

Notice of Violation

(3AAC 306.805)

This form, all information provided and responses are public documents per Alaska Public Records ACT AS 40.25

Date: 6/23/20

License #/Type: 15124 Marijuana Testing Facilities

Licensee: Fairbanks Analytical Testing, LLC

Address: 1521 Stacia Street, Suite A, Fairbanks, AK 99701

DBA: Fairbanks Analytical Testing

AMCO Case #: AM20-720

This is a notice to you as licensee that an alleged violation has occurred. If the Marijuana Control Board decides to act against your license, under the provisions of AS 44.62.330 - AS 44.62.630 (Administrative Procedures Act) you will receive an Accusation and Notice of your right to an Administrative Hearing.

Note: This is not an accusation or a criminal complaint.

FAT was using an incorrect dilution factor when performing potency calculations for concentrate sample results since they opened on 12/3/18. To perform the calculation correctly, a dilution factor of either 200 or 400 is supposed to be used. FAT was using a dilution factor of 250 for all concentrate test results. The results from performing the calculations in this manner would give potency concentrations of either 20% higher than actual concentration or 60% lower than actual concentration. FAT's use of a 250-fold dilution factor for all concentrate test calculations is out of compliance with their SOP. Per FAT during a July 8th phone call, this calculation error has been in place since analysis of their first concentrate sample. This action is in violation of 3 AAC 306.640 (a) Standard Operating Procedure and 3 AAC 306.635 (b) testing methodologies.

It was also found that calculations performed to adjust plant sample weights to account for moisture were done incorrectly. Performing these calculations incorrectly affects the potency results for all regulated potency parameters (THC, THC-A, CBD, CBD-A, and CBN). This action is in violation 3 AAC 306.635 (b) testing methodologies.

Fat has continued to fail to meet deadlines for compliance that have been set out by EHL since the onsite audit on 6/23/20, 16 times. 7/6/20, 7/7/20, 7/8/20, 7/13/20, 7/14/20, 7/16/20, 7/22/20, 7/24/20, 7/31/20, 8/12/20, 8/19/20, 8/21/20, 8/25/20, 8/28/20, and 9/4/20.

3 AAC 306.805 provides that upon receipt of a Notice of Violation, a licensee may request to appear before the board and be heard regarding the Notice of Violation. The request must be made within ten days after receipt of the Notice of Violation. A licensee may respond, either orally or in writing to the Notice. 3 AAC 306.810 (2)(A)(B)(C) failed, within a reasonable time after receiving a notice of violation, to correct any defect that is the subject of the notice of violation of AS 17.8 or this chapter.

IT IS RECOMMENDED THAT YOU RESPOND IN WRITING TO DOCUMENT YOUR RESPONSE FOR THE MARIJUANA CONTROL BOARD.

***Please send your response to the address below and include your marijuana license number in your response.**

Alcohol & Marijuana Control Office
ATTN: Enforcement
550 W. 7th Ave, Suite 1600
Anchorage, Alaska 99501
amco.enforcement@alaska.gov

Issuing Investigator: J. Rukes

Received by:

SIGNATURE: 

SIGNATURE:

Delivered VIA: Email

Date: 9/17/20

ALASKA DEPARTMENT OF COMMERCE, COMMUNITY, AND
ECONOMIC DEVELOPMENT
ALCOHOL AND MARIJUANA CONTROL OFFICE

In the matter of:)
)
Fairbanks Analytical)
Testing, LLC)
DBA Fairbanks Analytical Testing)
1521 Stacia Street, Suite A)
Fairbanks, AK 99701)
License # 15124)
Respondent)
_____) Accusation # AM20-720

NOTICE OF DEFENSE

The Respondent, pursuant to AS 44.62.390, hereby gives Notice of Defense in this proceeding. A hearing on the matters set forth in the Decision is hereby requested.

I. Respondent Initiating Request

Date: _____ Respondent's Name (printed): _____

Respondent's Signature: _____

Mailing Address: _____

| | | |
|------|-------|----------|
| City | State | Zip Code |
|------|-------|----------|

Phone Number: _____

OR

II: Attorney Representing Respondent (Note: An attorney is not required for this proceeding.)

Name of Attorney Representing Respondent: _____

Mailing Address: _____

| | | |
|------|-------|----------|
| City | State | Zip Code |
|------|-------|----------|

Phone Number: _____

Date: _____ Signature: _____

NOTE: This Notice of Defense/Request for Hearing must be signed by or on behalf of Respondent, must set forth Respondent's current mailing address, and must be filed **within 15 days** after the enclosed Decision was mailed or delivered to the Respondent, or within 15 days of the informal conference if one is requested. It shall be filed accordingly:

Administrative Officer
Department of Commerce, Community, and Economic Development
Alcohol and Marijuana Control Office
550 West 7th Ave, Suite 1600, Anchorage, AK 99501

STATE OF ALASKA

MARIJUANA CONTROL BOARD

In the matter of)
)
 Fairbanks Analytical)
 Testing, LLC)
 DBA Fairbanks Analytical Testing)
 1521 Stacia Street, Suite A)
 Fairbanks, AK 99701)
 License # 15124)
 Respondent)
)
) **Accusation No. AM20-720**

ACCUSATION(S) :

Petitioner, Glen Klinkhart, Acting Director of the Alcohol and Marijuana Control Office (AMCO), acting in his official capacity and upon information and belief, alleges as follows:

1. The attached narrative/complaint was prepared by Alcohol and Marijuana Control Office Investigator Rukes under AMCO case number AM-720. This accusation is based upon the work of Investigator Rukes and others whom I believe to be reliable and truthful.

Requests of the Marijuana Control Board

Based upon the information provide in the investigation the petitioner requests the following:

That the Marijuana Control Board find that the licensee, Fairbanks Analytical Testing, LLC DBA Fairbanks Analytical Testing, violated regulations multiple times as noted in the attached complaint.

All of which are violations of the following:

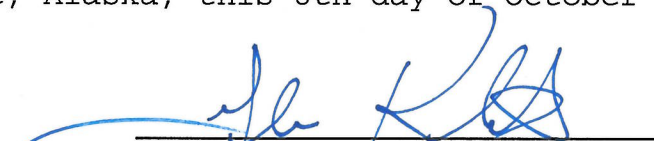
1. 3 AAC 306.640 Standard Operating Procedure Manual

2. 3 AAC 306.635 testing methodologies

The petitioner respectfully requests the Following:

1. That the Marijuana Control Board find that the respondent, Fairbanks Analytical Testing, LLC DBA Fairbanks Analytical Testing, committed the acts alleged above.
2. That the Marijuana Control Board find that based on these violations license suspension is warranted under at least 3 AAC 306.810(b) (2), 3 AAC 306.810(b) (5) and 3 AAC 306.815.
3. That the Marijuana Control Board suspend the marijuana testing facility's license for at least two months and not lift the suspension until Fairbanks Analytical Testing, LLC DBA Fairbanks Analytical Testing, has demonstrated to the satisfaction of the Alaska Department of Environmental Conservation Environmental Health Laboratory that all testing and calculations are being done correctly and in compliance with SOPs and regulation.
4. Additionally, place the establishment on probation for two years and fined \$10,000.00 for each of the two violations for a total of \$20,000 with \$10,000.00 suspended. The \$10,000 shall be paid before the license suspension is lifted. If the establishment violates any regulations w/in the next two years, the rest of the monetary fine shall be paid in full.
5. That the Marijuana Control Board provide any additional or substitute remedies it deems warranted under the facts as proven.

Dated at Anchorage, Alaska, this 8th day of October 2020.



Glen Klinkhart
Interim Director
State of Alaska
Alcohol and Marijuana Control Office

STATE OF ALASKA

MARIJUANA CONTROL BOARD

In the matter of)
)
 Fairbanks Analytical)
 Testing, LLC)
 DBA Fairbanks Analytical Testing)
 1521 Stacia Street, Suite A)
 Fairbanks, AK 99701)
 Respondent)
)
)

Accusation No. AM20-720

COMPLAINT

The affiant, Jeffery Rukes, Investigator for Alcohol and Marijuana Control Office (AMCO), acting in his official capacity and upon information and belief, alleges as follows:

INFORMATION/INVESTIGATION

1. Respondent, Fairbanks Analytical Testing, LLC DBA Fairbanks Analytical Testing, is the holder of a marijuana testing facility license, located at 1521 Stacia Street, Suite A, Fairbanks Alaska, license number 15124.
2. According to MCB records, Fairbanks Analytical Testing (FAT), LLC is owned by Dylanne Macomber 51% and Ronald Eads 49%.
3. The Marijuana Testing Facility license was first issued to Fairbanks Analytical Testing LLC, on 12/3/18.
4. Chief Investigator Hoelscher made a request on May 26th, 2020, to the Alaska Department of Environmental Conservation Environmental Health Laboratory to audit Fairbanks Analytical Testing for potency testing in response to a new equipment purchase. FAT had a prior flooding issue that damaged their original equipment.

5. On June 11th, 2020 Auditor Steve Crupi sent FAT an agenda for his visit that was to occur on June 23rd. (See Attachment A for the EHL audit report)

6. During the June 23rd visit, Crupi requested Alex Tackett, the Scientific Director, to reproduce previously reported potency results from the existing data of a plant and a concentrate sample. Crupi said that Tackett was not able to do so during his visit because he "froze up", being unable to find the relative instrument calibration data. Crupi said that he gave Tackett the benefit of the doubt because he could have been suffering from audit anxiety and gave Tackett until July 3rd to provide the results.

7. On July 6th Crupi again requested the reproduced results from Tackett by noon the next day, July 7th. An Excel spreadsheet that FAT uses to process data and calculate results was provided to Crupi July 8th at 12:52 a.m. Mr. Crupi stated that the spreadsheet contained calculation errors for the plant and concentrate matrices, which gives incorrectly calculated results, with the potential for a high or low bias, dependent on the matrix, for testing of the five regulated potency constituents. This is in violation of: 3 AAC 306.635 (b) testing methodologies

8. Crupi found that FAT was using an incorrect dilution factor when performing potency calculations for concentrate sample results. To perform the calculation correctly, a dilution factor of either 200 or 400 is supposed to be used. FAT was using a dilution factor of 250 for all concentrate test results. The results from performing the calculations in this manner would give potency concentrations of either 25% higher than actual concentration or 60% lower than actual concentration. FAT's use of a 250-fold dilution factor for all concentrate test calculations is out of compliance with their SOP. Per FAT during a July 8th phone call, this calculation error has been in place since analysis of their first concentrate sample. This action is in violation of 3 AAC 306.640 (a) Standard Operating Procedure and 3 AAC 306.635 (b) testing methodologies.

9. Crupi also found that calculations performed to adjust plant sample weights to account for moisture were done incorrectly. Performing these calculations incorrectly affects the potency results for all regulated potency parameters (THC, THC-A, CBD, CBD-A, and CBN). Later correspondence revealed edible results have also been calculated incorrectly since the start of business, carrying a 20% low bias. This is in violation of: 3

AAC 306.640 (a) Standard Operating Procedure Manual and 3 AAC 306.635 (b) testing methodologies.

10. FAT has continued to fail to meet deadlines for compliance directives that have been set out by EHL since the onsite audit on 6/23/20 as shown in the following timeline prepared by Mr. Crupi:

- 6/23/20 - Onsite audit for potency at FAT. Before leaving, left handwritten notes on edits needed to SOP and QA manual and listing of six findings and four items that will be subject of a future onsite or virtual follow-up. The most concerning of the six findings is technical director inability to find calibration curve as starting point to reproduce reported results for one plant and one concentrate sample. Requested follow-up by COB 7/3/20. This amount of time determined by Steve Crupi's personal leave of 6/25 - 7/3/20, so review would not start until 7/6/20. Generous time allotment for a data defense FAT should have been able to do onsite.
- 6/24/20 - Email to FAT summarizing the visit and reminding of the requirement due 7/3/20. Email to AMCO summarizing audit and findings, expressing concern about FAT's inability to reproduce/defend results during the audit.
- 7/3/20 - FAT submits updated QA Manual and SOP based on edit notes EHL provided during audit.

MISSED DEADLINE

- 7/6/20 - EHL email to FAT reminding of reported result defense that was due 7/3/20. Request new due date of 7/7/20 Noon. EHL email to AMCO expressing concern about overdue data defense from FAT. Technical Director responds by citing his background in neuroscience research and business of lab activities (i.e. client samples). Second EHL email to FAT acknowledging background, but does not relieve responsibility for submitting data defense in timely fashion. Second email to AMCO expressing concern about this response.

- **MISSED DEADLINE**
- 7/7/20 - FAT email indicating will have the data defense in the afternoon, which is after the noon due date. EHL AMCO notified about this latest missed due date. Email to FAT indicating delay unacceptable. FAT replies that ". . . it should take less than 24 hours, I apologize . . . "
- 7/7/20 - FAT submits calculation defense for finding 2 that consists of formula vs. actually demonstrating the basis for the potency 250-fold dilution factor. EHL reminds EHL that the data defense is priority.

- **MISSED DEADLINE**
- 7/8/20 - FAT submits data defense shortly after midnight; 12 hours after second due date/time. Missing from the data defense was the actual client reports. FAT consultant provides explanation for 250-fold dilution factor, audit finding 2. FAT later submits the actual client reports associated with data defense. EHL email to FAT requesting missing information and asking for clarifications on data defense presentation. Example, FAT using spectral identification when RT does not identify a peak, guessing a match with spectral library.
- 7/8/20 - 2:00 call with FAT and their consultant. SOP deviations discussed. Also revealed that all concentrate results have been reported incorrectly since business opening, either biased high 20% or biased low 60%. RT shifts occurred, but instrument not recalibrated. FAT consultant, Dr. Hagedorn, admonished FAT for not recalibrating. ("We talked about that, Alex.") EHL notified AMCO via email.
- 7/8/20 - Email to FAT with additional comments on data defense. QC assessment inappropriate. Internal standard data not included. CBD failing low, but yet data reported. Adjusted mass value for plant data being calculated incorrectly. With revelation of concentrate calculation error, asked FAT to investigate if edible calculation also an issue.

- 7/9/20 - FAT promises trending of IS demonstration by next week. Letter to FAT requesting action on items discussed in prior day call. (Ultimately, FAT did not submit trending until 8/3/20. Subsequent review revealed as incomplete.)
- 7/9/20 - AMCO letter to FAT requesting action on items with due date of 7/10 (edible calculation), 7/13 (updated spreadsheets for calculation, Analyte Target Verification section), and 7/14 (retention shifts occurred, but no recalibration - update the SOP).
- 7/10/20 - EHL issues audit report, listing onsite audit findings and 7/8/10 review of data defense. Email conversation with FAT regarding dry weight correction for plant material. Calculation incorrect. FAT states have been using since starting business (includes tare weight in division operation of calculation).

MISSED DEADLINE

- 7/13/20 - FAT responds, though late on the edible calculation, which FAT realizes edibles also incorrectly calculating since business start, biased 20% low. Still dispute EHL assertion that plant calculation is incorrect, insisting correct. Submitted spreadsheet still incorrect for Analyte Target Verification (i.e. QC assessments). States spectral match criteria added to SOP, but EHL states is incomplete. (Still incomplete as of 8/10/20.)

MISSED DEADLINE

- 7/14/20 - FAT submits updated SOP and flower calculation worksheet. Errors persist in both. Adjusted mass calculation is correct though (adjusts for moisture content; a method for reporting potency results on dry weight basis).
- 7/15/20 - Updated audit report, documenting progress, sent to FAT.

MISSED DEADLINE

- 7/16/20 - Call with FAT. Analyte Target Verification part of worksheet (QC assessments) still incorrect, including incorrect cell references. FAT SOP states

dilution not performed until about 20% above calibration. Requested submittal of linearity study. FAT says they've already done it. (As of 8/10/20, linearity study not yet provided by FAT.) Percent moisture formulae in SOP incorrect. SOP homogeneity section inconsistent with 3AAC306.650.

- 7/17/20 - EHL asked for status of linearity study. FAT said will have by midnight. EHL indicated by Monday, 7/20 is sufficient. (As of 8/10/20, not yet received from FAT.)

MISSED DEADLINE

- 7/22/20 - Linearity study not yet received. EHL asked for status. Also asked for implementation of corrected RPD and QC assessment calculation corrections.

MISSED DEADLINE

- 7/24/20 - New calculation templates received from FAT. EHL email to FAT pointing out errors. Adjust mass for plant back to being incorrect. RPD calculation still not correct and referencing incorrect cells. RT assessment still assessing incorrectly. Cell referencing off for results though doesn't seem to impact the final totals for potency. Still a tracking issue.
- 7/24/20 - FAT reply. Either acknowledges the errors noted in 7/24 EHL email or says will follow-up on.
- 7/28/20 - EHL email to FAT for updated ETAs on linearity study, corrected calculation sheets, and Agilent spectral match criteria. FAT email reply indicating delay due to needing to catch up on business needs. Agilent link did not successfully transfer.
- 7/29/20 - FAT re-sends Agilent link. EHL recommends a WebEx call to go over the spreadsheet calculation errors. 7/30 10 a.m. call is scheduled.
- 7/30/20 - Call with FAT. Covered errors in spreadsheet. Also, formula error in SOP. FAT commits to supplying Linearity study, response to CBD PT outlier, and updated calculation spreadsheets (for adjust mass calculation error and QC assessments) by tomorrow. Subsequent email communication with FAT

further clarifying adjust mass (dry wt. correction) issue. Calculation was correct in 7/14 version, but the following 7/24 version went back to being incorrect.

MISSED DEADLINE

- 7/31/20 - End of day email from Ron Eades (FAT) that Alex called in sick this morning.
- 8/3/20 - Email from Alex (FAT) with proposed statistical method for monitoring ISTD performance. EHL email to FAT acknowledging receipt.
- 8/4/20 - EHL email with review comments of ISTD trending, commenting this effort straying from more critical tasks.
- 8/10/20 - Due date for FAT response on non-critical items. Some critical items with due dates in mid-July outstanding, notably corrected worksheets for result calculation and QC assessment and linearity study report.

MISSED DEADLINE

- 8/12/20 - EHL evaluates FAT 8/10/20 submission. 15 findings in the report are outstanding, most significantly, plant potency calculation and QC assessments for all matrices. Due date of 8/19/20 established for the outstanding 15 findings.
- 8/12/20 - FAT emails, indicating "failed" designation for CBD for the PT a mistake, but did not supply acceptance ranges to justify. States position that the response is acceptable to CLIA, which is assumed to be applicable to AMCO.
- 8/13/20 - EHL emails to indicate cannot evaluate PT response in 8/10/20 submission because Absolute Standards' (PT vendor) documentation of acceptance ranges were not provided. FAT emails that planning to submit new linearity study by tomorrow afternoon. Notified FAT that new linearity study submission must include corrective action for the discarding of initial study due to bad standards and demonstrate linearity to 20% above the calibration standard, if the intention is to continue to make that a trigger point for a dilution step.

- 8/13/20 - Alex indicated he would have linearity study to EHL by 5:00 tomorrow, though technically not due until 8/19/20.

MISSED DEADLINE

- 8/19/20 - As of 7:00 p.m., linearity study not yet received, nor any of the other findings, requested due today in August 12 letter to include updated status on the 15 open findings. Critical among them are linearity study and calculation/QC assessment worksheets.
- 8/20/20 - Submittal from FAT, 1 day late. Incomplete. Missing IS response tracking, concentrate 400-dilution calculation spreadsheet, and some SOP items not addressed. Alex commits to submittal by 10 a.m. tomorrow.

MISSED DEADLINE

- 8/21/20 - No submittal. Alex took a leave day (sick?).

MISSED DEADLINE

- 8/25/20 - Alex commits to submittal today, including linearity study, IS response tracking. SOP update within the next two days. (No submittal occurred today. I offered to wait until 8/28/20.)
- 8/26/20 - Linearity study received. PT acceptance limits received separately.
- 8/27/20 - Communicated that 400-fold dilution concentrate spreadsheet missing.

MISSED DEADLINE

- 8/28/20 - Alex commits to providing missing spreadsheet next week. EHL emails specific SOP updates needed. These are repeat requests. Ask to complete all outstanding audit items by 9/04/20.
- 8/29/20 - Alex commits to finishing all tasks by end of next week (by 9/04/20).

MISSED DEADLINE

- 9/04/20 - Alex emails indicating cannot make today's due date due to moose hunting. Alex indicates can

complete by end of next week (9/11/20), possibly by Wednesday (9/09/20).

MISSED DEADLINE

- 9/11/20 - EHL email to FAT for status.
- 9/12/20 - Alex indicates he is working on it.
- 9/14/20 - EHL email to FAT for status. AMCO sends follow-up asking for status. Indicates having connectivity issues and will reply by end of this week (9/15/20). EHL re-issues summary of open items, allowing IS area tracking to be replaced by IS requirements in compliance document.

Prior History

1. A review of the Alcohol and Marijuana Office records shows the Respondent, Fairbanks Analytical Testing was issued a summary suspension by director McConnell on 8/19/2019 for a change of scientific directors without Marijuana Board Approval.
2. Prior AMCO administrator McConnell requested DEC, EHL's input for on 08/08/2019 to determine why FAT had detected microbials, specifically E.coli O157, on 26 occasions within approximately a one-month period (6/30/19 - 08/08/19). Review of the FAT microbial SOP revealed inapplicable text (e.g. chemistry testing quality control steps), citation regarding another lab's protocols (i.e. MWH Laboratories), and the fact the reported E.coli O157 detections came from a protocol that did not support the detections.

Requests of the Marijuana Control Board

Wherefore, Canntest, LLC, DBA Canntest, did violate multiple times regulations in accordance with:

3 AAC 306.640 Standard Operating Procedure Manual

(a) An applicant for a marijuana testing facility license and a licensed marijuana testing facility shall have a written manual of standard operating procedures, with detailed instructions explaining how to perform each testing method the applicant or marijuana testing facility uses and minimum standards for each test. The written manual of standard operating procedures must be available to each employee of the marijuana testing facility at all times. The written manual of standard operating procedures must cover at least (1) sample preparation for each matrix that will be tested;

(2) reagent, solution, and reference standard preparation;

(3) instrument setup, if applicable;

(4) standardization of volumetric reagent solutions, if applicable;

(5) data acquisition;

(6) calculation of results;

(7) identification criteria;

(8) quality control frequency;

(9) quality control acceptance criteria; and

(10) corrective action protocol.

(b) The scientific director of a marijuana testing facility shall approve, sign, and date each standard operating procedure, and each revision to any standard operating procedure.

3 AAC 306.635 testing methodologies

(a) An applicant for a marijuana testing facility license and a licensed marijuana testing facility shall (1) use as guidelines or references for testing methodologies (A) the American Herbal Pharmacopoeia's Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control, Revision 2014, adopted by reference; and

(B) the United Nations Office on Drugs and Crime's Recommended Methods for the Identification and Analysis of Cannabis and Cannabis Products: Manual for Use by National Drug Analysis Laboratories, dated 2009 and adopted by reference; and

(2) notify the board of any alternative scientifically valid testing methodology the marijuana testing facility proposes to use for any laboratory test it conducts; the board may require third-party validation of any monograph, peer-reviewed scientific journal article, or analytical method the

marijuana testing facility proposes to follow to ensure the methodology produces comparable and accurate results.

(b) An applicant for a marijuana testing facility license and the holder of a marijuana testing facility license shall observe good laboratory practices.

Dated at Anchorage, Alaska, this 24th day of September, 2020.



Jeffery Rukes

Investigator

State of Alaska

Alcohol and Marijuana Control Office

September 16, 2020



THE STATE
of **ALASKA**
GOVERNOR MIKE DUNLEAVY

**Department of Environmental
Conservation**

DIVISION OF ENVIRONMENTAL HEALTH
Environmental Health Laboratory

5251 Dr. Martin Luther King Jr. Ave.
Anchorage, Alaska 99507-1293
Main: 907.375.8200
fax: 907.929.7335
www.dec.alaska.gov

July 10, 2020

Glen Klinkhart, Director
James Hoelscher, Enforcement Supervisor
Alcohol & Marijuana Control Office
550 W. 7th Avenue, STE 1600
Anchorage, AK 99501

RE: Fairbanks Analytical Testing – Audit Report for June 23, 2020 Onsite Audit and July 8,
2020 Remote Audit Activities

Dear Director Klinkhart and Chief Hoelscher:

The report for the June/July 2020 potency testing audit of Fairbanks Analytical Testing (FAT) is available for your review. The audit of FAT resulted in findings discussed in the report included with this letter. The audit revealed calculation errors that impact a substantial number of potency results. Direction is needed from AMCO or the MCB regarding a path forward for correcting METRC entries and revised reports to clients of FAT.

If you have any questions or require additional information after reviewing the audit report, please feel free to contact me at steve.crupi@alaska.gov or (907) 375-7799.

Sincerely,

A handwritten signature in blue ink that reads "Steven R. Crupi".

Steven R. Crupi
State of AK – Environmental Health Laboratory
Quality Systems Manager

Cc: Dylanne Macomber, Fairbanks Analytical Testing
Alex Tackett, Fairbanks Analytical Testing



Alaska Department of Environmental Conservation
Environmental Health Laboratory
5251 Dr. Martin Luther King Jr. Ave., Anchorage, AK 99507

Alaska Cannabis Laboratory Oversight Program

On-Site Evaluation Report

Fairbanks Analytical Testing Laboratory

1521 Stacia Street, Suite A

Fairbanks, AK 99701

Report Date: July 10, 2020

Alaska Cannabis Laboratory Oversight Program On-Site Evaluation Report

Fairbanks Analytical Testing Laboratory
1521 Stacia Street, Suite A
Fairbanks, AK 99701

Audit Date: June 23 (onsite) and July 8 (remote), 2020
Report Date: July 10, 2020

Auditor: Steve Crupi

Introduction:

The primary responsibility of the Alaska Cannabis Laboratory Oversight Program administered by the State of Alaska Environmental Health Lab (EHL) is to ensure that laboratories that perform analysis on Alaskan cannabis plants and products are using methodology and appropriate quality controls approved and required by the Alaska Marijuana Control Board. The purpose of the EHL on-site evaluation of Fairbanks Analytical Testing Laboratory (FAT) located at 1521 Stacia Street, Suite A, Fairbanks, AK was to assess potency testing following the purchase of new test equipment. Enforcement Chief James Hoelscher requested the audit on May 26, 2020.

The on-site evaluation conducted on June 23 2020 covered FAT's personnel qualifications; standard operating procedures and quality manual for potency testing; proficiency testing results for potency; quality control and quality assurance; security; chain of custody; testing methods; specimen retention; space; records; and reporting of results.

During the audit, Alex Tackett (Scientific Director) was asked to reproduce results in a data defense as described in Finding #6 below. Mr. Tackett was unable to complete the process on the day of the audit. FAT was asked to submit a data defense by end of day July 3, 2020. On July 6, 2020, the data defense had not yet been submitted. The auditor requested FAT submit the data defense by noon the next day, July 7. The data defense was received early on July 8, just before 1:00 a.m. The data defense was reviewed on July 8 and two subsequent phone calls with FAT were held. The findings from the data defense review are listed in the report as Findings 7-12 below.

The conclusions of this combination on-site and remote evaluation are recommended to the Alaska Alcohol Marijuana Control Office (AMCO) in response to the audit request.

Results of the On-Site Evaluation:

1. **Action: Edits to the Quality Manual (QM) and Potency Standard Operating Procedure (SOP) are required to correct errors and inconsistencies between the two documents. FAT was given detailed notes of the auditor's findings.**

Fairbanks Analytical Testing Laboratory, June 2020 Initiated, Onsite Audit Report

Reference: 3 AAC 306.640 (Standard operating procedure manual).

Note: Updated versions of the SOP and QM were emailed to the EHL on July 3, 2020, and will be reviewed by the EHL.

2. **Action:** The potency SOP cites an overall dilution factor of 1:250 for the testing of plant material. FAT was unable to demonstrate on site how this factor was derived, possibly due to audit anxiety. FAT was requested to submit this demonstration by end of day July 3, 2020.

Reference: Good Laboratory Practices. “(b) The written standard operating procedures required under §58.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation.”

Note: The derivation of the dilution factor was demonstrated during a phone call on July 8, 2020. No further action required.

3. **Action:** FAT stated an intention to purchase a new chromatographic column for the potency testing. The auditor requested the performance of a method verification and submittal of the data for EHL prior to implementation for the testing of samples.

References: 3 AAC 306.640 (a) (3) “instrument setup”, 3 AAC 306.645.

4. **Action:** For the June 2020 potency PT sample, CBD was an outlier. A corrective action (CA) process was started, but not yet complete. The last notation for the CA process was to recalibrate the instrument for CBD. CA process closure must be demonstrated by an acceptable PT result for CBD. The acceptable result could be obtained through testing of a new PT sample, or retesting the original PT sample. The CA process requires closure with the testing of a new or retesting the original PT demonstrate an acceptable CBD result. Submit the corrective action and acceptable PT result to the EHL and AMCO by August 10, 2020

Reference: 3 AAC 306.620 (b) (2, 3).

5. **Action:** Internal standard responses are currently not being tracked to monitor instrument performance. An ongoing tracking mechanism is required. Submit a mechanism for ongoing tracking of internal standard responses by August 10, 2020.

Reference: 306.635 (Testing methodologies), “(b) An applicant for a marijuana testing facility license and the holder of a marijuana testing facility license shall observe good laboratory practices.”

Good Laboratory Practices. “(b) The written standard operating procedures required under §58.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of

equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation.”

6. **Action:** During the audit, FAT was asked to reproduce the reported potency results for a plant sample (lab ID 0108) and a concentrate sample (lab ID 0112). The Scientific Director was unable to locate the instrument calibration curve to begin the process. FAT was asked to submit a data defense for these two results by end of day July 3, 2020.

Reference: 3 AAC 306.635 (Testing methodologies), “(b) An applicant for a marijuana testing facility license and the holder of a marijuana testing facility license shall observe good laboratory practices.”

Good Laboratory Practices. “(b) The written standard operating procedures required under §58.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation.”

Note: The data defense was received on July 8, 2020. Actions stemming from review of the data defense are provided elsewhere within this report.

Results of the July 8 Remote Evaluation:

7. **Action:** Concentrate results have been calculated using an incorrect dilution factor (250-fold) vs. the dilution factors stipulated in SOP (200-fold or 400-fold). Mr. Tackett indicated the error has been in place since FAT started business. That being said, a solution to fix the errors going forward must be implemented. The calculation spreadsheet requires an update to accommodate the dilution factors unique to the plant, edible, and concentrate matrices. A suggestion is to create a calculation spreadsheet template for each matrix vs. changing the dilution factor in a calculation based on matrix. Ultimately, the specific process of the correction is up to FAT, but the correction must begin immediately and applied on any new tests going forward. Please submit to the EHL and AMCO, by Monday, July 13, 2020, corrective action (to include supporting evidence, e.g. updated calculation spreadsheet) to prevent recurrence. Corrective action(s) must be implemented effective with samples analyzed July 9, 2020 and forward.

***** NOTE:** Direction is needed from AMCO or the MCB regarding a path forward, to include extent of corrections, for METRC entries and revised reports to clients of FAT.

Reference: 3 AAC 306.635 (Testing methodologies), “(b) An applicant for a marijuana testing facility license and the holder of a marijuana testing facility license shall observe good laboratory practices.”

Good Laboratory Practices. “(b) The written standard operating procedures required under §58.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or

malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation.

8. **Action:** The calculation procedure for edibles was not part of the data defense presentation. Because errors were found in the plant (#9) and concentrate (#7) matrices, the edibles calculations must be evaluated. Please verify that calculations for edible matrices have historically incorporated the correct dilution factor and provide evidence to that effect. Evidence must include associated calculation spreadsheets and the associated client reports. The findings must be reported to the EHL and AMCO by Monday, July 13, 2020.

Reference: 3 AAC 306.635 (Testing methodologies), “(b) An applicant for a marijuana testing facility license and the holder of a marijuana testing facility license shall observe good laboratory practices.”

Good Laboratory Practices. “(b) The written standard operating procedures required under §58.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation.”

9. **Action:** The review of the updated data defense submitted July 8, 2020, revealed the calculation for the adjusted mass ultimately used to calculate plant results was incorrect. This finding was relayed via email late on July 8, 2020. This finding represents an SOP deviation; specifically, the percent moisture calculation provided in the SOP. Please determine how far back this calculation error impacts data reported for the plant matrix, by identifying the affected samples. The findings must be reported to the EHL and AMCO by Friday, July 10, 2020. By Monday, July 13, 2020, submit to EHL and AMCO a proposed corrective action plan (to include supporting evidence, e.g. calculation spreadsheet with corrected calculation) to prevent recurrence of this error.

***** NOTE:** Direction is needed from AMCO or the MCB regarding a path forward, to include extent of corrections, for METRC entries and revised reports to clients of FAT.

Reference: 3 AAC 306.635 (Testing methodologies), “(b) An applicant for a marijuana testing facility license and the holder of a marijuana testing facility license shall observe good laboratory practices.”

Good Laboratory Practices. “(b) The written standard operating procedures required under §58.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation.”

10. **Action:** The QC limit calculations in the ‘Analyte Target Verification’ section of the calculation spreadsheet are incorrect. This finding was relayed in email late on July 8, 2020. It impacts QC compliance determinations. Correct the calculation to support the

proper use of the QC limit calculations and submit evidence of the update (i.e. corrected calculation spreadsheet) to the EHL and AMCO by Monday, July 13, 2020.

Reference: 3 AAC 306.635 (Testing methodologies), “(b) An applicant for a marijuana testing facility license and the holder of a marijuana testing facility license shall observe good laboratory practices.”

Good Laboratory Practices. “(b) The written standard operating procedures required under §58.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation.”

11. **Action:** The data defense included a June 1, 2020 instrument calibration and June 4, 2020 sample analysis run. Two significant retention time shifts were noted during this 4-day period. Mr. Tackett noted these shifts were due to instrument optimization efforts. Instrument changes that impact retention times require re-calibration as a good laboratory practice. This requirement is not present in the SOP. Spectral information was used in lieu of the retention time metric to identify target constituents. The SOP only allows for the use of spectral information to identify a peak in situations of peak interference. The SOP is missing criteria specifying what constitutes a good spectral match.

Update the SOP to require recalibration after any instrument optimization and whenever a shift in retention time is discovered. Also, update the SOP to specify criteria required in a spectral match for the purpose of attempting peak identification. Spectral match may be used as a complement to using retention time as a means of peak identification, not as a replacement. Submit an updated SOP by Tuesday, July 14, 2020.

Reference: 3 AAC 306.635 (Testing methodologies), “(b) An applicant for a marijuana testing facility license and the holder of a marijuana testing facility license shall observe good laboratory practices.”

Good Laboratory Practices. “(b) The written standard operating procedures required under §58.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation.”

12. **Action:** The opening continuing calibration verification (CCV) for the sample analysis sequence of June 4, 2020, failed low for CBD. Samples were analyzed and reported without corrective action. Positive results for CBD were reported. This situation represents an SOP deviation. Initiate a corrective action evaluation for this deviation, explaining why CBD data were reported despite the outlier. The corrective action must also present steps taken to prevent recurrence of this situation. Submit the corrective action by August 10, 2020.

Fairbanks Analytical Testing Laboratory, June 2020 Initiated, Onsite Audit Report

Reference: 3 AAC 306.635 (Testing methodologies), “(b) An applicant for a marijuana testing facility license and the holder of a marijuana testing facility license shall observe good laboratory practices.”

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Submit the corrective actions by close of business on the due dates provided in each action item to both the EHL and AMCO. If you have any questions or require additional information regarding the contents of this report, email declabcert@alaska.gov with a cc: to the appropriate AMCO contacts, or call Steve Crupi at 907-375-7799.



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