Analytical Labs - Proficiency, Variance & Standardization

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Proficiency Testing

Why Does the Cannabis Industry Need Testing?

- Safety
- Reliability
- Fairness
- Transparency
- Improve Performance & Methodology
- Regulation

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Why Is It So Important For Cannabis?

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Why Should We Test The Testers?

- Safety – Can a Lab Do What They Say?
- Reliability – Can Consumer Believe Lab?
- Fairness – Consumer Gets Dose They Pay For?
- Transparency – Industry Sees Equipment & Methods That Perform the Best
- Improve Performance & Methodology – Objective Feedback For Self Improvement
- Regulation – Barometer for How Industry Is Performing

There Are Several Challenges Particular To This Matrix

- Lack of Federal Oversight – 30 Sets of State Regs
- No Standardized Methods – At Least 7
- Diverse Equipment – Different Per Analyte & Matrix
- High Diversity/Rapid Evolution in Matrices
- Legal Challenges With Cannabinoids
- **Variance**

Variance Deserves More Attention

Variance in commonly expected and accepted (20% - FDA- This is presumed to be under the best of circumstances in industries with standard matrices and standard testing methods)

Cannabis Has a Greatly Increase Likelihood of Higher Variance

- Batch Sampling
- Cannabinoid Instability/Degradation
- Lack of Standard Methods Increases Variance
  - Sample Prep for Gummy vs. Chocolate
  - QPCR vs. RSG/LCM

You Came For The Data

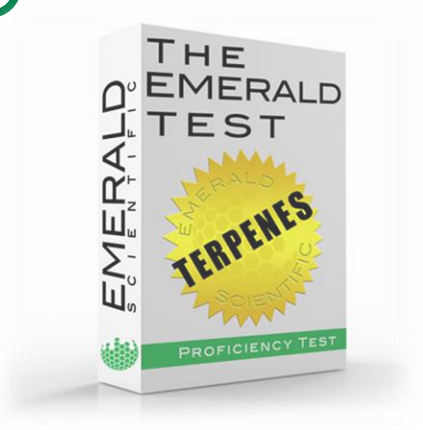
- Best Barometer By Which To Judge Progress of The Industry Is DATA
- ILC/PT's Provide LOTS of Data To Learn From
- I Brought Data From 6 Rounds Over The Last 4 years

Evolution of Program Over Time Tells a Story

	2014	2015	Spring 2016	Fall 2016	Spring 2017	Fall 2017	Spring 2018
Total # PT's Offered	1 P	1 P	2 P	4 P,M1,Ps,RS	5 P,M1,Ps,RS H	7 P,M1,M2,Ps RS,H,T	12 P,M1,M2,M 3,M4,Ps,RS, H,T(Hemp)
Total # Analytes	1	4	16	30	40	51	?
Total # Participants	14	24	36	40	56	58	77

P=Potency RS=Residual Solvents M1=Microbial 1 M2=Microbial 2 PS=Pesticides T=Terpenes H=Heavy Metals

2014 – Crack & Shoot THC



- 14 Labs
- 19 Values Reported
- All Labs +/- 25%

Breakdown of Instrumentation used to analyze (-)-Delta 9-THC, CAS # 01972-08-3:

Instrumentation	Number of Laboratories
GC – FID	6
GC – MS	4
LC – UV Vis	5
TLC	1
SFC – PDA	1
LC – PDA	2

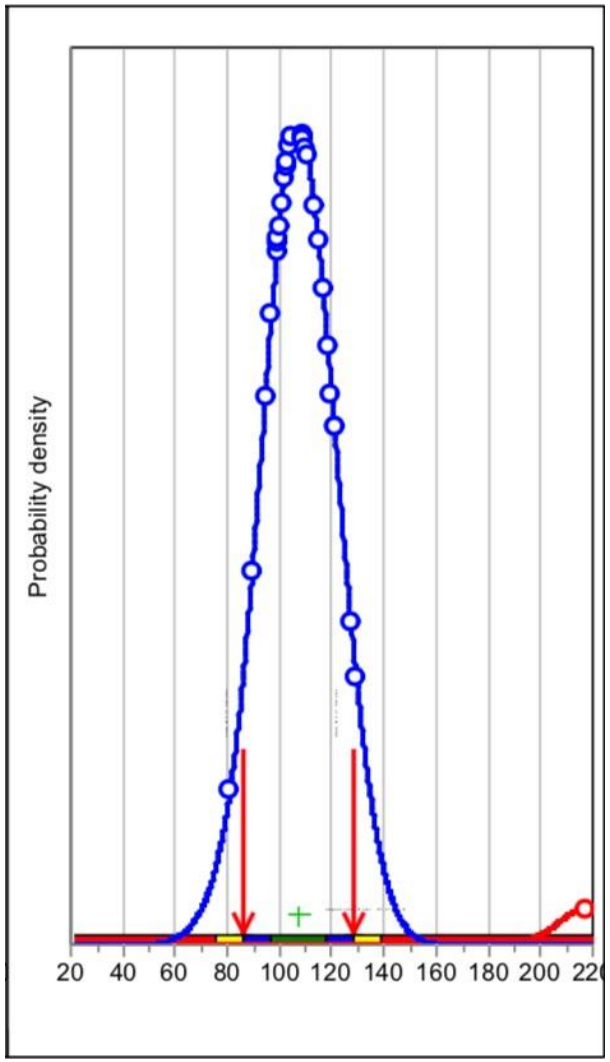
Progress Demonstrated

50 Emerald Potency Test Fall 2017

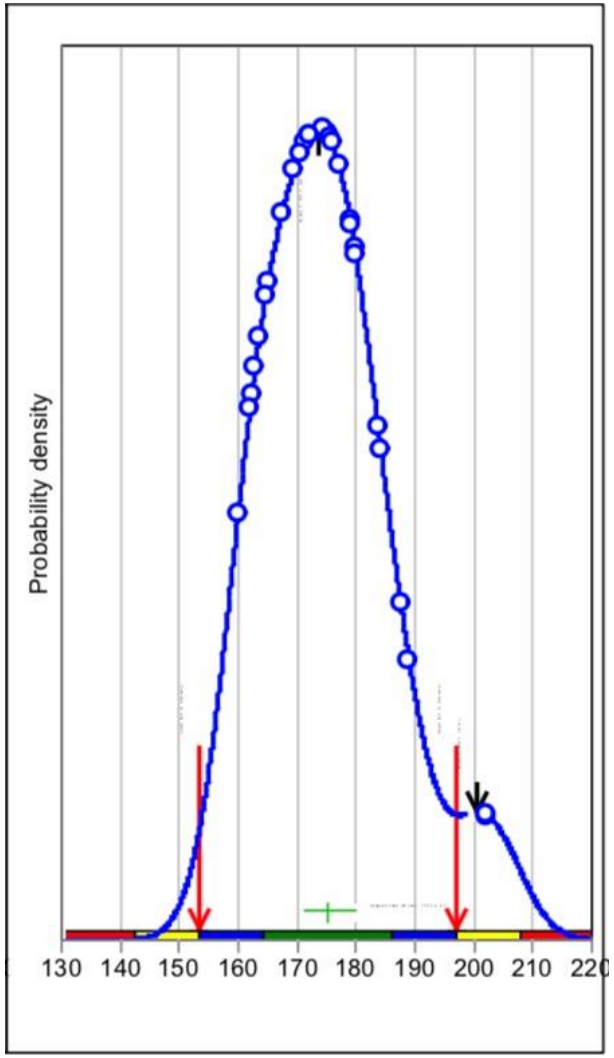
Analyst	Tetrahydroc µg/mL	Tetrahydroc Acid A	Total THC µg/mL
8118	0.802	0.872	0.848
9032	0.389	0.348	0.418
9057	0.856	-1.025	0.128
9219	0.856	-0.349	0.408
9541	-0.348	-1.331	-0.703
9542	-2.432	-1.898	-2.053
9548	0.497	0.675	0.608
9815	0.694	-0.437	1.258
9845	0.658	0.130	0.478
–	–	–	–
Statistical method	ISO 5725-2	ISO 5725-2	ISO 5725-2
Assessment	|Z|<=2.000	|Z|<=2.000	|Z|<=2.000
Consensus Mean	64.3	82.4	136.0
Target s.d.	5.6	4.6	10.0
Rel. target s.d.	8.65 %	5.57 %	7.35 %

Potency Total THC

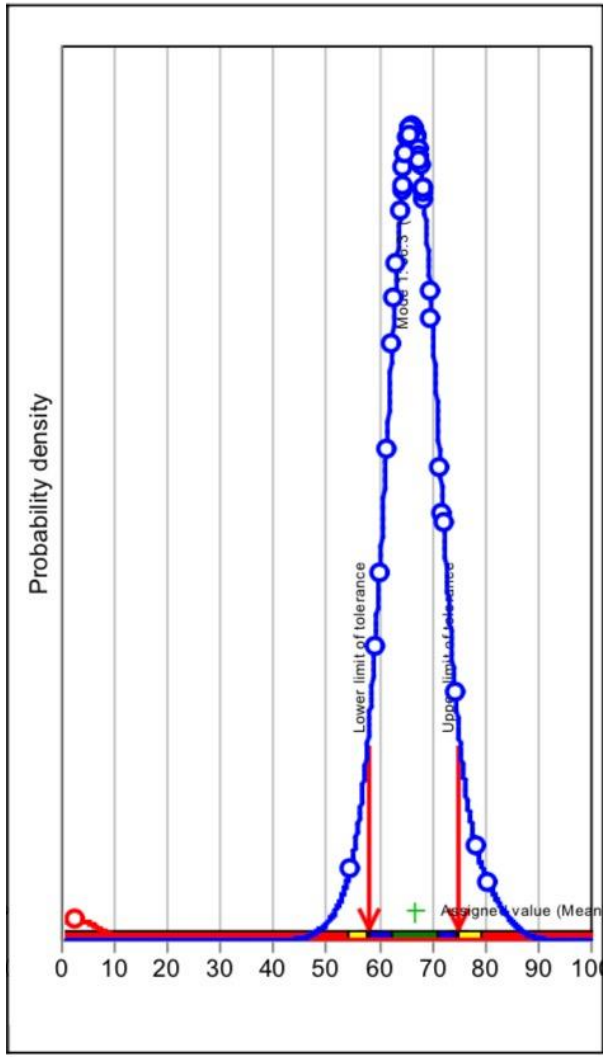
Spring 2016



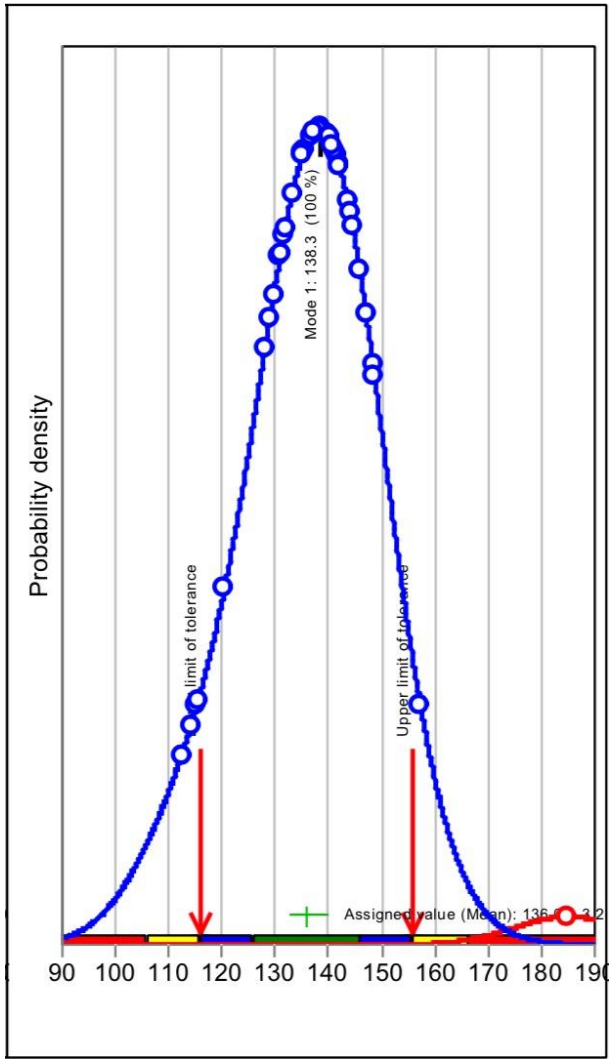
Fall 2016



Spring 2017



Fall 2017



Let's Talk Variance Again

2017 Fall ILC/PT Results

- 97% of participants were within 20% of consensus mean
- 20% Variance is generally considered normal/acceptable
- This Flower testing at 20% THC may be anywhere from 16-24%
- **The VALUE of Flower labeled at 16% is significantly different than Flower labeled at 24%**

How Are Labs Performing on Other Key Test?

The Emerald Test Advisory Panel Sets Performance Criteria for Labs to Earn The Emerald Badge (Range of 10%-30% Depending On Analyte of Interest)

- Quantitative Microbial Panel (+/- 30%) of 34 Participants 28 Received Badges
- Qualitative Microbial (Salmonella) All 31 Participating Labs Received Badges
- Pesticide Screening (Qualitative, Identify 21 of 22 Analytes Present) of 25 Participants 22 Received Badges
- Terpenes (First Time Offered) 21 Labs Participated With Only 4 outliers (+/- 2 σ) Across 8 Analytes

It's Not ALL Roses!

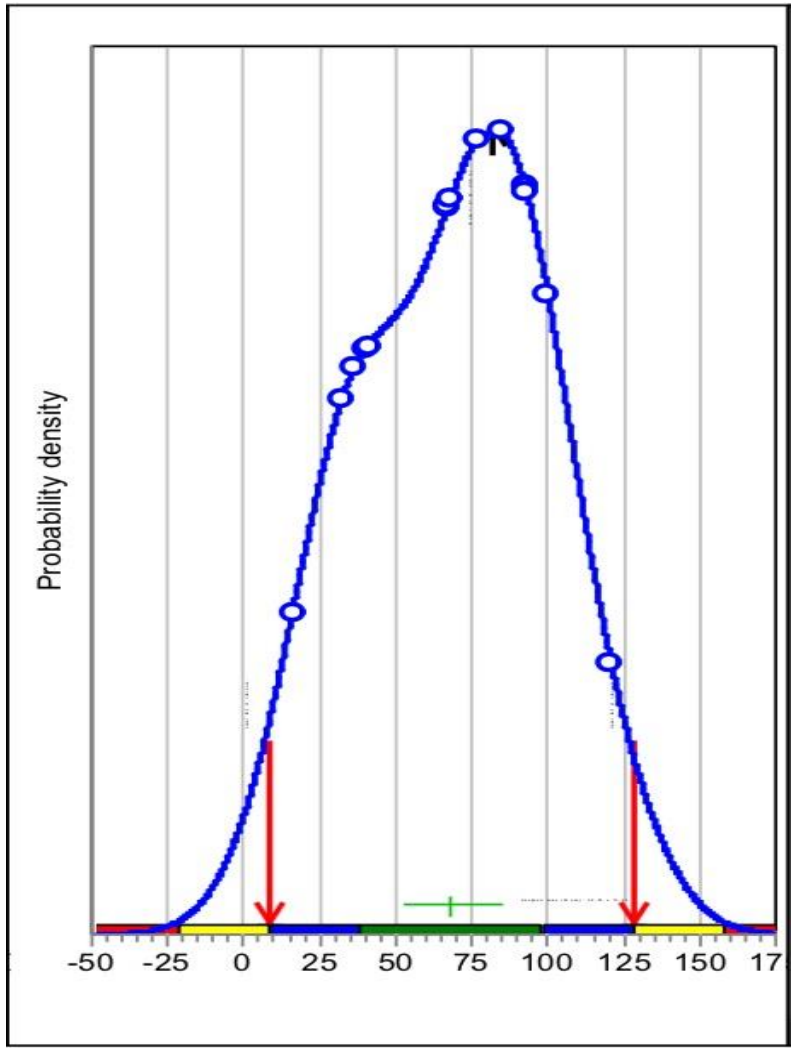
- Heavy Metals – Only half of the participating labs earned a badge (+/- 20%)
- Residual Solvents – 36 Labs Participated Only 14 Within +/-30% + Large disparity in reported values, Z-Score ranges unreasonable- No Badges Awarded
- Labs generally do a great job identifying every pesticide in our hemp-based PT, but some more work will most likely have to be done to bring quantitative results in line

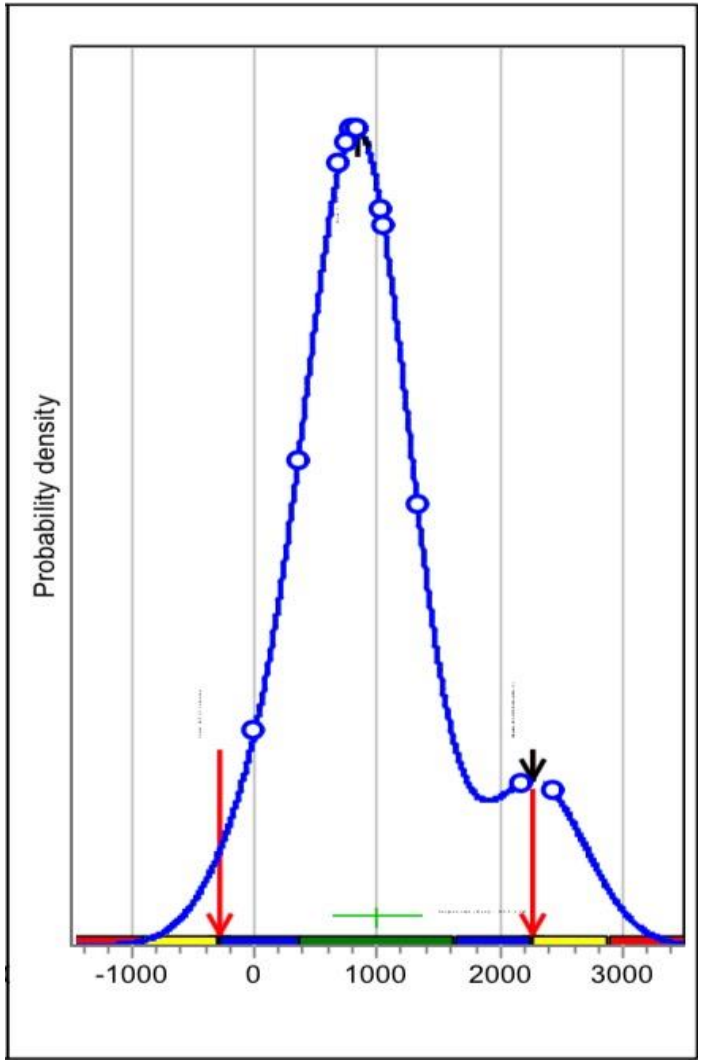
Spring 2016

Fall 2016

Residual Solvent N-Butane

In n, n-dimethylacetamid





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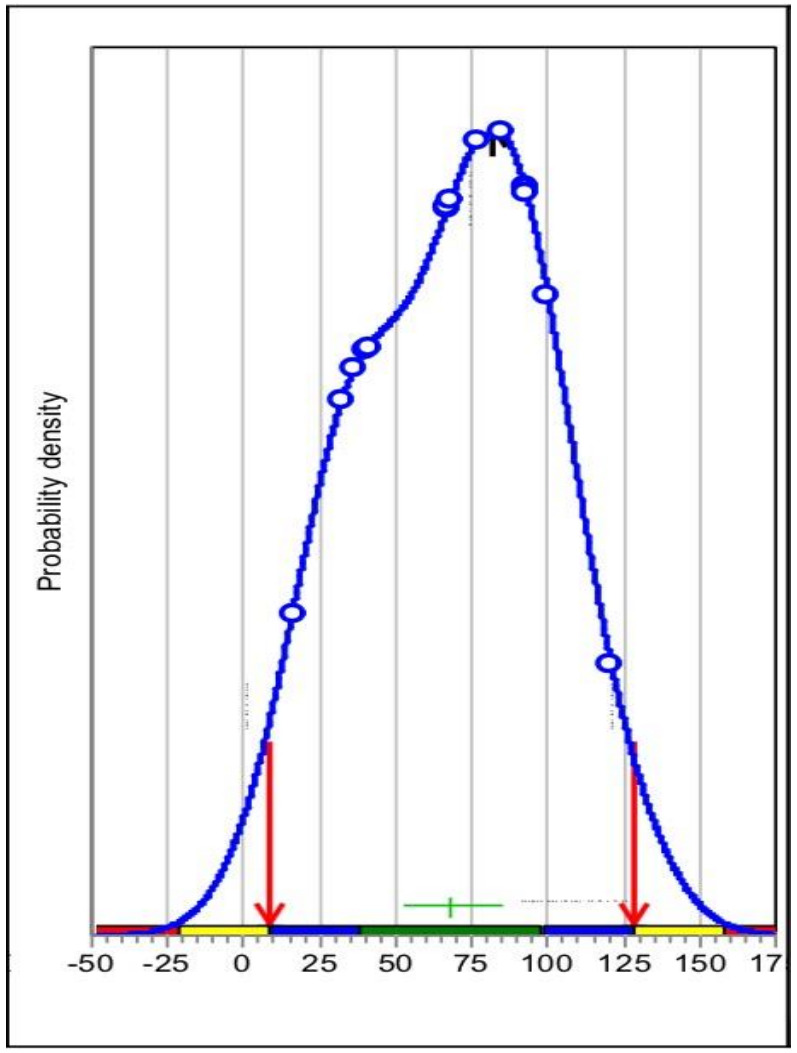
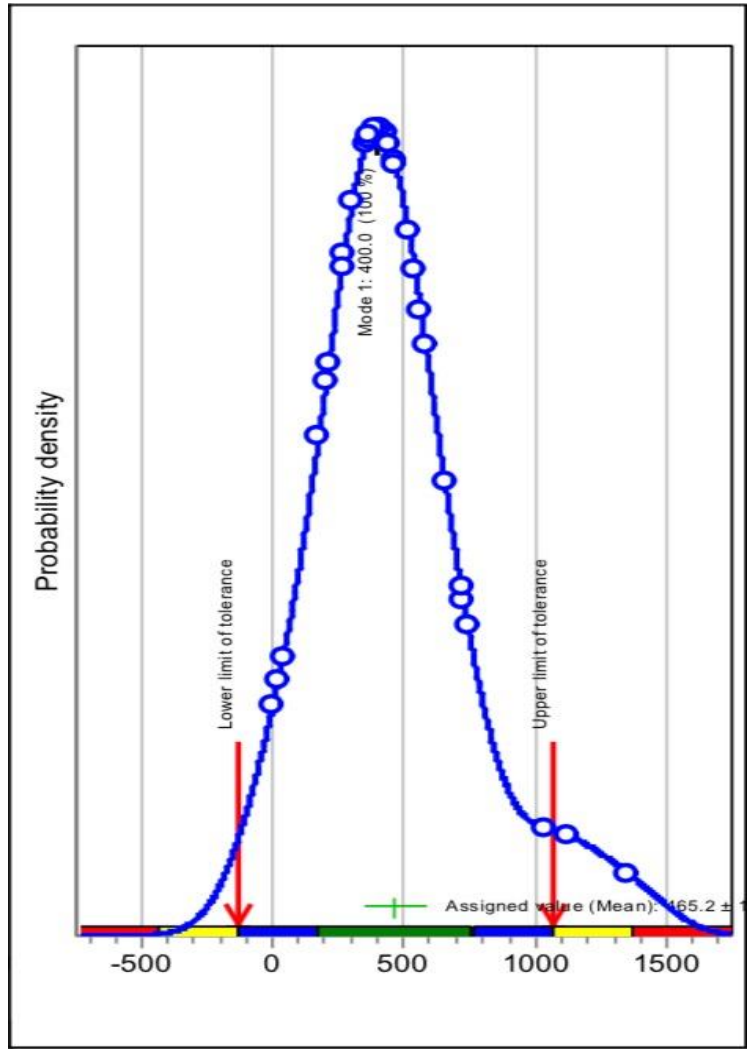
Spring 2017

Fall 2017

Residual Solvent N-Butane

Hemp Oil





2018 Spring Round

- 77 Labs
- 12 Different Tests Offered
- 312 Test Registered
- Watch For The Results
- Ask Your Lab To Prove They Participate and Pass a PT Program – Emerald Badge in Our Case!

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What To Look Forward To

- More Diversity in Matrices
- Adding More Sample Preparation To Tests
- More States Adding PT Requirements
- More Labs Using PT Participation to Gain Accreditation (ISO 17025)