canadian government regulations allows research licenses for psilocybin and a host of other psychedelic compounds for his lab in Vancouver. “So right now, we have LSD, MDMA DMT, Ibogaine, 5-MeO-DMT, and all of those compounds,” he said. “The first question we focus on is analytics, because if you get your hands on psychedelic mushroom, there's a little bit of psilocybin in there, and a lot of psilocin, which is almost twice as potent as psilocybin. Having a lot of psilocin in a mushroom is good. The problem is that it's very unstable and degrades and

oxidizes very quickly. So, you actually want your mushroom with a lot of psilocybin. That's the most stable form and then you only have to control the transformation to psilocin when you make your tea or when you ingest it.”

In a testing laboratory during the sample preparation method, operators are degrading the mushroom, so they're changing the result while they're testing it. “The test methods are not yet well developed. That is our main focus right now—to develop better test methods to be able to establish the right concentration in the mushroom and not the artifact that we see after we destroy the mushroom.”

### What is Solventless... Really?

Nick Tanem, the owner and operator of Essential Extracts, a public speaker and activist, said he is the guy who coined the word “solventless” (5). “I reserve the term solventless for mechanical separations, but it's actually not an extraction,” he said. “Whereas butane, ethanol, or CO<sub>2</sub> would be used in extractions, where you're actually extruding the oil from within the trichome head.”

Solventless is more of a mechanical separation rather than an extraction, he said, meaning that an operator is mechanically separating the trichome head from the plant material. “Once we are talking about rosin, we are talking about extruding those oils via mechanical means without the use of any chemical solvents,” said Tanem.

Most, if not all, of today's forms of extractions going for different consistencies and new end products can be done by mechanical means, Tanem explained. “It's for some of the newest products on the market in the last two to five years, like live rosin cartridges, because we've been able to mechanically separate this oil without the use of any chemical solvents and get it into a vaporizer or cartridge form,” he said.

With states like Pennsylvania outlawing any additions or subtractions to

a vaporizable form, such as added botanical terpenes or even added cannabis-derived terpenes back into a formula, live rosin cartridges are becoming even more popular. “I'm getting a lot more work,” he said. “That's where a lot of the industry is going, understanding that we're able to now recreate these consistencies and products without the use of chemical solvents.”

### Borrowing from the Freeze-Dried Fruit Food World

Tanem shared that his clients are constantly asking about the cartridge technique and how to get the rosin form into the right viscosity that's usable in the vaporizable form for either the cartridge or any other the hardware that's out there on the market. “A lot of my clients are also asking about specifics on the freeze dryers,” said Tanem (6). “We brought freeze dryers in about 2015 from the freeze-dried fruit world into the cannabis world.”

The freeze dryer allows an operator to mitigate the chance for microbial contamination. “When we're talking about mechanical separations, we're using water. When we use water combined with plant material, there's the chance for more microbial growth,” he said.

With a freeze dryer, an operator can remove 100% of the plant matter, and 100% of the water. There is no chance for mold microbial growth at that point. “So that's a really, really big step in the scaling up or the industrializing of our industry and creating safer products,” he added.

Tanem said that the whole solventless process is huge. “In the beginning, it didn't get as much traction as I thought it would. And at this point, you know, almost 10 years later, after coining that term, it's a huge part of the industry,” he said. “People are asking about scaling up that process.”

That's what Tanem has been focusing on: Scaling up the processes, going bigger, trying to compete with the big money coming in. “But doing that while retaining



our craft, the knowledge and skill set that we've learned over the last couple of decades here in this space," he added.

## Bring in the Engineers

Darwin Millard is a mechanical engineer by training who specializes in mechanical and solvent-based extraction methodologies for isolating the various phenolic secondary metabolites from botanicals. "It was like, as a mechanical engineer, I could build and design slurry pumps for the fracking industry, or I could jump headfirst into Colorado's fledgling medical cannabis program at the time. So, I did that. And I wouldn't change anything for the world," he said.

Millard is the chief science officer for Final Bell, based in Canada, and Final Bell is the Canadian arm of a multinational operator that has several larger co-packing and coprocessing facilities that are intended to provide those services for the legal cannabis marketplace. In his role as chief science officer, he is helping the company with research and development into new and labor and cost saving process improvements and systems.

Final Bell does solventless extractions in bulk, as well as big cartridge filling and co-packing for various clients. With a broadening product range, and an equipment and process system evolution underway, what is being done with extractions today? "It more or less depends on what your end product is," Millard said.

Millard said it's important to ask yourself these questions: What are you trying to make? Are you trying to compete in the highly competitive concentrates and extracts game, where it's all about hype? Do you have the right strains? Or are you just trying to make a bulk ingredient that you are going to sell at the cheapest price possible to a larger copacker or coprocessor who is making products for other people? Or are you going to try to make some small batch artisanal terpenes run?

"If you don't know what you're trying to extract, or why you're trying to extract

it, then you could theoretically make anything with anything," he said. "And there are other implications you might want to take into consideration when looking at these various different types of extraction systems that are out there."

Extraction is not a dark science because people have been extracting various analytes of interest from complicated botanical mixtures for a very long time, Millard explained. "It's almost unimaginable to think about a plant as something that we've kind of coevolved with for so long and know so little about, in comparison to if we were to find an unknown plant, flower, or frog species or insect or something in the Amazon," Millard said. "But with cannabis, it's almost like we've just discovered some new life form at the bottom of the ocean."

The issue of heavy metals and other contaminants in extracted products seems to be under control for now, but there is still a significant issue with them in the black market. "The cannabis plant is a very strong phytoremediator of heavy metals and other elemental impurities," he said (7). "So, depending on where and how you are growing it, there could certainly be opportunities for elemental impurity contamination."

Contaminants that are of concern to anyone growing an agriculture product include pharmaceuticals and personal care products, hormones, steroids, alkyl-phenols, flame retardants and pesticides. They can get pulled up into a crop as a crop grows, and end up in the food chain even after processing. That's where standards development organizations such as the American Society for Testing and Materials (ASTM [8]) International and their technical committee, called D37 on Cannabis (9) comes in, trying to create standards that will help promote

product quality and ensure consumer and environmental health and safety.

## Conclusion

There are many forms and many methods of cannabis extraction being used today. But these machine processes need more controls, and more controllable features, to reproduce the same concentrate every time. That's one of the goals of a medical cannabis business—to make formulations that are consistent and can be counted on by the patient. But beyond the medical market, general consumers in adult use states have an expectation that their products will be safe and consistent as well.

What is left to explore today is operator education of the extraction process, and the bringing together of more of the brain power of engineers and extractions operators to answer common problems or explore new concepts. When these minds meet, the future of cannabis extractions will surely be all the stronger.

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### ABOUT THE COLUMNIST

**DAVID HODES** has written for many cannabis publications, and organized or moderated sessions at national and international cannabis trade shows. He was voted the 2018 Journalist of the Year by Americans for Safe Access, the world's largest medical cannabis advocacy organization.

## Medical Cannabis Is Here and It's Here to Stay:

### *How Americans for Safe Access, the Nation's Largest Member-Based Cannabis Advocacy Organization, Protects Patient Rights*

BY ERIN MCEVOY

**W**HAT MORE NEEDS to be done for patient rights, protections, and access to cannabis in the United States? In this interview, Abbey Roudebush, Director of Government Affairs for Americans for Safe Access (ASA), explains the goals of ASA and provides an in-depth analysis of their annual State of the States report. She explains why medical cannabis access is a pertinent issue, the myriad obstacles patients still face in securing protections, and how to advocate for the rights of medical cannabis patients.

**Q:** Can you tell us about your background and your role with Americans for Safe Access (ASA)?

**A:** **Abbey Roudebush:** At Americans for Safe Access, I am the Director of Government Affairs. I oversee our policy and advocacy in all 50 states as well as at the federal government level. It's our mission to provide safe, equitable legal access to medical cannabis for patients across the United States.

Prior to joining ASA in September 2021, I worked for almost four years at the Epilepsy Foundation, where I worked on a lot of access to care issues, including access to medical cannabis, in all 50 states and at the federal level. Before joining the Epilepsy Foundation, I worked at the state level in New York, where I was involved in passing the Compassionate Care Act.

I have about eight years of experience within cannabis policy and almost as many years in patient advocacy. I'm really enjoying my role at ASA, where I get to combine my passions for patient advocacy and cannabis policy to help ensure that patients across the country have access to treatment options.

**Q:** What are ASA's goals and plans for medical cannabis advocacy in the next few years?

**A:** **Roudebush:** We have a lot of really exciting plans. First and foremost, our goal for the past 20 years has

been, and will continue to be, getting access to patients. Not only access to medical cannabis, but access to legal protections and other measures that will help patients.

We've seen a majority of the states across the country pass medical cannabis programs, but that's really just the start of medical cannabis advocacy. It's not the end. We've achieved one goal, but we are continuously working to improve these programs and to improve the legal protections such as housing and custody protections within these programs.

We are striving to improve things like affordability and the financial obligations that patients are required to meet. We're also trying to ensure that underserved areas have access to medical cannabis. One of our top priorities is to continue to pass these programs where they don't exist, while also improving programs across the United States.

At the federal level, we're looking to pass legislation that will protect patients and that will fix some of the federal laws that conflict with state laws. For example, the fact that cannabis is a Schedule I drug means that through the Drug Free School Zone Act, children and adolescents who use medical cannabis cannot access their treatment on school grounds. We're also focusing on employment protections for federal employees who are medical cannabis patients and on housing protections, particularly for those who receive housing through the Department of Housing and Urban Development (HUD).

We're also looking to set up some sort of national coordinating entity or government agency that will be able to help coordinate access to medical cannabis across the United States to set the basic requirements for what these programs must provide for patients. The states will then be able to go above and beyond that while still making sure that no matter where patients are in the country, they can rely on a minimum standard of care when it comes to cannabis.

In terms of research, we are working to improve policies to make it easier for researchers to work with cannabis and get data that the United States is sorely lacking.

**Q:** Can you tell us more about how ASA has helped improve access to cannabis for research?

**A:** Roudebush: One of our top priorities at the federal level is to help remove some of the barriers for research, including removing cannabis from Schedule I to a different schedule to allow researchers to access it easier.

We're also invested in helping to pass other policies such as the Feinstein/Grassley/Schatz bill (Cannabidiol and Marijuana Research Expansion Act) or the Blumenauer bill (Medical Marijuana Research Act) that can help researchers. Because one thing that I hear most from doctors, and also lawmakers, is that we need more data, but the data is extremely hard to get, so ASA is continuing to put priority on making medical research happen.

Right now, any cannabis policy on the federal level is slow moving, and so we're doing our best and hopefully something will pass soon to help alleviate those burdens for researchers.

**Q:** ASA's State of the States report for 2021 was released in February (1). What is the goal of this annual report?

**A:** Roudebush: The biggest goal is to give people a snapshot of what medical cannabis access looks like across the country. Every year, we give all 50 states and five territories a letter grade based on how well the medical cannabis program serves and protects patients in that state or territory.

This year, we revamped the whole report based on a lot of feedback from patients, legislators, and other advocates around the country. We looked at our

report from previous years and thought that it no longer accurately reflected the patient experience, and so we re-evaluated and reassigned points. We added categories and included a penalties category. We graded all states and territories on 120 different metrics that range from patient rights, civil protections, and affordability to consumer protections and health and social equity so you can see which states have the best medical cannabis programs and which states have the worst. We also provide each state with recommendations on things that they can do to improve their program.

The report cards are the main feature of the report, but the report itself is a great resource for policymakers, advocates, and patients across the country to learn why all 120 metrics are important to patients. There are also legislation models or regulation language in there for policymakers and other recommendations on things that they can do to improve patient lives. So, each year the report is published to help educate lawmakers on where we are, how we've improved since last year, but also how we can keep improving in the future.

**Q:** How is the report unique compared to other assessments of medical cannabis programs?

**A:** Roudebush: We don't look at just one aspect of a medical cannabis program. I know that there are a lot of reports out there that look at equity within medical cannabis programs and we look at equity as well, but we really try to look at it from a 360° patient view. What are all of the things that a patient may experience or that may impact their ability to have access to cannabis? Every year we also release a patient survey to gather feedback from real patients about their state's program and we incorporate that into our report as well.

**Q:** How is the data for the report collected, organized, and analyzed?

**A:** Roudebush: That is a big question. It's done over many, many months. We start by looking at the previous year's rubric to see if there's anything that we want to tweak, to reassign points for, or if there are any categories that we want to add. We check to see if there were any oversights left out the year before or if there's an emerging issue that is important now.

Then we finalize the rubric and assign the points. Once we do all that, we dive straight into research. We have a giant Excel document that has all 50 states and territories and on each of those is all 120 metrics. We start by researching, reading the law, reading the regulations, and trying to find the provisions in the laws and regulations that correspond with our rubric.

And then we assign points to it based on another written rubric. You can find it on our website: [www.safeaccessnow.org/rubric](http://www.safeaccessnow.org/rubric). For all 120 categories, we explain why this metric is important and how we graded it. In our other spreadsheet, we assign a grade to it and then leave a note on that spreadsheet with the citation or the legislative regulatory language as our source.

Then once that's done, we go back through and see if there's anything that we missed or anything that has passed while we were doing our initial research. That's something that happened a couple of times this year. We would give a state one grade, but while we were grading, the legislature passed something or the governor signed something and we went back and changed the grade.

**Q:** Since the report came out, have any states been surprised by their scores, especially considering the new grading rubric you implemented?



**A:** **Roudebush:** I'm not sure if any states have been surprised, but it seems like Colorado has been the most interested in their change of score. Just the change in grading alone lowered its score, but Colorado this year also passed a piece of legislation that is the single largest rollback of any state medical cannabis program that we've seen in the country. They lost a ton of points because of that rollback and as a result Colorado has been really interested in their new score considering the rubric and that legislation.

**Q:** **What most surprised or encouraged you about the results of the report?**

**A:** **Roudebush:** I think what most surprised me was how the data we have on affordability matches exactly what patients tell us day in and day out. I have never doubted a patient who has told me that medical cannabis is expensive in their state and that they have trouble affording it because I know how much this can cost. I hear every day about affordability being a problem.

When we looked at policies that states can have to help patients with affordability, it's just crazy to me that it's the lowest scoring category overall out of all of them. The highest scoring state in that category only received a 60%. I know the states hear every day about affordability being a problem, and yet they're not doing anything to help out with it. On the one hand, it was most surprising to me just because the scores in that category were so low. But on the other hand, it wasn't surprising because it just confirmed what our patient advocates are telling us. It is really hard to see that states are falling behind so far in that.

One other thing that has surprised me is the reactions we're getting. Even though a lot of the grades for the states are lower than they have been in years past, we've been hearing a lot of positive things like, "I'm glad that you revamped

the rubric because I think this grade is more accurate than last year's grade was." That's made me feel great about our change in rubric. Our goal was to show what matters to patients. And what we're hearing from both policy makers and patients is that our new grading scale has achieved that and gives a more accurate insight into the program.

One thing that did encourage me about the report is that one of the highest categories overall is civil rights and patient protections. A lot of states are doing really well in providing for patients in that way. It's great that states are really working to legally protect patients because that was a big problem for a long time.

**Q:** **What would best help improve the affordability of medical cannabis? For example, do you think medical reimbursement will happen one day?**

**A:** **Roudebush:** It is my dream that medical reimbursement will not only happen one day, but one day soon. I think that might be a little bit of a stretch—at least the "soon" part. But I do think eventually medical reimbursement will happen for medical cannabis patients, especially when insurance companies can look to the fact that if medical cannabis is treating someone, it's keeping them out of a hospital and it's keeping them out of emergency rooms. It could keep them from needing additional surgeries or other treatments.

Helping patients to afford medical cannabis now could help insurance costs in the long run. States can and should right now help to provide financial assistance, real substantial financial assistance, especially to low income, elderly veteran individuals to help them afford the product.

Additionally, a lot of states allowed telehealth visits during the initial

lockdowns of COVID-19, but a lot of states have since let that lapse and no longer allow telehealth. So, then patients also have the hurdle of actually traveling to a doctor to get that recommendation when it's something that they could easily do 15 minutes on their computer from home. And if you go to a doctor specifically for a cannabis recommendation, some insurance will not cover that visit.

Another important thing states can do is do away with their registration fees. It can be a big hurdle for patients to have to pay to even be able to access cannabis in the first place. That's especially true in states that have passed recreational adult use laws.

There's no need for patients to be paying for the same access that adults have. For example, Oregon charges patients \$200 every year to register for their medical cannabis program, but because they also have recreational adult use, any adult in the state can walk into a dispensary for free. It's not the same to say, "Well, don't pay the \$200, just go to a recreational dispensary," because by being a registered medical cannabis patient, patients receive extra legal protections and other things that don't exist in the recreational market. Patients need the protections of the medical cannabis program, especially when Oregon is making hand over fist revenue on the recreational cannabis side. There's just no reason for them to also have the highest registration fee for patients in the country.

*This interview was edited for length and clarity, to read the full interview with Abbey Roudebush, please visit <https://www.cannapatientcare.com/view/medical-cannabis-is-here-and-its-here-to-stay-how-americans-for-safe-access-the-nations-largest-member-based-cannabis-advocacy-organization-protects-patient-rights>.*

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# Sustainable Psychedelics:

## *A Chat with CSC West Speaker, AC Braddock*

By *Josh Crossney*

I recently spoke with 2022 Cannabis Science Conference West psychedelic science track speaker, AC Braddock to discuss her upcoming presentation entitled “Psychedelic Sustainability.” AC is an industry pioneer and CEO of Eden Labs, a trusted innovator of extraction and distillation technology for the cannabis and health products industries since 1994.

**Q:**

**We’re really excited that you’re going to be joining us this year at our newly launched psychedelic science track. AC, you have been a friend of the show for many years and you typically have spoken in our analytical science track about the extraction process with cannabis products. We’re excited to switch it up a little bit this year and give you the chance to speak about one of your other fortes in the industry. If you don’t mind, would you share with the readers what initially got you involved in the cannabis and psychedelic industries?**

**A:**

**AC Braddock:** The initial push was just looking at—and this was in the 90s, just looking at triple A personality types who are really driven and stressed out and had lost connection with their health, their wellness themselves, maybe nature—just finding a way to use plant medicine and nature to reconnect. That is the bottom-line drive and it has to do with all plants, basically.

**Q:**

**Can you share a little bit about your work with Eden Labs and exactly what Eden Labs does for those that might not be familiar?**

**A:**

**Braddock:** Eden Labs is a 27-year-old botanical extraction and distillation company, and we work with a wide array of different botanicals. But the founder, Fred Chester, had started working in cannabis in the mid-90s and then brought commercial extraction to the cannabis industry in 1996.

And then I, basically, before there were any conferences talking about extraction whatsoever, I lobbied them hard. I’m sure I was quite annoying, but they weren’t talking about extractions. Now that is the primary thing people talk about.

So, Eden Labs is just trying to share, teach, and educate and bring the plant medicine and botanical industries around to the forefront because we have forgotten as a culture and it’s sad. It’s sad for humans and the unbelievable amount of benefit, but also just that spiritual connection that we’ve lost. I think that is very obvious in our world today.

**Q:**

**You really have been a pioneer in this industry for many years. So, what was it like really being one of the first female leaders in this industry that was a pioneer in the early, early days and now cut to 2022? There’s a lot of different groups that are talking about inclusion, the LGBTQ community, people of color, unwriting the war on drugs. We’re seeing**

**A:**

**more women’s organizations now, but I’m talking back to a time where you would look around a room and you probably would feel alone. What was it like then? And what is it like now seeing a lot more women and minority involvement in general?**

**Braddock:** There was definitely a time in the early days and there would be 100 guys in a room and two women. It was interesting, but it’s not really all that different than a lot of other business events anywhere. So, it was kind of on par. And you learn as a woman to deal with that and as a person of color. And it’s never comfortable.

But as the industry grew, a lot more people jumped in before you had to have millions of dollars to be able to start a business. There was a tremendous growth of people of color and women. Then that switched and those numbers dropped. We always talk about balance in things, right? It’s not really balance, like life balance, it’s not really balance. It’s equity. And if there’s not equity that you have, you’re off balance. And then there’s a loss of creativity and there’s a loss of stability and there’s a loss of vision. Unless you have all of these people at the table, we’re never going to develop into a truly wholesome industry.

It’s a cultural shift, obviously, in the younger generations that you know for true to seek equality and equity in in business and not have business focus on money, but have business focus on people and solving problems. And as science-based people, that’s all we do. I

mean, we're here to solve problems.

As the business world catches up to that kind of philosophy where it's like, all right, health and wellness, happiness, what's more important here? What's going to really push humanity forward or just stalemate us or keep us back completely?

**Q:** Your talk at Cannabis Science Conference West is called "Psychedelic Sustainability." Can you share a little preview of what people might hear in your talk? What are your thoughts on how quickly the psychedelic industry is emerging?

**A:** **Braddock:** Well, I think 2020 and 2021 were extremely painful for people, and we were stuck inside, which means we were inside. And that allowed us to slow down and take some time for reflection. While all of this crap was going on in the world that was, you know, really scary and really disturbing. It also allowed some people to be like, "Oh, I'm at home, I can experiment a little bit." So, I think that that was really the push and the drive for it to happen faster.

I think people also couldn't connect with anybody and psychedelics, traditionally, in a shamanistic practice has always been about community connection. It's how they gathered

people together. It's how they shared how they're going to treat each other, the vision for what they were going to be doing for the next year or two or whatever. What I wanted to talk about is that connection and the fact that psychedelics and ethnogens are used ritualistically. It's therapeutic. And so that means it has to be ongoing, which means you can't keep flying to South America to do this because that's just not environmentally conscious, it's not sustainable. And you're diluting those cultures in a way, and you're overusing those methodologies to find what you really need, which you could find at home in a community that you have created or that already exists.



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Or that there are methodologies and rituals that have been historically in your area where you live, that have been denigrated to the point that they're non-existent. And all you have to do is revive them then you have a consistent, sustainable, therapeutic way to re-ground and connect with yourself and nature and your community.

**Q:** Obviously, we are the Cannabis Science Conference, so we have to feature all the great science and research. But with the psychedelic science track, it was also important to us to feature a number of indigenous voices who have been the gatekeepers of this knowledge of medicine for millennia.

**A:** Braddock: They should absolutely be involved. We have a lot to learn from them because they are closer to those connections, because culturally, Western culture has lost it. But they are also asking that we be respectful and conservative and understand the primary points of why this happened and continues to happen. And it doesn't become spiritual tourism.

**Q:** We have had some really interesting conversations about one of the downfalls of certain psychedelic drugs can be the digestive issues. A lot of times if people are trying psilocybin, for instance, sometimes the way their body metabolizes it, they can tend to have upset stomachs and issues with that. What are your thoughts on this topic?

**A:** Braddock: Well, we are very interested in all of the plants and have come up with a way to concentrate and do a really beautiful

extraction of psilocybin that removes the nausea. It increases the onset, shortens duration a little bit, which I think is a benefit for a lot of people.

Then when you start to put it in products, it doesn't taste like mushroom because a lot of people don't like that. I personally like the taste, but a whole lot of people don't. So, we're solving some problems (perceived problems) with it and increasing efficacy. It's been really exciting and it's ongoing. But right now, what we've come up with is pretty good. It's pretty exciting.

**Q:** Well, that's so important because just like cannabis, even now, there's a lot of products in the market that are not regulated and a lot of people that are extracting, however they're doing it, putting it into chocolate bars, putting it into candy or whatever the case may be. So really having that science behind the extraction process and trying to get into a more regulated place with that is really a good place to be. Is your role at Eden Labs' in the psychedelic science space centered around processing and extraction, just like in cannabis then?

**A:** Braddock: Yes. We're constantly working on botanical extractions and finding safe ways to provide therapeutic plant medicine to people, so you can feel good about it. You can titrate it as it's needed. But I've

also been doing some sitting with people in some guided journeys for a few years, which has been very rewarding for me. It's been lovely to see people like really settle into themselves and lose some of the fear of things that were based on nothing.

Everybody has these insecurities or fears—we all have them. And then getting into these kind of states where you just have more clarity, you're like, well, why am I worried about that? Why do I have that fear? I don't need to. And so it's just a really nice centering to see people find that strength within themselves that I have just loved to be a part of.

**Q:** Obviously, we have the conference coming up in May. Are there any other talks that you've been able to see on the agenda that you're excited to hear?

**A:** Braddock: My gosh. There's so many of them. I really want to see Dr. Lakisha Jenkins, the Nurses Network panel, and Ashéninka Mino and Bernadette Torres. There's just so many. The show is—it's just really exciting. I'm going to sit through almost all of them. I'm actually thinking about bringing my own chair.

*This interview was edited for length and clarity, to watch the full video interview with AC Braddock, please visit: <https://www.cannabissciencetech.com/view/psychedelic-sustainability-ac-braddock-shares-a-preview-of-her-cannabis-science-conference-west-talk>.*



#### ABOUT THE COLUMNIST

**JOSH CROSSNEY** is the columnist and editor of "Cannabis Crossroads" and a contributing editor to *Cannabis Science and Technology*® magazine. Crossney is also the founder of Cannabis Science Conference and now serves as Director of Cannabis Events at MJH Life Sciences™. Direct correspondence to: [JCrossney@mjlifesciences.com](mailto:JCrossney@mjlifesciences.com)

# Analysis of Natural Cannabinoids and Metabolites from Urine Using Styre Screen® HLB and SelectraCore® C18 Column on LC-MS/MS

**AS MORE STATES** in the US legalize marijuana for recreational and medical use, it is important to be able to accurately and precisely quantify cannabinoids from biological matrices. This application note outlines a solid phase extraction (SPE) procedure for cannabinoids in urine and a 12-minute liquid chromatography-tandem mass spectrometry (LC-MS/MS) method. The panel includes isomers  $\Delta^9$ -THC and  $\Delta^8$ -THC, which were successfully separated using C18 core-shell column.

## INSTRUMENTATION:

Samples were extracted on Styre Screen® HLB SPE column (SSHLB063, 3mL 60mg sorbent). SelectraCore® C18 core-shell Column (SCS27-C181021, 100 mm x 2.1 mm, 2.7  $\mu$ m) with a guard cartridge was used to analyze the extracts on Shimadzu Nexara LC-30AD w/MS-8050 LC-MS/MS system. Water & methanol containing 0.1% formic acid were used as mobile phase A and B respectively.

## CONCLUSION:

A LC-MS/MS and SPE extraction method was developed for the analysis of four natural cannabinoids and the two major  $\Delta^9$ -THC metabolites in urine. The addition of 1 mL of acetonitrile in the sample preparation helps prevent analytes from sticking to the test tube. The relative recovery of all analytes at low, medium & high concentrations was greater than 90% with a relative standard deviation of less than 8%. Apart from COOH-THC and OH-THC, all other analytes had matrix effects between +10% and -10%.



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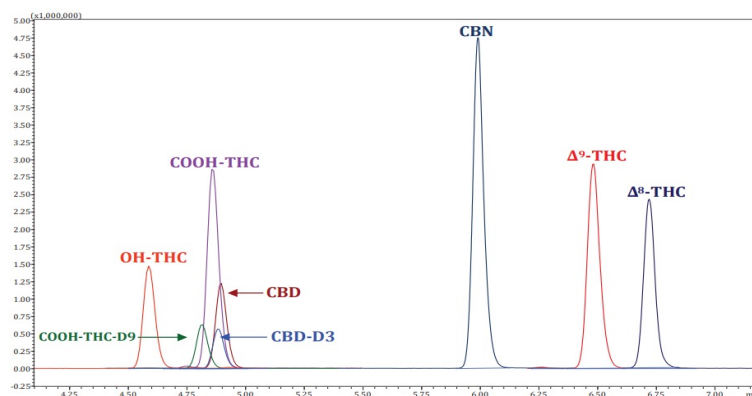
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Relative recovery of target analytes (N=5)

Analyte	5 ng/mL	RSD	25 ng/mL	RSD	50 ng/mL	RSD
$\Delta^9$ -THC	98%	4%	97%	2%	99%	2%
$\Delta^8$ -THC	93%	4%	94%	2%	95%	1%
OH-THC	103%	3%	99%	1%	105%	3%
COOH-THC	94%	7%	95%	3%	100%	2%
CBD	96%	4%	98%	1%	100%	1%
CBN	99%	4%	93%	2%	96%	1%

**FIGURE 1:** Chromatogram of an extracted 50 ng/mL urine sample



## Extraction Procedure:

<b>Sample pre-treatment</b>	1 mL Urine + 1 mL Acetonitrile + 1 mL pH 7.0 phosphate buffer Vortex and centrifuge samples for 10 minutes at 3000 rpm
<b>Condition</b>	2 mL methanol 2 mL pH 7.0 phosphate buffer
<b>Load</b>	Load the samples at 1 to 2 mL/min
<b>Wash</b>	3 mL DI water 3 mL 50% methanol
<b>Elute</b>	3 mL 60:40 methanol: hexane <i>Note: shake or vortex elution solvent well before use</i>
<b>Post elution</b>	Evaporate and reconstitute in mobile phase or methanol

## Fundamentals of Supercritical Fluid Extraction:

### Using Carbon Dioxide as an Environmentally Friendly Solvent for Extraction of Cannabis

BY CRAIG A. PERMAN

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*With increasing legalization and demand for medical and recreational cannabis and hemp products, preparation of pure oil concentrates is becoming widespread. While liquid solvents can be used for production of concentrates, traditional solvents such as alcohols or propane gas pose hazards because of their flammable nature. Further, residual solvent can remain in the end product. Supercritical fluid extraction (SFE), using carbon dioxide (CO<sub>2</sub>), is emerging as a method of choice within the cannabis industry for preparation of pure products. Although CO<sub>2</sub> is typically thought of as a gas, or a solid like dry ice, it can be transformed into a useful and safe extraction solvent through the application of mild pressure and temperature increases just above ambient conditions. Using commercially available equipment, SFE represents an efficient and safe extraction alternative to conventional solvent extraction yielding cannabis and hemp oils with no solvent residues. This article describes the nature of supercritical fluids and how they can be used in the cannabis industry. A schematic diagram of a one pass extraction system is described.*

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**A**S LEGALIZATION AND demand for medical and recreational cannabis and hemp products increases, the extraction of leaf and bud for preparation of concentrated oils is becoming commonplace. While liquid solvent-based methods are available for the generation of concentrates, traditional liquid solvents such as alcohol or propane gas pose hazards because of their flammable nature. Supercritical fluid extraction (SFE), using carbon dioxide (CO<sub>2</sub>), is emerging as a favored method within the cannabis industry. Although CO<sub>2</sub> is typically thought of as a gas, it can be transformed into a useful and safe extraction solvent through

an increase of pressure and temperature. SFE represents a powerful extraction alternative to conventional solvent-based methods yielding cannabis oils with no solvent residue. Furthermore, the use of SFE avoids many potentially serious hazards to personnel while yielding a purer product to the end user.

#### **What is a Supercritical Fluid?**

The most familiar of three states of matter is typically seen in water—ice as solid, water as liquid, and gas or vapor. Other chemical compounds such as carbon dioxide can also exist in three states. For carbon dioxide, we are familiar



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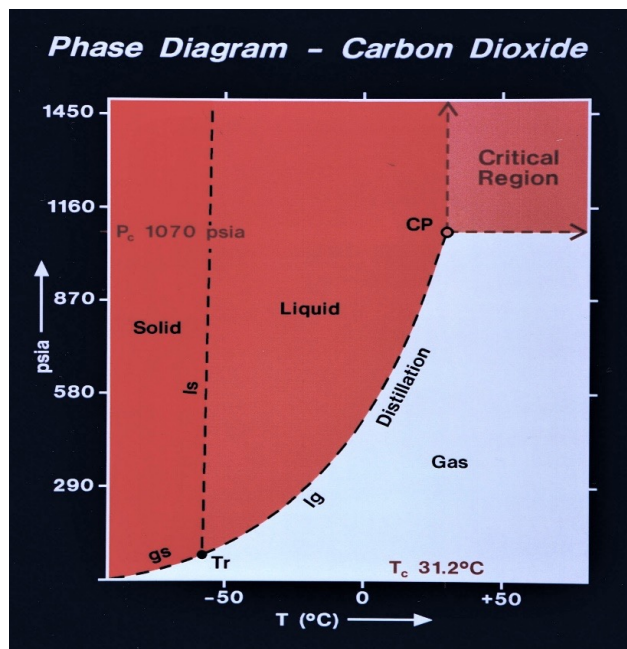
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**Figure 1:** Idealized phase diagram for carbon dioxide.**Table 1:** Critical point of carbon dioxide

Temperature	31.2 °C
Pressure	1078 psi (73.3 atm)

with the invisible gas which we exhale, and as a byproduct of fermentation and combustion. The solid, known as dry ice, is used for keeping materials cold, while liquid CO<sub>2</sub> must be held under pressure to remain in the liquid state. But there is another less familiar state of matter known as a supercritical fluid (SCF).

While there is nothing “super” or even “critical” about such fluids as the name might imply, its unique capabilities under specific process conditions of temperature and pressure make it useful in extraction applications. SCF offers multiple advantages when used for extraction. This is because an SCF has intermediate properties between more familiar states of matter, and it can diffuse through solids like a low-density gas, but dissolve materials similar to liquid solvents. In addition, close to the critical point, small changes in pressure or temperature result in significant changes in density, permitting many properties of a supercritical fluid to be altered or “tuned.” SCF CO<sub>2</sub> is also considered a “green” solvent because of its low environmental impact as it is not considered a volatile organic compound (VOC). Many other substances such as water and small molecules like organic hydrocarbons (propane, butane) can

also exist in a critical state though under much different temperature and pressure conditions. However, these fluids do not offer the same advantages as CO<sub>2</sub> and their use is generally more restricted.

The description of a supercritical fluid, sometimes referred to as a critical fluid, is any substance existing above its critical point (CP) of temperature and pressure. This concept is best understood by inspection of the phase diagram in **Figure 1**. There are two prominent intersections in the phase diagram. The first is the Triple Point (Tr), a unique combination of temperature and pressure of 5.2 atm (76.5 psi) and 56.4 °C. Here CO<sub>2</sub> can simultaneously coexist in three phases in equilibrium as a solid, liquid, and gas. The second notable intersection and of importance for this discussion is the critical point at the end of the gas-liquid distillation or equilibrium curve. The CP is the highest temperature and pressure at which a gas and liquid can coexist. Beyond this is the critical region where no change in temperature or pressure will liquefy the gas. Within this region, due to its compressibility, large changes of fluid density can be achieved with variations in pressure and temperature.

Since there is no phase change or liquid-gas phase boundary (such as along the distillation curve) there is no surface tension. This lack of surface tension and low viscosity compared to liquid solvents means that an SCF can readily diffuse into a matrix, enhancing rapid extractions. By retaining gas-like diffusivity it easily penetrates dry media to rapidly dissolve solutes (substance to be extracted) while maintaining near liquid-like solvation behavior. As efficient extraction is diffusion-based, it dissolves the solute, then diffuses from the matrix while retaining the solute as with a conventional liquid solvent. By comparison, an extraction using an organic liquid may take several hours, whereas supercritical fluid extraction can be completed in 10-60 min (1) depending on the substrate extracted.

Although several low molecular weight gases can be used for SFE, CO<sub>2</sub> is the most attractive because it combines the solvation power of liquid solvents such as hydrocarbon solvents or alcohols with safety, nontoxicity, and nonflammability. All this can be achieved under mild process conditions, minimizing potential product thermal degradation. Furthermore, because of changes in extraction temperature and pressure process conditions, its solvation characteristics can be modified or “tuned.” Carbon dioxide is the most common supercritical fluid because of its desirable properties.

While many small molecules (especially gases) have their own unique critical properties, most are not as useful as carbon dioxide. This is because the critical property of CO<sub>2</sub> falls in a range where low temperature and pressure process conditions make it attractive, especially for heat labile materials.



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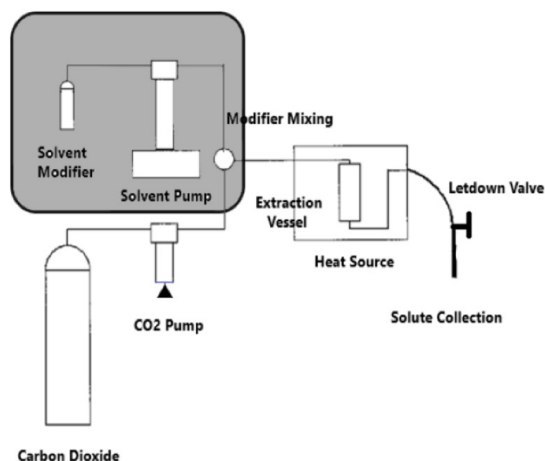


“SCF offers **multiple advantages** when used for extraction. This is because an **SCF** has intermediate properties between more familiar states of matter, and it can **diffuse** through **solids** like a low-density gas, but dissolve materials similar to **liquid solvents**.”

**Table II:** Physical and thermodynamic properties of gas, liquid, and critical fluid (1)

	Density kg/m <sup>3</sup>	Diffusivity mm <sup>2</sup> /s	Viscosity (cP)
Gas	1	1-10	0.01
SCF	100-1000	0.01-0.1	0.05-0.1
Liquids	1000	0.001	0.5-1.0

**Figure 2:** Schematic of SCF extraction system with modifier mixing single pass system.



These properties are listed in **Table I**. Whereas, normal liquid solvents have fixed densities of around 1 (as with water) a CF has variable densities from about 0.3 to 0.9 grams/cm<sup>3</sup>. This changeable density affects its ability to dissolve, hence recover, valuable extractants such as cannabis oils. **Table II** shows a comparison of properties among gases, liquids, and supercritical fluids.

### Supercritical Fluid Extraction

Supercritical fluid extraction (SFE) is the process of separating one component (the extractant or solute) from another (the matrix) using a supercritical fluid as solvent. Extraction typically occurs from a solid matrix, but can also take place from liquids especially for fractionation. SFE is often used as a sample preparation step for analytical purposes, but is easily scaled to extract large quantities of a desired material.

Typical extraction processes occur on a continuous basis as fresh SCF is recirculated through an extraction vessel. Once the SCF is laden with solute, it flows into a subcritical pressure vessel or through a pressure letdown valve for product collection. Reduction of pressure from the critical state to a gas at ambient pressure decreases solvation and the solute (oil) drops out and is then recovered. The solute, now at atmospheric pressure, will readily lose any residual CO<sub>2</sub> leaving no contaminants.

The SCF is then recompressed for recycle back to the extraction vessel after pumping up to the desired process temperature and pressure. A continuous flow is thereby maintained. If an SCF expands from a pressure letdown valve, heat must be added to the valve as the rapid expansion, known as the Joule-Thomson effect, can cause the valve to freeze and plug. The schematic in **Figure 2** shows a simple one pass extraction system where SCF CO<sub>2</sub> is vented to atmospheric pressure and the solute is collected at the end of a letdown valve. The shaded area represents a modifier extension which may be eliminated if cosolvents are not used.

Carbon dioxide's wide availability, low-cost, and food grade status make it ideal as an extraction solvent, and the most widely used SCF extractant. Separation of extraction products are easily achieved on reduction of pressure from the critical state as products are not soluble in gaseous CO<sub>2</sub>. Supercritical fluid CO<sub>2</sub> is suitable as a substitute for organic solvents and is currently used in a wide range of industrial and laboratory processes particularly where heat sensitive materials are extracted. Supercritical fluids have long been used in the food industry for the extraction of a variety of materials such as oils from hops, caffeine from coffee beans and teas, fractionation of edible fats and oils such as wheat germ oil, green coffee oil, rice bran oil, or palm oil, along with many other valuable food-related products (1). Many

other vegetable oils, essential oils, fatty acids, phospholipids, and bioactive compounds are also processed using SCF (2).

### Property Modifiers

Supercritical carbon dioxide is considered a nonpolar solvent (similar to nonpolar hydrocarbons such as propane, butane, and hexane, for example). While CO<sub>2</sub> readily solubilizes oil type compounds such as cannabis oils, it does have an affinity for polar molecules (more water soluble) especially at higher pressures, so it is capable of dissolving materials of this nature. In some cases, to extract polar molecules more efficiently, a cosolvent such as ethanol, known as a modifier, may be added in small percentage to the CO<sub>2</sub> process stream enhancing the extractability. Extractions using modifiers in supercritical carbon dioxide will require slightly altered temperature and pressure parameters to maintain conditions above the CP. However, as the primary constituents of cannabis are soluble in hydrocarbon (nonpolar) solvents, they will readily dissolve in pure SCF CO<sub>2</sub>.

### Commercial Equipment

Many companies have developed extraction systems for use for supercritical extraction (3,4). With the advent of lab-scale and pilot-scale technology in this industry, commercial equipment is readily available. Units can range in size from benchtop units of a few milliliters in size to large process scale equipment capable of extracting kilogram quantities of material (5). Such equipment uses SCF CO<sub>2</sub> where materials to be extracted are treated in large, pressurized vessels of several thousand liters. Product is then recovered by pressure let-down through a valve or a collection chamber where pressure is reduced to atmospheric conditions.

### Summary

The use of supercritical fluid CO<sub>2</sub> for the extraction of cannabis oils provides many advantages compared to the use of conventional solvents because of its nontoxic and nonflammable nature. Its availability, low-cost and food-grade status make it an ideal solvent. Also, because only mild conditions are required for processes, (temperature 31.2 °C and pressure 1078 psi), no product degradation is likely to occur, and products remain free from residual solvents. Extraction equipment is readily available for pilot-scale and commercial extraction operations making SFE the method of choice for cannabis extraction.

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### about the author

After 25 years as a research chemist for 3M Company in St. Paul, Minnesota, **CRAIG A. PERMAN** moved to Colorado. While at 3M he authored more than 20 patents in a diversity of areas including supercritical fluid processing, new molecule synthesis, and processes for the preparation of high strength, low-density polymer foams. He is currently president of Aqua Technica Inc., working in the area of solid phase extraction products for environmental water analysis, and technical writing. He has authored numerous publications and articles and has presented nationally and internationally at many conferences. Direct correspondence to: [permancraig\\_a@hotmail.com](mailto:permancraig_a@hotmail.com).

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## Improving Quality in Cannabis Testing Laboratories: Making ISO/IEC 17025 Work for Your Laboratory and Customers

BY KATHY NUCIFORA

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*The legalization of medicinal and adult use of cannabis in many states has resulted in state-by-state variability in the regulatory requirements that affect cannabis growers, producers, and testing laboratories. While many approaches to regulation exist, what they all share is the goal of providing regulators, industry leaders and, most importantly, consumers with greater confidence that cannabis and cannabis-infused products are safe to use. Cannabis testing laboratories play an essential role in establishing this safeguard. Many states require these laboratories to obtain accreditation to the ISO/IEC 17025, General Requirements for the Competence of Calibration and Testing Laboratories, for licensure. The technical aspects of the standard serve as an effective foundation for quality in the laboratory; however, the comprehensive management system is equally important. Pursuing technical acumen in the laboratory with an equal company-wide commitment to the pursuit of quality is the winning combination to achieve excellence in serving customers and ensuring the safety of cannabis products.*

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**T**HE LACK OF universal requirements for achieving, documenting, and maintaining quality practices in cannabis testing laboratories is evident as the trend toward state legalization of medicinal and adult use of cannabis continues in the United States. States have developed a wide variety of requirements with the goal of ensuring safety for consumers, patients, and the public. Many states require conformance with ISO/IEC 17025, General Requirements for the Competence of Calibration and Testing Laboratories (1). The ISO/IEC 17025 standard can be an effective foundation on which to build a quality cannabis testing laboratory, but it is not the entire structure. Laboratories must effectively and actively implement a comprehensive management system to realize the full value of ISO/IEC 17025 accreditation. Meaningful accreditation requires not only foundational quality

standards, but also a commitment by laboratory leadership and engagement of the entire laboratory team.

### Discussion

The importance of accuracy in cannabis testing laboratories for protection of the public has been receiving media attention, most recently from a case in Michigan involving the recall of cannabis products due to “inaccurate and/or unreliable results” from a testing laboratory (2). Potency and terpene profiles are important for effective medicinal and adult use of cannabis, but assurance that products are free from harmful contaminants such as pesticides, residual solvents, mycotoxins, and bacterial contaminants are also of paramount concern to public safety.

Founded in 1947, ISO refers to the International Organization for Standardization. The purpose of the



organization is to develop and publish international standards that convey consumer confidence across the globe that products and services are safe, reliable, and of worthy quality. Scientific experts and quality management leaders develop standards through consensus-building processes. Standards are updated, as needed, to incorporate breakthroughs in science, technology, modern methods, and best practices. Updates also address evolving customer, government, and societal requirements and expectations.

Laboratories rely on a broad array of standards from sources including regulatory bodies, analytical methods, and materials to ensure the reliability and accuracy of their test results. In the cannabis testing industry, one of the most common standards is ISO/IEC 17025 (3). ISO 17025 was developed in collaboration with the International Electrotechnical Commission (IEC). Both organizations have a long history of producing International Standards. ISO/IEC 17025 was most recently updated in 2017.

ISO/IEC 17025:2017 covers structural and resource requirements, along with technical process requirements. In addition, ISO/IEC 17025:2017 incorporates the principles of ISO 9001, which centers on the implementation and operation of a management system. A well-designed and implemented management system is the cornerstone of a quality operation, and must be maintained throughout the accreditation cycle. Similar to a comprehensive quality assessment (QA) program in a clinical laboratory setting, cannabis testing laboratories must not only control records, monitor processes, and identify corrective actions, but must also proactively evaluate risks and opportunities associated with laboratory activities to (1):

- give assurance that the management system achieves its intended results;
- enhance opportunities to achieve the purpose and objectives of the laboratory;

- prevent or reduce undesired impacts and potential failures in the laboratory activities; and
- achieve improvement.

When developing, operationalizing, and maintaining laboratory systems to ensure quality and technical competency, adopting a risk-based approach can prove valuable. Consider the risks, opportunities, and operational process, systems, and training that must be established and continuously maintained to meet the testing laboratory's business and customer requirements. This, and many other requirements in the standard, takes active engagement and a deep commitment to quality by the management team.

In preparing to demonstrate conformity to ISO/IEC 17025:2017, laboratories first need to obtain a copy of the current standard. This article does not purport to explain the standard in its entirety, but rather to provide a brief overview of some of the requirements covered in eight clauses of the standard, and to emphasize the importance of commitment and engagement of the entire laboratory team.

### **Clauses 1, 2, and 3 in ISO/IEC 17025:2017**

These three clauses are informational and specify the scope of the standards, normative references, and terms and definitions. Clause 3 is helpful for becoming acquainted with ISO terminology.

### **Clause 4: ISO/IEC 17025:2017 - General Requirements**

Requirements 4.1–4.1.5 speak to the importance of safeguarding impartiality of the testing performed. [Note: *Impartiality* is defined under the ISO standard as “presence of objectivity.” Furthermore, “Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the

laboratory.] The management team is expected to demonstrate in words and actions its commitment to safeguarding impartiality in laboratory activities. If any conflict of interest or other risk to impartiality is identified, swift action is also expected.

Requirements 4.2–4.2.4 emphasize the central role of confidentiality of customer information and laboratory activities under ISO/IEC 17025:2017. Care must be taken to ensure that customer information and laboratory activities performed on behalf of the customer are confidential. There may be times when release of information is required by law. It is the laboratory's responsibility to inform the customer, in advance, what information will reside in the public domain.

Furthermore, information obtained from other sources about a customer must also be kept confidential. Personnel, including external contractors, are expected to maintain customer confidentiality in accordance with the laboratory's established policy or terms of employment or contract.

### **Clause 5: ISO/IEC 17025:2017 - Structural Requirements**

Requirements 5.1–5.7 outline the organizational expectations of ISO/IEC 17025:2017. Among the general structural requirements for testing laboratories are:

- Operating as a legal entity, including identification of any parent organization.
- Identification of the management structure, including roles and responsibilities.
- Definition of the laboratory activities, including identifying any laboratory activities, which are conducted away from the permanent facility, and included under the laboratory's accreditation, as well as listing those activities outside of the laboratory for which

the laboratory is not claiming accreditation.

It is important to ensure that the laboratory has clearly defined functional roles and responsibilities at all levels of the organization and that personnel have the authority and resources to perform their assigned laboratory activities. The management team has the responsibility to ensure that communication is occurring regarding the effectiveness of the management system and conveying the organizational values regarding the importance of meeting customers' and other requirements to all staff.

### Clause 6: ISO/IEC 17025:2017 - Resource Requirements

Requirements 6.1–6.6.3 outline the resource expectations of ISO/IEC 17025:2017.

#### General

Generally, it must be clear that the laboratory possesses the resources, facilities, equipment, systems, and support systems needed to provide services to its customers.

#### Personnel

Laboratories are expected to ensure that persons involved in laboratory activities are trained and competent to perform their jobs. Records must be kept of training and competency. Additional requirements are listed below.

- The laboratory is required to have a managerial chart identifying key personnel and their roles in the organization, such as technical directors and supervisors.
- Each person must be qualified for the positions that they hold, as defined by the laboratory.
- Some states require specific education, experience, or licensure for laboratory personnel. The laboratory must include these requirements in the laboratory manual, job descriptions, or

other documentation.

- Personnel, who perform any part of the testing process, must be evaluated and determined to be competent before they begin laboratory examinations. Competency evaluation must be continuously updated and monitored by supervisors.
- Good record keeping on hiring, training, and evaluating competency must be maintained in accordance with the laboratory's human resource policies, processes, and procedures.
- Finally, personnel performing laboratory activities must demonstrate a commitment both in word and in action to safeguard confidentiality and impartiality.

#### Facilities and Environmental Conditions

Requirements for ensuring that the facility and environment is suitable for performing laboratory activities safely and accurately include, for example:

- Environmental conditions must be monitored and documented according to established facility and environmental procedures.
- Measures must be taken to secure access to the laboratory and information technology, including designated authorities and responsibilities, and restrictions as needed.
- Process controls must be in place to ensure laboratory activities are not negatively affected by potential sources of interference such as contamination, environmental conditions, distractions, and so on.

#### Equipment

The term laboratory equipment extends beyond the instrumentation or analyzers to include other items such as reagents, reference materials, software, and measuring instruments.

Generally, the specific requirements related to equipment used to perform

laboratory activities are designed to ensure that equipment it is suitable and fit for its tasks, maintained, calibrated, updated, and verified.

#### Metrological Traceability

Testing laboratories are required to maintain metrological traceability of its measurement results under the ISO/IEC 17025:2017 standard.

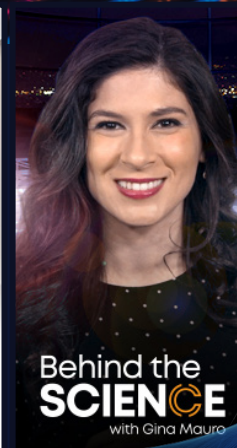
Equipment used by laboratories to produce measurement results must be calibrated and verified for each tested analyte using only reference materials (RM), certified reference materials (CRM) or, in cases of proprietary or unique methods, materials that can demonstrate appropriate metrological traceability. In cases where it is not possible to obtain metrological traceability to the International System of Units (SI), laboratories may use certified reference materials from a competent producer or use consensus standards, methods, or procedures that are clearly defined and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

#### Externally Provided Products and Services

When subcontracting and purchasing products and services those products and services must be suitable for laboratory activities and procured in accordance with the laboratory's criteria for evaluation and selection of external providers. In addition, the laboratory must demonstrate how it routinely monitors the performance of external providers and how it re-evaluates performance over time. The laboratory is expected to communicate any requirements to external providers related to the products or services to be purchased.

### Clause 7: ISO/IEC 17025:2017 - Process Requirements

Requirements 7.1–7.11 outline the process expectations of ISO/IEC 17025:2017.



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While all clauses are important within the ISO framework, the process requirements are extensive and should be studied carefully to ensure that the many operational processes, which are central to managing and producing quality results, are indeed satisfied.

### *Review of Requests, Tenders, and Contracts*

It is important that the laboratory engage and serve its customers in a way that supports clear communication and cooperation, ensures that customer requests are clearly defined, documented, and understood, and that the laboratory has the capability and resources to meet unique customer requirements. This will strengthen the laboratory's commitment to the highest quality experience.

Laboratories are prohibited from either directly or implicitly implying that certain activities are covered in its scope of accreditation when this is not the case.

### *Selection, Verification, and Validation of Methods*

The selection and verification of methods is vital to providing customers with valid and accurate results. Procedures for the evaluation of measurement uncertainty and statistical techniques for the analysis of data are a necessity. All methods, procedures, and supporting documentation must be current and readily available to laboratory personnel.

When introducing a new method, performance parameters should be established by the laboratory. Recognized reference methods should be used when available and appropriate for the laboratory's activities. It is imperative that the laboratory verify that a method can be performed properly before it is implemented. This includes verification of statistical parameters such as precision, measurement range, measurement uncertainty, and limit of detection, as established by the laboratory.

In addition, if the laboratory changes the standard methods used for testing, or the method is modified by the laboratory, the method must be validated to confirm the method can achieve required performance. The records of the method verification must be retained.

### *Sampling*

The importance of proper sampling in ensuring an accurate, high quality laboratory result cannot be overstated. If the laboratory is performing sampling for customers, there must be a sampling plan, including the method for carrying out sampling of substances, materials, and products. If sampling is occurring away from the laboratory, it is important that the laboratory convey the sampling plan and method to the site where sampling is being conducted and ensure that those responsible for performing sampling are trained and competent in the sampling procedure. Sampling plans, whenever feasible, should incorporate relevant statistical methods.

This section also covers requirements for documenting and maintaining sampling records.

### *Handling of Test or Calibration Items*

The laboratory must have a procedure for the transport, receipt, handling, protection, storage, retention, and disposal of testing materials when calibration services are included in the laboratory activities.

### *Technical Records*

The appropriate technical records must accompany each laboratory activity. The technical record for each laboratory activity must include the date, the person responsible for that activity, the test result, report, and any data or information that is important to assist with determining the effects of measurement uncertainty and more. Clear records must be kept along with traceability of

any modifications to the original observations, including the person responsible for the changes made.

### *Evaluation of Measurement Uncertainty*

Measurement uncertainty is a key consideration in laboratory testing and is commonly seen as the statistical representation of the dispersion or range of values that can be attributed to what you are measuring. Contributions to measurement uncertainty must be identified and clearly documented, including those related to sampling and the analytical method.

### *Ensuring Validity of Results*

Laboratories are required to rely upon internal and external controls to ensure the ongoing validity of test results. The primary purpose of controls is to ensure that the test procedure is performing in accordance with the validated method. The laboratory must develop an appropriate monitoring process and all activities must be documented. Examples of controls include: use of alternative instruments validated to provide traceable results; function checks of measuring and testing equipment; use of control charts; intermediate checks on measuring equipment; replicate tests; retesting of retained materials; correlation of results for different characteristics; intra-laboratory comparisons and participation in proficiency testing. In some states, specific regulatory requirements may apply so it is beneficial to review state laws related to quality control and proficiency testing requirements.

### *Reporting of Test Results*

Laboratory results must be reviewed and authorized before they are reported. Results must be reported accurately and clearly in accordance with the agreements between the laboratory and its customers. In addition, ISO/IEC 17025:2017 is very specific about the

# Are You Still High? THC Metabolites in Urine

In humans, cytochrome P450 contains three primary enzymes involved in the metabolism of  $\Delta^9$ -tetrahydrocannabinol (CYP2C9, CYP2C19, CYP3A4). These enzymes are mostly found in the liver, but can occur in other lipophilic tissues like brain, small intestine, heart, and lungs. THC elimination in the body is dictated by the accumulation of the compound in both adipose tissue and plasma and, due to the lipophilicity of THC, the determination of the concentration through excretion is difficult.<sup>1,2</sup> Likewise, states have passed regulations allowing for the legal use of both medicinal and recreational cannabis while workplaces in those states continue to dictate safety regulations with a zero tolerance drug policy culminating in a urine test to determine compliance. With more than 100 THC metabolites, detection of the most abundant, 11-hydroxy-THC, 11-carboxy-THC glucuronide, and 11-carboxy-THC, hold the most focus. Typically, between 80% and 90% of the THC consumed is excreted as carboxylate and hydroxylate metabolites.<sup>3,4</sup>

The Hamilton PRP-C18 reversed-phase column offers good selectivity and peak shape when detecting the three major components of THC metabolites in urine. As shown in Figure 2, samples spiked with metabolites in urine show good correlation in low concentrations and rapid sample analysis can be achieved in under eight minutes. In addition to good column performance, all Hamilton columns come with value added features that include great chemical and thermodynamic stability and increased lifetime due to their PS-DVB backbone.

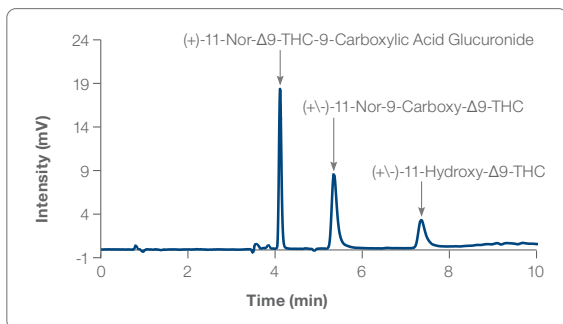


Figure 1: Most abundant THC metabolites.

Author: Adam L. Moore, PhD

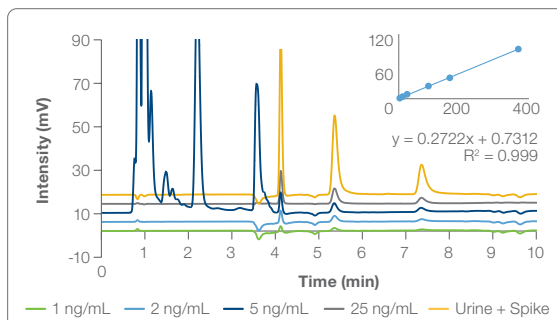


Figure 2: Urine sample spiked with 3 ng/mL of THC metabolites.

## Column Information

Packing Material	PRP-C18, 5 $\mu$ m
P/N	79676

## Chromatographic Conditions

Gradient	0.00–2.00 min, 5%B 2.01–3 min, 5–50%B 3.01–8 min, 50–95%B 8.01–10 min, 95%B
Temperature	35°C
Injection Volume	5 $\mu$ L
Detection	UV at 230 nm
Dimensions	150 x 4.6 mm
Eluent A	10 mM $\text{CH}_3\text{COONH}_4$
Eluent B	$\text{CH}_3\text{CN}$
Flow Rate	2.0 mL/min

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common elements of a test report so be sure to review those elements and include them in the laboratory test report.

### Complaints

The laboratory is required to implement a process for handling complaints to include an acknowledgment to the complainant, confidentiality, investigation of the complaint, assessment of the validity of the complaint, and decisions and actions taken to resolve the complaint.

### Nonconforming Work

All noted instances where laboratory activities failed to adhere to the laboratory's documented policies and procedures for conformance to ISO/IEC 17025:2017 must be identified as a "nonconformity" with a corrective action cycle. The nonconformity procedure is in place to ensure that operational and technical laboratory activities are continuously conducted in accordance with the laboratory's policies and procedures, customer requirements, and best practices. The laboratory must establish procedures describing the actions to be taken when a nonconformity is identified.

Nonconforming events can be addressed based upon risk levels, with the highest risk nonconformities given the highest priority. In some cases, it may be necessary to inform customers of the nonconformity and any impact on testing results, if applicable. Records of corrective actions to address the nonconformity must be retained.

### Control of Data and Information Management

The laboratory's information management system must be protected from unauthorized access and safeguarded from tampering, theft, and loss of data. This requirement applies to computerized and noncomputerized data and information systems. Systems must be maintained in a way that ensures the

integrity of the data and information.

To the extent interfaces are relied upon, those interfaces between systems must be validated for proper functioning. Software configurations must be authorized, documented, and validated before implementation. In cases where data is being transferred, the data must be checked, including a check to ensure any calculations are appropriate and accurate.

### Clause 8: ISO/IEC 17025:2017 – Management System Requirements

Requirements 8.1–8.9 outline the management system requirement of ISO/IEC 17025:2017.

Generally, this clause outlines the management system requirements to ensure that the laboratory can achieve continuous, consistent conformance to the ISO/IEC 17025:2017 requirements. Through the management system, the laboratory has the opportunity to systematically evaluate the laboratory activities, initiate correct action cycles for nonconformities, evaluate whether nonconformities have affected the integrity of reported results, respond to customer complaints, and more.

If the laboratory management system is established and maintained in accordance with ISO 9001, and has shown that it is capable of supporting consistency in laboratory conformity to the requirements of ISO/IEC 17025:2017, then the ISO 9001 established system can satisfy the intent of these management system requirements.

### Management System Documentation

Management system documentation is important in conveying the many values, behaviors, policies, and processes that must be operationalized to ensure that laboratory activities are clearly and competently performed by trained staff, resources are well deployed and maintained, and customers receive

excellence in service. It is a system that can lead to meaningful improvement and support the organizational and business goals while addressing risk and capitalizing on opportunities.

Success in the laboratory's pursuit of quality management and technical competence is largely dependent on the commitment at the top of the organization. An engaged management team is one indicator of success. In addition, all personnel performing laboratory activities must have access to all parts of the management system documentation related to the responsibilities and authorities of their position.

It is not only essential to have the system of documentation, but also to be able to demonstrate through evidence how application of the system leads to improvement. A systematic focus on nonconformities and initiating and closing corrective action cycles over time can improve laboratory operations, competence, and results.

### Control of Management System Documents

Management system documentation must be controlled to ensure that the documentation-in-use reflects the latest in policy and procedures. As is also the case with the creation of new documents, changes in documents must be approved for adequacy before they are distributed or become available to staff or customers. Documents must also be routinely reviewed and updated as necessary. A system for uniquely identifying documents is an excellent strategy for keeping documentation organized and accessible.

### Control of Records

Management system records must be legible, consistent with confidentiality requirements, and clearly identified. Furthermore, controls are needed to store, protect, back-up, archive, retrieve, retain, and dispose of records. The period for retaining records must

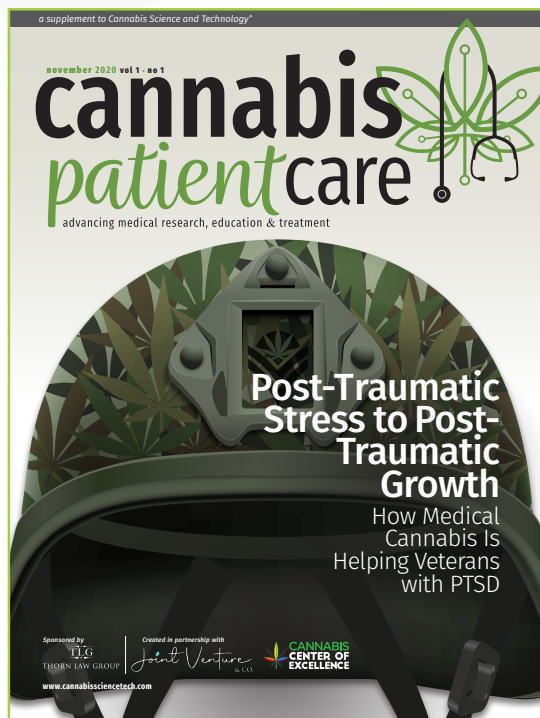


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be consistent with the laboratory's contractual obligations.

### *Actions to Address Risks and Opportunities*

A continual assessment and consideration of risks and opportunities makes good business sense. Assessing risk and opportunities can occur at all layers of the organization and, in many cases, this is an activity that already happens every day; staff members are meeting the needs of customers today while having their eyes on future opportunities and threats. The purpose of this requirement is to create an intentional focus on routinely reviewing the risks and opportunities facing the specific laboratory and the industry as a whole, and determining when the laboratory should implement action plans to mitigate the risk or take advantage of the opportunity.

### *Improvement*

As has been previously addressed, a central goal of a management system is to find, select, and act upon opportunities for improvement. The management system, if done well with a sustained focus, will enable the laboratory to identify a number of opportunities and improve the laboratory over time. This requirement also speaks to the value of implementing a customer feedback process, which can generate a wealth of information and ideas for improvement.

### *Corrective Actions*

Corrective actions must be taken to correct nonconformities identified internally or during external assessments. The first step to take when a nonconformity is identified is to examine the factors and conditions leading to the nonconformity. This is critical to development of a corrective action plan that does not just fix an incident, but attempts to prevent that incident from occurring again. Not only

is it important to correct problems and nonconformities, but also to monitor the effectiveness of any corrective action taken. Corrective action cycles should be well documented and can be a powerful tool for organizational learning and sustained improvement.

### *Internal Audits*

Internal audits are an established tool to support organizations as they assess different areas of their business on a rotating planned schedule. The goal of audits is to evaluate whether the management system is working and whether various departments or teams within the laboratory are following policy, protocols, and established best practices. It can be seen as an opportunity for learning and offers a chance to right the ship before it has gone too far off course. Consider internal audits as a calibration activity in being proactive in setting things right. It is also a great opportunity to engage new members of the team in business policy, practices, and protocols.

Internal audit activities must be documented and outcomes shared with applicable supervisors or managers. Nonconformities identified during internal audits require evaluation and timely corrective action cycles. Audits are also a good source of data to identify improvement opportunities.

### *Management Reviews*

As a final component to the management system, laboratories seeking to show conformity to ISO/IEC 17025:2017 must engage in routine management reviews. Management reviews are conducted with many participants from various areas of the laboratory who come together to evaluate the fulfillment of the management system. This is an opportunity to look backwards and forwards to consider the performance of the management system, and assess

the need for changes and improvements. Allocation of resources and training may also be topics for discussion in the context of meeting goals. All inputs since the last review and any new inputs are considered to ensure timely closing of corrective action cycles.

### *Summary*

Cannabis testing laboratories, whether testing products for medicinal or adult use, have a responsibility to provide accurate test results for potency, terpenes, and contaminants to build the public trust in the safety and efficacy of cannabis products. While ISO/IEC 1725:2017 can provide a good foundation for building a quality laboratory, each laboratory must establish analytical parameters, define personnel qualifications, and develop detailed procedures that reflect the needs of the laboratory and its customers. Laboratories should think of ISO/IEC 1025:2017 accreditation as a tool toward reaching the goal of accurate testing, rather than holding ISO/IEC 17025:2017 accreditation itself as the goal. This takes commitment from the top of the organization to those performing clerical functions, sampling, processing specimens, and performing testing.

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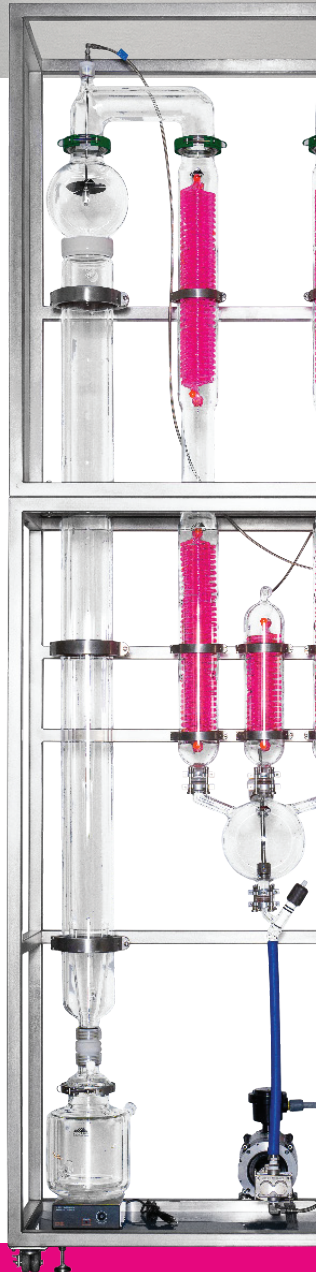
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