



Cannalysis



Cannalysis is committed to promoting policies and regulations that enhance consumer safety and transparency. Our commitment is firm in ensuring Californians are consuming safe, compliance tested cannabis products purchased through licensed retail channels.

An Alarming Trend

Recently, there has been a disturbing increase in vaping related deaths and illnesses. The CDC and FDA are investigating these illnesses to determine the cause for the sudden increase in the number of people either suffering or dying after vaping. Vitamin E acetate, a compound used to thicken vaping liquids, has been implicated in the rise in the rate of observed lung illnesses. Vitamin E Acetate is colorless and odorless, has similar viscosity to cannabis oil but is much cheaper. Vitamin E acetate, which is sold legally, is commonly used as a nutritional supplement and in skin-care products but its inhalation toxicity is not known.

While the link between lung illness and Vitamin E Acetate is not certain, there has been an increase in requests to have products tested for the presence of Vitamin E Acetate. Cannalysis dedicated resources and personnel towards developing a robust and scientifically validated method for Vitamin E Acetate in vape products to meet the industry demands and improve consumer transparency.



**1,080 Reported
Illnesses**



**100+ People
Affected In CA**



**24 Total Deaths
As Of 10/8/19**



**48 States Have
Reported Cases**



Study Background

Cannalysis launched a study into investigating the prevalence of Vitamin E Acetate in the regulated market with over 20 partners. The study highlights legal and responsible cannabis operators that are creating safe and compliant products for consumers, free of potentially harmful additives. Furthermore, our data and analysis is intended to help educate legislators, consumers, and the public that California compliance tested products are safe.

In order to complete the study of the presence of Vitamin E Acetate in vaping products from the licensed market, 112 samples were collected and analyzed. For 76 of the samples, a trained Cannalysis sampler visited the licensed facility and collected an unbiased representative sample from a batch in a randomized manner. Our sampling approach for the study is identical to regulatory compliance standards. The remaining samples were, and continue to be, submitted by operators directly to our testing facility. The samples were analyzed for the presence of Vitamin E Acetate by LC-MS/MS to ensure the highest level of accuracy and precision.

Thank You To Our Participants



Sunday Goods



Test Methodology

Testing for Vitamin E Acetate and Vitamin E by LC-MS/MS

Swetha Kaul, Ph.D. and Ritu Arora, Ph.D.



The dynamic range of the Vitamin E Acetate assay is 0.01% to 0.5%. Calibration curves for Vitamin E Acetate was acquired in the range of 10ppb to 500ppb and exhibited excellent linearity.



The calibration was run 5 consecutive times to demonstrate the precision and stability of the method.



The percent CV for the 5 injections was 6%, which demonstrates the excellent precision that is observed using this method.

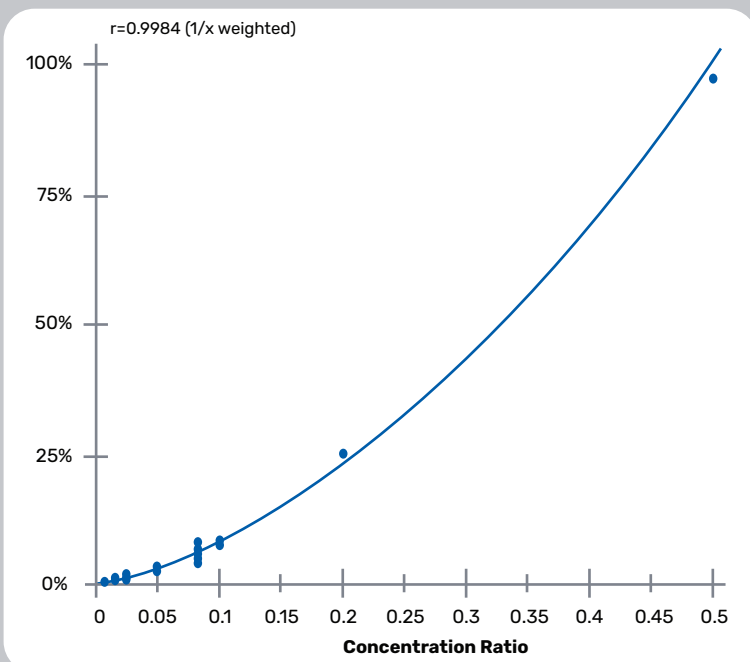


The accuracy ranges from 83% to 118% and is generally within 10% of the expected value. These values indicate that the accuracy expected to be obtained with this method will meet regulatory requirements.



The ion ratios for each of the injections demonstrates that reliable ion ratios are obtained even at the low concentration calibration point for this method.

Analyte Name	RT (min)	Q1 Mass (Da)	Q3 Mass (Da)
Vitamin E	3.53	431.20	165.17
Vitamin E	3.53	431.20	137.15
d6-Vitamin E (IS)	3.54	437.25	171.20
Vitamin E Acetate	4.38	473.25	207.07
Vitamin E Acetate	4.38	473.25	165.14

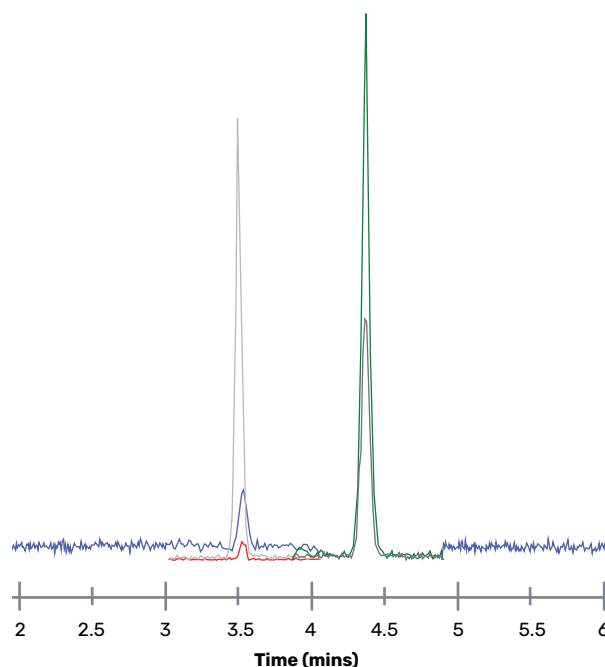


Column: Agilent Poroshell 120 EC-C18, 2.7 μ m
Dimension: 100 x 4.6 mm
Mobile Phase: Solvent A: 0.3% Formic Acid, 5 mM Ammonium Formate in Water
Solvent B: 0.3% Formic Acid, 5 mM Ammonium Formate in Methanol

Gradient:

Time(min)	%B
0.0	95
0.5	100
5.0	100
5.1	95
7.0	95

Flow Rate: 1.2 mL/min
Column Temp: 50°C
Injection Volume: 5 μ L
Detection: SCIEX Triple Quad™ 3500 with ESI Source

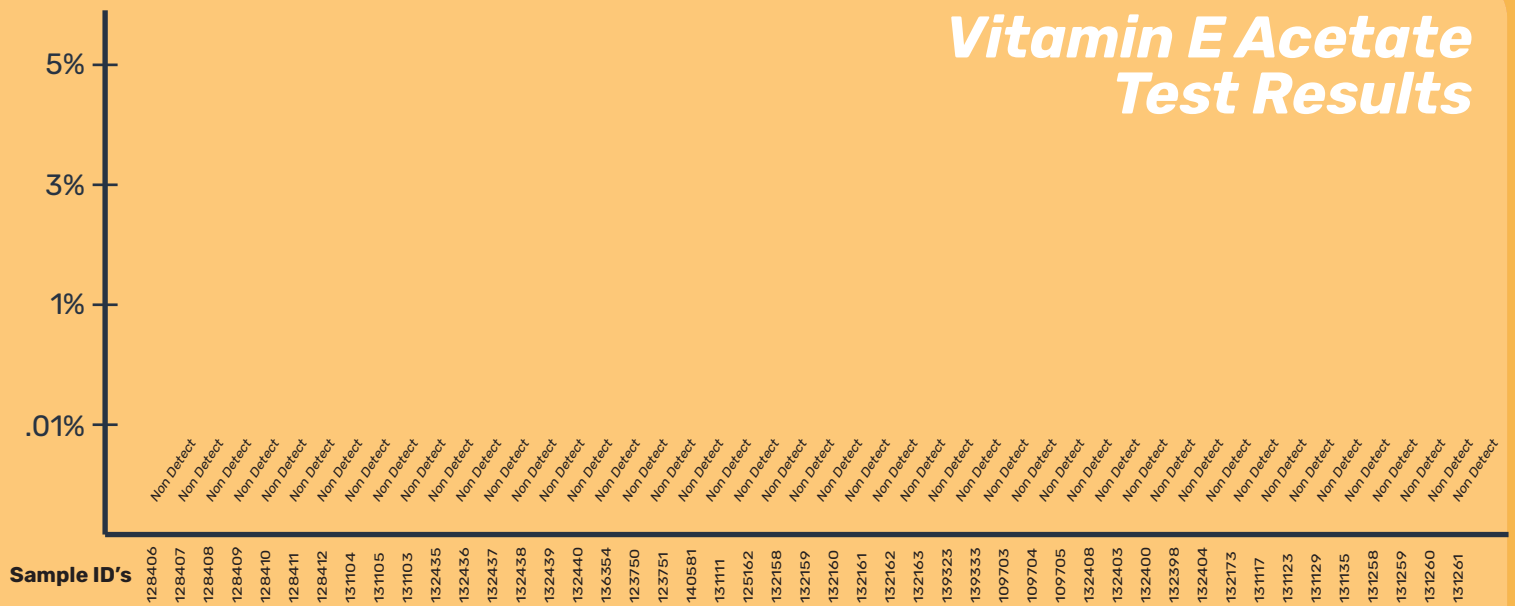


Brand Results

Cannalysis is committed to achieving accurate and reproducible results through unbiased and well documented sampling. We utilized our proprietary 3-D modeling software to ensure true randomness when collecting samples for this study.

Of the 112 samples that were analyzed by Cannalysis for this study, Vitamin E Acetate was not detected in products obtained from licensed facilities. The limits of quantification (LOQ) of Vitamin E Acetate in this assay was 0.01% and none of the licensed products contained Vitamin E Acetate at levels higher than the LOD. Furthermore, Cannalysis used the strictest protocols in both sample collection and analysis to ensure the highest level of confidence in the reported results.

Vitamin E Acetate Test Results



Sample ID's

128406
128407
128408
128409
128410
128411
128412
131104
131105
131103
132435
132436
132437
132438
132439
132440
136354
123750
123751
140581
131111
125162
132158
132159
132160
132161
132162
132163
139323
139333
109703
109704
109705
132408
132403
132400
132398
132404
132173
131117
131123
131129
131135
131258
131259
131260
131261



21 COMPANIES PARTICIPATED



112 SAMPLES RUN TO DATE



RANDOMLY SAMPLED FOR BRAND STUDY



NO DETECTIONS



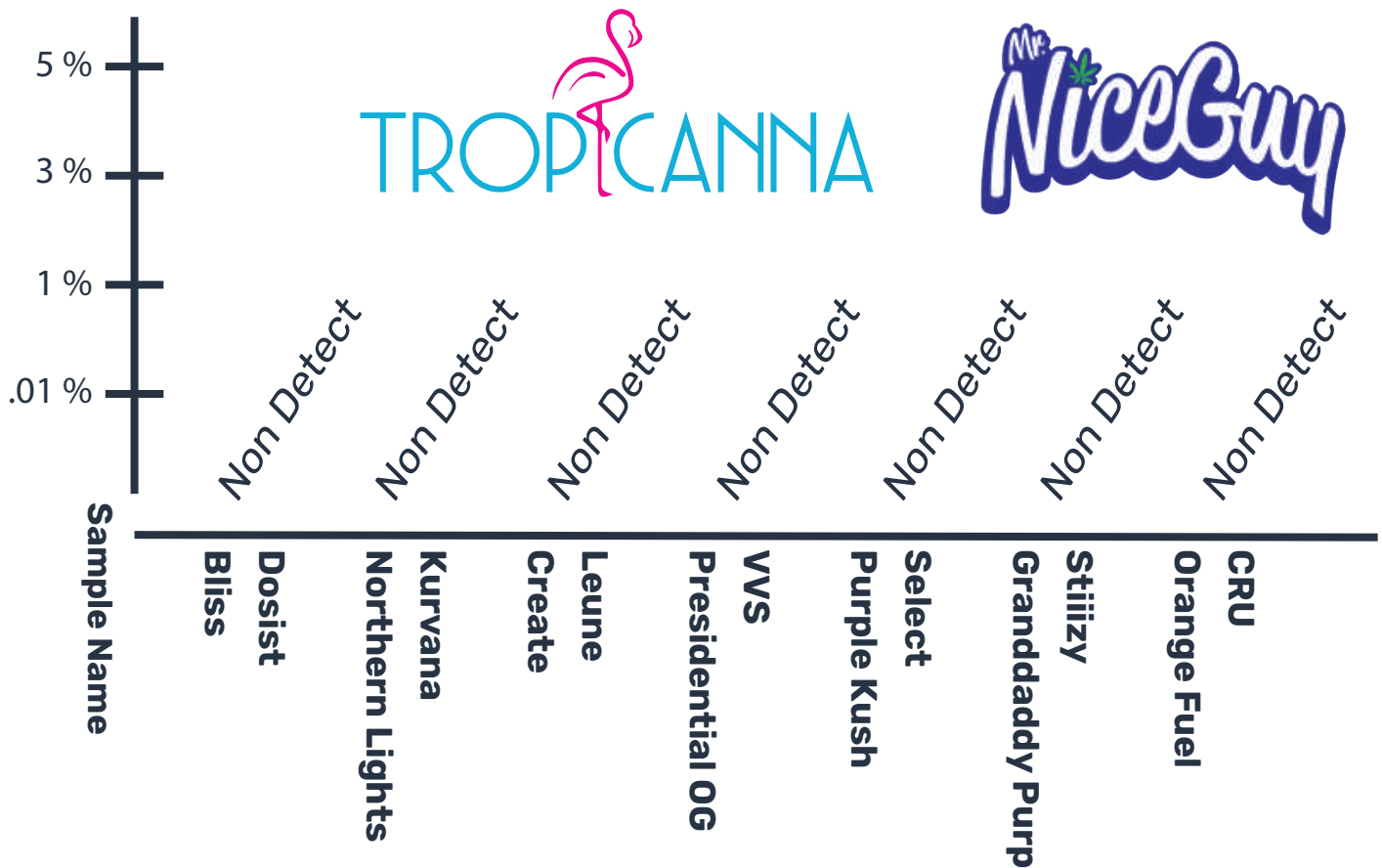
ADVOCATES FOR A MORE TRANSPARENT MARKET

Retail Results

IN ADDITION to efforts which detail the current state of licensed legal manufactures as they pertain to Vitamin E Acetate, Cannalysis partnered with 2 legal retailers in an effort to prove further that licensed operators are providing consumers with legal safe cannabis.

In this portion of the study a Cannalysis sample technician adapted our random sampling tool in a retail environment to select several vape cartridges from various brands. These cartridges were then tested for the presence of Vitamin E Acetate.

The results of this coincided with the brand study in which none of the selected samples contained Vitamin E Acetate at levels higher then the LOD of our method.



Discussion

The large sample size of this study supports the conclusion that Vitamin E Acetate is not typically used in the legal cannabis market. The use of additive and cutting agents such as Vitamin E Acetate appears to be more prevalent in the unregulated market and based on a recent CDC report containing interviews with vaping-associated injury patients, “the vast majority reported using illicit THC-containing products sold as prefilled cartridges and obtained from informal sources.” This highlights the need to combat unlicensed retail and educate consumers on how to identify legal cannabis products from illegal ones.

Based on the findings of our study, Cannalysis believes that any additional regulations or proposals to ban the sale of cannabis vaping products would be unnecessary and counterproductive – it would have the unintended consequence of driving consumers to unregulated and potentially unsafe illicit markets. Any ban on vaping would likely lead to an increase in vaping-related illnesses associated with illegal products.

The legal cannabis industry and the licensed cannabis testing labs are well equipped to deal with testing and removing the use of any agent/s identified by the FDA and CDC as the underlying cause of the vaping-related illnesses. The industry is motivated to help in any efforts to investigate the use of any agents of interest and the study presented in this document demonstrates that.

References

- 1. U.S. Food and Drug Administration.**
<https://www.fda.gov/consumers/consumer-updates/vaping-illness-es-consumers-can-help-protect-themselves-avoiding-tetrahydrocannabinol-thc-containing>
- 2. Centers for Disease Control and Prevention, Smoking and Tobacco Use.**
https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html
- 3. David Downs. Amid Vape Pen Lung Disease Deaths: What Exactly Is Vitamin E Oil?**
https://www.cdc.gov/vcco/basic_information/e-cigarettes/severe-lung-disease.html