Supplemental audit report in support of the Laboratory Certification Supporting Initiative I-502

Laboratory Name: Peak Analytics

Date onsite audit Performed: June 15th, 2017

Audit Team: Tammie Mussitsch, Jim Duncan & Jason Lupoi

Laboratory Personnel participating in Audit (include title): Lindsay Hubbell, Scientific Director & Kenny English, Quality Manager

Objectives of Assessment
The assessment was conducted to assess the laboratory operations in support of the requirements outlined in the I-502 initiative as articulated in WAC 314-55-102 and supporting implementation documents.

Scope

The laboratory was assessed in the following areas:

- Potency
- Microbial Analysis

Recommendations for WSLCB

Based on the audit findings listed above the following status is recommended for the Peak Analytics

- *Suspend Certification status until the requested materials are provided to satisfactorily close the deficiencies noted below.

Summary

An on-site audit was deemed necessary after review of the testing results from Q1 of 2017 for Peak Analytics. The data was pulled from the traceability system and supplied as an excel spreadsheet. Upon review of the data it was noted that Peak had an unusually low number of Microbial failures during this timeframe. The failure rate at Peak was approximately 1.69% while the average for the other certified labs was approximately 11% for the same time frame. While the potency data for the same timeframe did not show statistically higher numbers for the results it was determined that a review of the potency procedures was warranted since a complaint against this lab had been filed with the WSLCB.

During the un-announced audit performed at Peak Analytics on Thursday, June 15th numerous deficiencies were noted that we feel put the validity of the current testing process at risk. The deficiency/discrepancies are noted in detail below. We are recommending suspension of certification until the lab can provide adequate corrective actions to ensure all deficiencies are addressed and the lab process are meeting the requirements as stated in chapter 315-55 of the WAC.

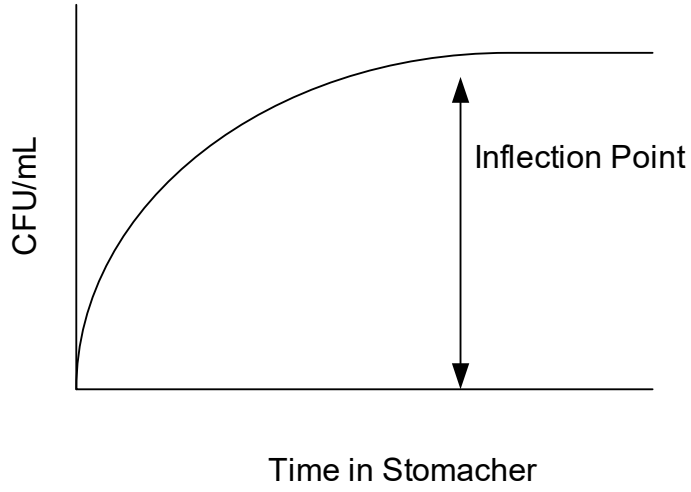
Audit findings:

- A Micro Proficiency sample was provided by the auditor to Peak Analytics at the onset of the audit. Peak was to perform the testing and submit results directly to the RJLG team. The results are summarized below.

Test	Result	Units	Acceptable / Not Acceptable
E. coli	31,500	CFU/g	38520/ 18500-58560 - ACCEPTABLE
Salmonella 001	positive	1	ACCEPTABLE
Salmonella 002	negative	0	ACCEPTABLE
Salmonella 003	negative	0	ACCEPTABLE
Total coliform	32,400	CFU/g	75520/51000-100000 – NOT ACCEPTABLE
APC	72,900	CFU/g	86400/65900-107000 – ACCEPTABLE
EB	27,000	CFU/g	85320/ 61900-109000 – NOT ACCEPTABLE
Yeast and mold	13,500	CFU/g	11700/2870-20500 – ACCEPTABLE

- The microbiology sample prep method used is not adequate. Detailed discussion below:
    - A two-paddle stomacher is used to macerate the sample in a sterile stomacher bag. The instrument is made to accept two samples, one for each paddle. Peak Analytics has a large amount of samples and chose to save time in this step rather than determine the best way to prep the samples as sample volumes increased. Peak is placing 5 or 6 bags in the instrument, it cycles for 30 seconds; the samples are then taken out and processed. As the auditor observed the process they noted that some samples are not touched by the paddles as they are either in the middle or on the edge. Others are pushed together and cushion each other from maceration.
    - An employee who uses the stomacher was asked to adjust the method by using one bag at 30 seconds and it appeared to allow for better maceration. The process was continued for additional cycles until we reached a total of 90 seconds and the material began approaching a macerated state.
    - The current approach of a shorter cycle time and multiple bags are not allowing for an efficient preparation of the sample. It is the auditor's opinion that there a number of microbes that are not being accounted for and the test is biasing to less numbers and hence passing rather than presenting an accurate analysis.
    - This is unacceptable lab practice and should not have been allowed by the Scientific Director.
    - To correct this deficiency, the lab must do a study that generates the data to create a graph such as the table in Figure 1. The study should contain at least two samples from each matrix Peak assesses for microbiology and at least 10 time points 30 seconds each. The study must also include the different matrices that the laboratory tests that require maceration.

Figure 1.



- The laboratory is using balances that were not verified with a calibrated weight set that spans the samples sizes being used. For example, a 0.5 g sample should be bracketed at 0.1 g, 0.5 g, and 1.0 gram. Only one calibrated weight was available at 100g size and the additional weights available were past due for calibration. Please refer to Attachment 1 for Cal Certs. The weights were also being stored in a small plastic back which does not protect them from damage. Storage should be in a suitable container that prevents them from being damaged.

- Documentation for pipette calibration was not available at the time of the audit. *Documentation for pipette calibration must be available to confirm calibration.* Also, pipettes must be verified on a consistent basis.

- There were no bench sheets for microbiological assays. The bench sheet should report dilutions, incubation temperature, time in the incubator, time retrieved from the incubator, counts at each dilution that yield countable plates, and any other data deemed appropriate. The microbial counts are included on the customer reports, but does not tie back to any other forms.

The following discrepancies were noted during the review of the Potency data and procedures:

- Calibration Data:
    - The CBG calibration provided had only two data points. *The minimum required is 4.*
    - CBDA value on 061517 732AM reads 8.14 µg/mL when the calibration curve provided starts at 10 µg/mL. The *value appears to be outside the calibration range.*
    - THC and THCA ran on 061517 736AM had smaller peak areas than the standards but higher reported concentrations (THCA: 100 µg/mL standard has area of 1997.8; daily check value of 1918.9 had calculated value of 105.6). *This is not possible but no explanation was included with the documentation as would be expected.*
    - Lab performs a daily two-point check of low and high standards, and uses an old calibration curve to calculate the potency of their samples. This complies with SOP, but implies that the full calibration curve is run on a monthly basis; monthly checks are apparently performed; there is no indication,

however, in the SOP that the full calibration is run even on a monthly basis. Using an old calibration curve to calculate the potency of newly measured samples, regardless of the two-point check, assumes that nothing else changes with the other cannabinoid standards. *This is not in line with standard good lab practice.*

- Calibration curve reports µg/mL but their SOP says ng. *Discrepancy between their SOP and actual practice. It should be noted that Lindsay did provide a different SOP after the lab audit that showed µg/mL units.*
- % cannabinoids calculation does not create a percent basis. *The laboratory uses a factor that is not explained in their SOP as part of this calculation. It is not known whether the routine conversion to a percent has been factored in to this formula outlined in the SOP. The calculation as described cannot provide an answer in the units required by the Traceability system.*
- Delta-8 THC not included in standards calibration, but was listed on certificates of analysis; Lindsey commented that they previously provided this cannabinoid and CBC, using a different LC, but they do not provide this anymore. Therefore, no C of A recently submitted to clients should have this data included. *Any reported analyte must have a calibration standard available to determine the final value.*

- Pulled samples:
  - THCA retention time varies widely; Lindsay commented that some of these chromatograms were collected on an old HPLC, in 2016 but the instrument was no longer in service. A sample from 02/18/2017 had a THCA retention time as 4.186 min. A sample from 01/12/2017 had a THCA retention time of 9.798 min. *We do not typically expect to see this amount of variation in retention times.*
  - THCA peaks from flower are very broad, not baseline resolved, and the minutes range from 5-10 minutes. *We do not typically expect to see peaks this broad.*
  - Fucking Incredible (FI) strain 8589 (ID 22313) listed as having 0% moisture, and also contains over 10% THC. All of these FI samples contained 6.8-10.4% THC. Lindsey commented that she did not know why the sample would come out with 0% moisture. Samples dried to produce 0% moisture would falsely inflate the Potency values. *While it is not the something the lab could manipulate they should be flagging these and following up with the grower and the WSLCB.*
  - A sample from Cannagenesis called Bear OG 1447 listed 16.1% THC. Cannagenesis strains all possessed 9.4-16.1% THC. *This is quite a bit higher than what we have seen in the past. We feel this grower and data set should have been flagged and reviewed further*.
  - Winton provided a Blue Dream sample that was listed as 37.2% THCA. We asked to see the calibration data used to calculate this percentage, and requested that they hand calculate the value. Lindsay searched for the data, but could not locate it. She did mention that some of the other calibration data from the same time period showed measured potencies about 1.5x higher than they would have expected. When asked if they thought that the 37% Blue Dream reflected a typical Blue Dream strain, and they said no. When asked if they thought this number was also 1.5x too high, they agreed, and commented that the client received this potency value for the sample. *This sample should have been investigated for adulteration and possibly flagged to the WSLCB.*

- SOP states they take pictures of samples during the foreign matter testing. When asked they stated they no discontinued this practice. They do a visual inspection of the plant, and did not catch at the time that the growers were manipulating the sample potency by adding kief and other trim. This is inconsistent with the Certificate of Analysis we were presented with. The COAs do include pictures. Please see examples attached as Attachment 1.

- Sample Preparation:
  - The lab chooses not to grind the samples to achieve some level of homogeneity prior to extracting the cannabinoids for analysis. They chop the flower with scissors, and then mix with the extraction solvent. After vortexing, they tilt the vial, and use a syringe to remove a representative aliquot. This is not a reproducible practice, despite their thought that they were removing the portion from the "exact same spot". Lindsay later admitted that they investigated their sample preparation practice after they began to receive negative publicity, and they found that the measured potencies were higher when they grind the sample, likely due to a more efficient extraction. Despite this finding, they have not changed their protocol, which implies that they are concerned they will have higher potency numbers than what the negative feedback indicated. This would mean that they are purposely not homogenizing the sample with the intent to lower the potency values obtained from their analysis.

  - *Based on the noted discrepancies above we are requesting applicable SOP updates as well as additional validation studies be performed. Validation protocols must consist of a minimum of 10 samples and include the standard validation parameters of accuracy, range, linearity, precisions and specificity. Matrix extensions must also be included as applicable.*

  - *We are also requesting a Demonstration of capability (DOC) study for each analyst performing the Potency and Residual solvents testing. Given that the scientific director is also one of the testing personnel we require a DOC from the Director as well.*

Prepared by: TAMMIE MUSSITSCH, JAMES DUNCAN & JASON LUPOI

RICE LAKE Traceable Calibration CERTIFICATE

ANSI/NCSL Z540-1-1994; Part 1 & ISO/IEC 17025 Accredited

Traceable Report Number: 2412854B

Contractor: KENT REED DISTRIBUTING
15050 CEDAR AVE S #116-337
APPLE VALLEY, MN 55124

Purchase Order Number: 13842

Client: PEAK ANALYTICS LABORATORY TESTING SERVICES
5373 GUIDE MERIDIAN
SUITE F-201
BELLINGHAM, WA 98226

Date Received: 14 Mar 2016

Date Calibrated: 16 Mar 2016

Contractor Requested Recall Date: No Recall Requested

Temperature Range: 21.38 °C

Pressure Range: 716.31 mmHg

Relative Humidity Range: 50.39 %

Air Density Range: 1.1242 mg/cm3

NIST Certificate Number: 684/286541-15,684/284451-14
Although there are two NIST numbers, one or both may apply.

Tested By: 22

Procedure: Modified Substitution (WI05-0023)

Description of Weights: 100 g Satin Finish Weight, NIST Class F, S/N 6HXP

Nominal Value	ID	Conventional Mass Corr. As Found (mg)	As Found In Tol	As Left (mg)	As Left In Tol	Unc. (mg)	*k*	Tol.* (mg)	Balance Used	Standard Set Used	Assumed Density (g/cm3)
100 g	6HXP	4.6	Y	4.6	Y	2.4	2	20	1221Q	D563Q	7.84

☐ This report contains data not covered by the NVLAP Accreditation if the box is checked.

Check with your local state agency for certification of compliance on Legal for Trade items.
The weight tolerance class is referenced in the Description of Weights. Unless otherwise noted, weights tested meet the requirements of the class.
*The specifications for the weight classes can be found in NIST Handbook 105-1, ASTM E-617 or OIML R111.

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An ISO 9001 registered company

Dated 17 Mar 2016

Dan Demers, Metrologist

NVLAP Lab Code 105001-0

PN 64784 11/15

RICE LAKE Traceable Calibration CERTIFICATE

ANSI/NCSL Z540-1-1994; Part 1 & ISO/IEC 17025 Accredited

Traceable Report Number: 2412854A

Contractor: KENT REED DISTRIBUTING
15050 CEDAR AVE S #116-337
APPLE VALLEY, MN 55124

Purchase Order Number: 13842

Client: PEAK ANALYTICS LABORATORY TESTING SERVICES
5373 GUIDE MERIDIAN
SUITE F-201
BELLINGHAM, WA 98226

Date Received: 14 Mar 2016

Date Calibrated: 16 Mar 2016

Contractor Requested Recall Date: No Recall Requested

Temperature Range: 21.36 °C

Pressure Range: 716.30 mmHg

Relative Humidity Range: 50.80 %

Air Density Range: 1.1242 mg/cm3

NIST Certificate Number: 684/286541-15,684/284451-14
Although there are two NIST numbers, one or both may apply.

Tested By: 22

Procedure: Modified Substitution (WI05-0023)

Description of Weights: 10 g Satin Finish Weight, NIST Class F, S/N 6HXT.

Nominal Value	ID	Conventional Mass Corr. As Found (mg)	As Found In Tol	As Left (mg)	As Left In Tol	Unc. (mg)	*k*	Tol.* (mg)	Balance Used	Standard Set Used	Assumed Density (g/cm3)
10 g	6HXT.	0.82	Y	**0.82**	Y	0.25	2	2.0	638Q	D563Q	7.84

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Dated 17 Mar 2016

Dan Demers, Metrologist

NVLAP Lab Code 105001-0

PN 64784 11/15

RICE LAKE Traceable Calibration CERTIFICATE

ANSI/NCSL Z540-1-1994; Part 1 & ISO/IEC 17025 Accredited

Traceable Report Number: 2412854

Contractor: KENT REED DISTRIBUTING
15050 CEDAR AVE S #116-337
APPLE VALLEY, MN 55124

Purchase Order Number: 13842

Client: PEAK ANALYTICS LABORATORY TESTING SERVICES
5373 GUIDE MERIDIAN
SUITE F-201
BELLINGHAM, WA 98226

Date Received: 14 Mar 2016

Date Calibrated: 16 Mar 2016

Contractor Requested Recall Date: No Recall Requested

Temperature Range: 21.34 °C

Pressure Range: 716.28 mmHg

Relative Humidity Range: 51.09 %

Air Density Range: 1.1243 mg/cm3

NIST Certificate Number: 684/286541-15,684/284451-14
Although there are two NIST numbers, one or both may apply.

Tested By: 22

Procedure: Modified Substitution (WI05-0023)

Description of Weights: 2 g Satin Finish Weight, NIST Class F, S/N 6HXU.

Nominal Value	ID	Conventional Mass Corr. As Found (mg)	As Found In Tol	As Left (mg)	As Left In Tol	Unc. (mg)	*k*	Tol.* (mg)	Balance Used	Standard Set Used	Assumed Density (g/cm3)
2 g	6HXU.	0.34	Y	0.34	Y	0.14	2	1.1	638Q	D563Q	7.84

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PN 64784 11/15

Peak Analytics
Laboratory Testing Services

OG Wreck

Flower

Subdued Excitement
Ferndale, WA
(360) 398-6123
nick@subdued-excitement.com

Sample: OG Wreck
Type: Flower
Sample ID: 1963 3593 5608 1723
Lot No.: 6033 4414 3000 3151

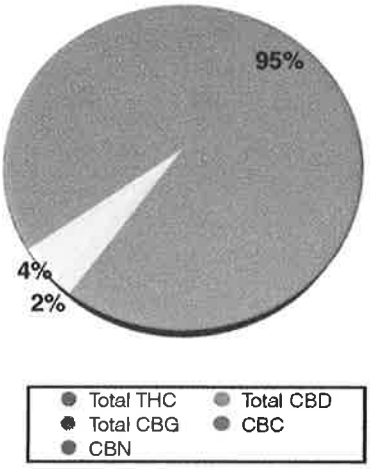
UID: 1041
Received: 02/01/2016
Tested: 02/02/2016
Approved By: L.Hubbell

Potency Test Results

Analyte	% by weight
THC-A	22.8%
Δ9 THC	0.8%
Δ8 THC	ND
CBD-A	0.2%
CBD	0.2%
CBG-A	0.9%
CBG	ND
CBC	ND
CBN	ND
Total THC	**20.8%**
Total CBD	**0.4%**
502 Total Cannabinoids	**21.2%**
Total Cannabinoids	**24.9%**

502 Total Cannabinoids = Total THC + Total CBD
Total Cannabinoids = Sum of all Cannabinoids

Cannabinoid Ratio



Residual Solvent Analysis

Parts Per Million (PPM) None Detected (ND)

Solvent	PPM
Acetone	N/A
N-Butane	N/A
Isobutane	N/A
Pentane	N/A
Isopentane	N/A
Propane	N/A
Hexanes	N/A
Ethanol	N/A
Ethane	N/A
Isopropanol	N/A

Moisture:

Moisture Content: 4.07%

Foreign Matter Inspection

Visual Inspection	Pass/Fail
	PASS

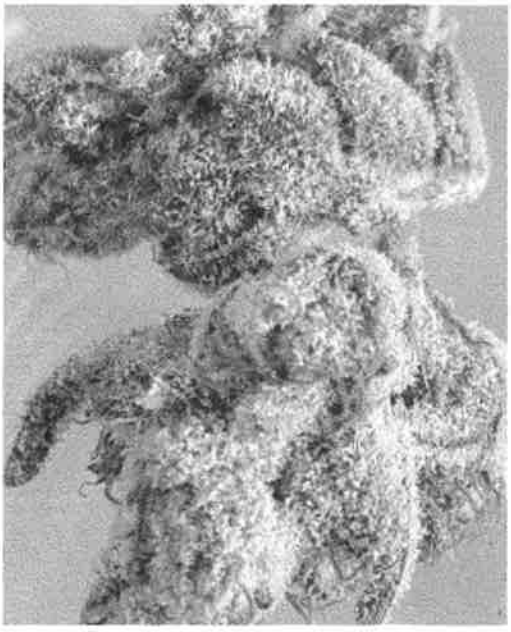
Microbial Analysis

Microbe	CFU/G
Yeast & Mold	200
E.Coli	N
Salmonella	N
Total Coliforms	40
Aerobic Plate Count	200

Terpene Profile

Analyte	PPM
Pugelone	N/A
Linalool	N/A
Borneol	N/A
β-Myrcrene	N/A
Limonene	N/A
Terpiniol	N/A
Sabinene	N/A
α-Pinene	N/A
Isophytol	N/A
Carene	N/A
Camphene	N/A
Nerolidol	N/A
Caryophylene	N/A
Phellandreone	N/A
Cineole	N/A
Humulene	N/A

OG Wreck



Lab Information

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