THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Commerce, Community, and Economic Development

ALCOHOL AND MARIJUANA CONTROL OFFICE
550 West 7th Avenue, Suite 1600
Anchorage, AK 99501
Main: 907.269.0350

June 3, 2021

Dylanne R. Macomber, Co-Owner/Manager
Ronald Eads, Co-Owner
Fairbanks Analytical Testing, LLC
1521 STACIA ST STE A
FAIRBANKS AK 99701

Hand Delivered

Re: Notice of violations to be corrected within 30-days.

Dear Dylanne Macomber & Ronald Eads:

By virtue of the "Stipulated Mediated Settlement Agreement,"[1] and the associated Order and adoption of the Order by the Alaska Marijuana Board on May 6, 2021, Fairbanks Analytical Testing ("FAT") was audited on May 18-19, 2021 by the Alaska Department of Environmental Conservation Environmental Health Laboratory ("EHL"). This audit was conducted as part of the Alaska Cannabis Laboratory Oversight Program. An "On-Site Evaluation Report" of that audit was produced on May 25, 2021 and provided to FAT. Copies of the Report and Agreement are attached to this letter for your reference. As you know, notification of the corrective actions to each of the EHL findings taken by FAT along with supporting documents must be provided to the EHL by 5:00 p.m. on June 25th.

The audit of FAT by the EHL has revealed substantial deficiencies and violations (listed in the findings below) in the areas of quality control and quality assurance, chemistry

[1] *In the matter of: Fairbanks Analytical Testing, LLC d/b/a Fairbanks Analytical Testing, Respondent*. April 15, 2021/May 6, 2021. OAH No. 20-0973-MCB; Agency Reference No. AM20-720.

and microbiology that must be corrected by FAT. In the Mediated Settlement Agreement FAT as the Respondent agreed that:

> [a] future probation violation(s) is conditioned upon an error(s) and/or violations(s) found in an audit described above or for failure to timely respond to audit information request within thirty calendar days. Further, it is understood by the parties that Respondent's failure to respond and/or correct an error/violation found in an audit within thirty calendar days will act as a "trigger-point" for a probation violation. Additionally, it is understood by the parties that this provision encompasses all applicable cannabis regulations and the Cannabis Testing Laboratory Compliance Document that has been adopted by the Board via regulation.[2]

Because of the findings reflected in the audit of May 18-19, 2021, FAT must respond to the findings in this Notice to the Alaska Alcohol and Marijuana Control Office ("AMCO") by 5:00 p.m. on the 30th calendar day following the day of service of this letter. Failure to adequately respond and take necessary corrective action constitutes a violation of your probation and may result in suspension of your license.

Quality Control ("QC") and Quality Assurance

Findings No. 1 & No. 2.[3] During the audit visit, requested potency test data was not accessible or traceable. File management activities the day before the audit rendered the entire body of raw potency data generated by FAT as not accessible from the instrument computer. Requested files were downloaded from archive storage (only FAT's Scientific Director has access rights to access archived files) but FAT was unable to exactly reproduce the areas and concentrations leading up to the client report. Additionally, FAT was unable to demonstrate sufficient documentation for manual integration activities.

Specifically requested were the analytes in the plant material of client sample 2103FBA0239.0951 and for the Spring 2021 Emerald Scientific Potency Proficiency Test. By extension, the inability to reproduce the plant data also impacts the ability to reproduce data for other matrices (e.g. concentrates, edibles). The auditor observed the accessibility issue impacts data over approximately the prior six months. Auditor observations for manual integration are limited to specific data requested; however, FAT personnel stated that data management activities have not changed since beginning of operation. These

[2] Mediated Settlement Agreement No. 20-0973-MCB ¶3 pg. 2.

[3] 3 AAC 306.635 (a) (3), LCD, pg.10.

issues are a barrier to defending data, which is a liability if the data requires defense due to an emerging public health concern that must be addressed.

Finding No. 3.[4] FAT could not make available client reports issued prior to March 2021. The EHL requested two weeks before the audit, client reports from August 2020, November 2020, and March 2021 for viewing during the audit. The Office Manager of FAT interviewed during the audit said reports prior to her start of employment in March 2021 were too hard to find since she did not understand the filing system previously used for client reports. Requested client reports must be retrievable and readily available upon request.

Finding No. 4.[5] The latest versions of the Quality Manual and SOPs were not approved by the Alaska Marijuana Control Board or its contractor. The current SOP revisions are 12/19/2020 for Potency, 1/14/2021 for solvents, and 10/20/20 for the Quality Manual. One purpose of this SOP review is to ensure FAT is working within the confines of regulation and their method validation study, which forms the basis for any necessary data defense.

Finding No. 17.[6] A potency instrument calibration performed on 2/2/2021 did not include all analytes, for which FAT was testing. This calibration included quality control analytes but did not include the target cannabinoids. Recalibration activities must include all analytes. Calibrating only the quality control analytes places into question the accuracy and precision of the cannabinoid concentration results.

Finding No. 18.[7] The HPLC (potency) chromatography column was changed on 4/13/2021, and the instrument was not recalibrated afterward. Installing a new column can impact elution times and response intensities for targeted analytes, thus requiring a new instrument calibration. The accuracy level of client results since this date is uncertain.

Finding No. 19.[8] The calculation of the sample percent moisture was incorrect for potency reporting of plant material. The potency result of flower or plant material is based on the dry weight of the sample, so an incorrect moisture calculation correlates to incorrect

[4] 3 AAC 306.620 (b).

[5] 3 AAC 306.640 (b).

[6] 3 AAC 306.635 (b).

[7] 3 AAC 306.635 (b).

[8] 3 AAC 306.645 (b)(1)(B)(i).

flower potency results. The potential bias is situational, with trending possible in either direction.

Finding No. 20.[9] The potency confirmation wavelength used for testing (215 nm) is not the same confirmation wavelength documented in the SOP (360 nm). This change strays from the method validation, creating a source of uncertainty in a scenario where defense of the data is needed. Additionally, a 5 nm difference from the primary wavelength (220 nm) is questionable in terms of sufficient separation to confirm analyte identities.

Finding No. 21.[10] Two calibration curves are maintained for potency. A gap exists between 150 ppm (top of the lower concentration calibration) and 200 ppm (bottom of the higher concentration calibration curve). This gap between calibrations leaves a 50-ppm area of uncertainty. It is unknown if samples were reported based on data existing within this gap.

Microbiology

Finding No. 23.[11] FAT is recording media prep data, enrichment data, and microbiology analysis data on post it notes, gloves, or other locations for later transfer into the microbiology spreadsheet but does not retain these original documents in any format. Original documentation of observations and measurements must be treated as permanent records and retained. Since transcription errors can occur, original documentation must be treated as a permanent record for comparisons in case questions arise, or the data needs to be defended.

Finding No. 25.[12] FAT's procedure is to run a positive and negative control with every batch. Documentation of performing these controls does not exist and therefore QC documentation for the media does not exist. All media quality control checks must include a positive (target organism), negative (non-target organism), and sterility control on a per lot basis, prior to use. These quality control checks are used to show that the media works as expected. Without documentation of these tests, FAT cannot demonstrate the media works as expected. If media does not work as expected, false negatives and false positives may occur.

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[9] 3 AAC 306.635 (b).

[10] 3 AAC 306.635 (b).

[11] 3 AAC 306.635 (a) (3), LCD pg. 8.

[12] 3 AAC 306.635 (a) (3), LCD pg. 8, pgs. 14 -15.

Finding No. 27.[13] FAT has made changes to procedures without updating the SOP. Specifically, FAT is making SMAC and TSB in-house but has no procedures for this in the SOP. Also, the SOP states to autoclave the media (DRBC) but FAT is using a pressure cooker. Following a written SOP is required by regulation and helps ensure proper procedures are followed and followed consistently. The SOP describes the validated methods, so by not following the SOP, FAT is using methods that haven't been shown to be effective by validation, which makes the data questionable if not unreliable.

Finding No. 29.[14] FAT is not entirely following the Micro SOP SOP-FA-003. The SOP reflects the manufacturer's method, except as noted in Finding #30; however, during the analyst interviews the following discrepancies between FAT's SOP and how the method is run were noted.

- The SOP states FAT screens samples for STEC using the Compact Dry Plates. FAT is skipping this step.
- For SMAC plates and the DRBC plates, the SOP states FAT inoculates the plate with 0.1mL of sample and spreads the inoculum. During the audit, the analyst added an unmeasured amount of sample material and an unmeasured amount of growth media.
- For the Compact Dry SL Plates, the SOP states FAT inoculates the plate with 1mL of sample. FAT is actually adding 0.1mL of sample and 1mL of sterile water to the plate.
- The SOP states to autoclave the media and take the pH but the media is being sterilized using a pressure cooker and the pH is not being taken.
- The SOP states that for any colony growth on the SMAC, each colony will be individually tested with the latex assay. The analyst only transferred one colony during the demonstration during the audit. When asked if each colony is individually tested, the analyst stated "no".

Following a written SOP is required by regulation and helps ensure proper procedures are followed and followed consistently. The SOP describes the validated methods, so by not following the SOP, FAT is using methods that haven't been shown to be effective, which can make the data questionable. Taken together, findings Nos. 23, 27, and 29 make it impossible for FAT to show with any degree of certainty how any sample was prepared or run.

[13] 3 AAC 306.340.

[14] 3 AAC 306.640.

Finding No. 30.[15] The microbiology SOP requires updating. Some procedures do not follow the manufacturer's method; other procedures are missing from the SOP; some information in the SOP does not directly pertain to daily testing activities.

- The SOP contains portions of the validation study which are not repeated during sample analyses.
- The SOP requires control spikes (LCS/LCMS) for each batch, but instructions are not given on how to prepare the spikes, nor what to do if a failure occurs.
- The SOP does not provide prep instructions or QC requirements for the TSB media.
- The SOP does not list required controls for *Salmonella*, nor describe how to prepare the controls.
- The instructions for Compact Dry SL plates for *Salmonella* in the SOP do not match the manufacturer's instructions.
- The SOP does not provide prep instructions for the SMAC used for sample testing.
- The SOP lists negative and sterility controls for SMAC but does not require a positive control, does not list the frequency of controls, and does not describe how to set up the controls.
- The SOP lists a positive control for DRBC but does not require a negative control, does not list the frequency of controls, and does not describe how to set up the controls.
- The SOP contains instructions for preparing DRBC and states the approximate shelf life of the poured plates is 1 week. The DRBC preparation worksheet lists the retention period as 2-4 weeks.
- Multiple instances of the *Aspergillus* characteristics section were observed where the text does not match up with the information presented in the SOP table.
- The SOP does not clearly state how control organisms are made and maintained, nor how long they are kept.

Again, FAT is required to correct and submit notification of the corrective actions taken to each of these findings and submit supporting documents described above to the EHL by 5:00 p.m. on June 25, 2021 and to this Notice to AMCO by the 30th calendar day following the service of this letter.

While preparing this correspondence, it is was noted that as of June 2, 2021, Alaska Business License records reflect that FAT's Alaska Business License No. 1060409 expired on December 31, 2020. I have attached that record for your reference. As a reminder, it is required that all marijuana establishments and businesses in Alaska have current business

[15] 3 AAC 306.635 (a) (2), 3 AAC 306.640.

licenses. Unless FAT has already addressed this matter, FAT should apply for a license as soon as possible. Failure to do so may result in a Notice of Violation.

Very truly yours,

ALCOHOL & MARIJUANA CONTROL OFFICE

By: Glen Klinkhart
Executive Director

GEK/rjh

Encl.: Stipulated Mediated Settlement Agreement
On-Site Evaluation Report
Business License record

Law.oah.ecf@alaska.gov

BEFORE THE ALASKA OFFICE OF ADMINISTRATIVE HEARINGS ON REFERRAL BY THE MARIJUANA CONTROL BOARD

In the matter of: Fairbanks Analytical Testing, LLC. d/b/a Fairbanks Analytical Testing, Respondent.	OAH No. 20-0973-MCB Agency Reference No. AM20-720

MEDIATED SETTLEMENT AGREEMENT

The parties, Fairbanks Analytical Testing, LLC, d/b/a Fairbanks Analytical Testing (Respondent) by and through its attorney of record Lance Christian Wells of the Law Offices of Lance Christian Wells, LLC, and the Alaska Alcohol and Marijuana Control Office (AMCO) by and through its attorney of record Richard Moses with Alaska Attorney General's Office agreed to mediate the above-captioned matter.

On March 2, 2021, the parties along with their undersigned attorneys of record participated in a ZOOM mediation before Administrative Law Judge Lawrence Pederson from the Office of Administrative Hearings. The parties reached an agreement to resolve this entire matter subject to board approval as follows:

PROPOSED DECISION AND ORDER

- Respondent admits that the Board has jurisdiction over this matter.
- The Marijuana Control Board (Board) will place Respondent on probation for a period of two years. The term of probation shall begin the date the Board accepts this agreement.
- The Board will suspend Respondent's license to operate its testing facility for two months. The Board will fully suspend this license suspension during this probationary period set forth above subject to the terms and conditions set forth below.
- The Board will impose a $2,500 fine, which Respondent must pay to AMCO within thirty calendar days of the Board's acceptance of this agreement. Failure

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to pay this fine within 30 days after adoption by the Board is a violation of this agreement and the probationary terms.

- While on probation, Respondent is subject to random audits by AMCO by DEC acting on behalf of AMCO. Respondent should expect to be audited a minimum of one time per probation year.

- Respondent is responsible for the cost of a maximum of one audit per probation year, which is capped at $5,000 per audit. Any costs in excess of the $5,000 per audit will be paid by AMCO. Any costs associated with a second or subsequent audit per probationary year will be paid by AMCO.

- A future probation violation(s) is conditioned upon an error(s) and/or violation(s) found in an audit described above or for failure to timely respond to audit information request within thirty calendar days. Further, it is understood by the parties that Respondent's failure to respond and/or correct an error/violation found in an audit within thirty calendar days will act as a "trigger point" for a probation violation. Additionally, it is understood by the parties that this provision encompasses all applicable cannabis regulations and the Cannabis Testing Laboratory Compliance Document that has been adopted by the Board via regulation.

- Respondent's failure to pay the $2,500 within the agreed-upon timeframe will constitute a violation of this agreement and is itself a trigger point for a probation violation.

- It is further understood between the parties that all or part of the suspended portions of the fine and/or period of license suspension can be imposed in the event Respondent violates the terms of probation listed above.

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- This mediation agreement shall be placed upon the Board calendar as soon as possible for the next scheduled board meeting for their consideration of this agreement.

- These agreements are not an admission by either party.

- Each party shall be responsible for their own attorney fees and costs incurred in this matter.

IT IS HEREBY FURTHER ORDERED that this Proposed Decision and Order shall take effect immediately upon its adoption by the Board and is a public record of the Board and the State of Alaska. The state may provide a copy of it to any person or entity, including other licensing boards, federal, state, or local governments, or other entity making a relevant inquiry.

DATED this 15th day of April, 2021 at Anchorage, Alaska

ALCOHOL & MARIJUANA CONTROL OFFICE

By: _____
Glen Klinkhart, Director

DATED this 14 day of April, 2021 at Fairbanks, Alaska

Fairbanks Analytical Testing, LLC.
d/b/a Fairbanks Analytical Testing

_____
Dylanne Macomber, co-owner

DATED this 14 day of April, 2021 at Fairbanks, Alaska

Fairbanks Analytical Testing, LLC.
d/b/a Fairbanks Analytical Testing

_____
Ronald Eads, co-owner

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BEFORE THE ALASKA OFFICE OF ADMINISTRATIVE HEARINGS ON REFERRAL BY THE MARIJUANA CONTROL BOARD

In the matter of:	)	
	)	
FAIRBANKS ANALTICAL	)	OAH No. 20-0973-MCB
	)	
	)	Agency Reference No. AM20-720

CERTIFICATE OF SERVICE

I certify that on April 15, 2021, true and correct copies of the **MEDIATED SETTLEMENT AGREEMENT, ORDER** and this *Certificate of Service* were served on the following via email:

Lance C. Wells
lwells@gci.net

Sabina Figueroa
Law Office Assistant

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BEFORE THE ALASKA OFFICE OF ADMINISTRATIVE HEARINGS ON REFERRAL BY THE MARIJUANA CONTROL BOARD

In the matter of: Fairbanks Analytical Testing, LLC. d/b/a Fairbanks Analytical Testing, Respondent.	OAH No. 20-0973-MCB Agency Reference No. AM20-720

ORDER

The Marijuana Control Board (Board) for the State of Alaska, having examined the Stipulated Agreement and Proposed Decision and Order, signed by the Respondents and the Director of the Alcohol & Marijuana Control Board, hereby adopts the Stipulated Agreement and Proposed Decision and Order in this matter.

This Stipulated Agreement and now Final Decision and Order take effect immediately upon signature of this Order in accordance with the approval of the Board.

This Order is a public document.

DATED this 5th day of MAY, 2021

Marijuana Control Board

By: _____

Chair

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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: May 25, 2021

Alaska Cannabis Laboratory Oversight Program
On-Site Evaluation Report

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

Audit Date: May 18-19, 2021
Report Date: May 25, 2021

Auditors: Shera Hickman and Kelly Snyder

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 determine the laboratory's capability to operate under 3 AAC 306, the FAT Quality Manual (QM) and Standard Operating Procedures (SOPs), and the State of Alaska Cannabis Testing Laboratory Compliance Document (LCD) (Revision 9/30/19). The Code of Federal Regulations Title 21, Part 58 (21CFR58) was employed as a resource for providing definition and clarity to Good Laboratory Practice (GLP) references in 3 AAC 306.

The on-site evaluation conducted on May 18-19, 2021 covered FAT's personnel qualifications; standard operating procedures for each testing methodology used; proficiency testing results; quality control and quality assurance; security; safety; chain of custody; testing methods; specimen retention; laboratory space; records; and reporting of results. The following tests were reviewed in this audit:

- STEC*, Salmonella* and *Aspergillus* by cultural methods
- Potency in plant material, concentrates, and edibles
- Residual Solvent Analysis

Results of the On-Site Evaluation:

Finding 23 has a short deadline and should be addressed first.

Personnel:
It is unknown if the staff have met the educational requirements for their respective positions, since the laboratory provided the CV for the Scientific Director, but not for other staff. Internal training documents exist, but staff have not documented demonstration of capability for the specific methods which they perform via performing proficiency tests.

Laboratory Personnel Interviewed:
Dylanne Macomber - Manager
Alex Tackett – Scientific Director
Alicia Lenze – Technician
Alex Boyle – Technician
Jessica Angelanis – Office Manager

Quality Control and Quality Assurance:

1. *Finding:* During the audit visit, the laboratory could not trace potency test data. The day before the audit began, an issue with the potency data storage on the lab bench computer rendered the entire body of raw potency data generated by the laboratory as not accessible from its primary location. This necessitated the scientific director downloading the auditor-requested files to the benchtop potency workstation from the archive. The scientific director was the only employee with permission to access the archived files. The files were not saved in a format which preserves the original integration, instead the data file and its matching method revision had to be acquired and downloaded from the archive to reintegrate the peaks. However, the matching method revisions were not found for the requested data files, and the reintegrated peaks had peak areas which did not match the areas used to calculate the reported results. (All raw un-integrated data and supporting information necessary to recreate calculations are available.)

   During the audit visit, the laboratory was not able to show the auditor a single integrated analyte or QC peak whose integration matched the integration area found on the calibration and calculation template spreadsheet. Specifically requested were the analytes in the plant material client sample 2103FBA0239.0951, and the Spring 2021 Potency Proficiency Test, and their associated CCVs. Since these requests were not answered, the auditor was not able to request the same type of data to evaluate the method performance in other matrices (e.g. concentrates, edibles, drinks).

   Reference: 3 AAC 306.635 (a) (3), LCD, p.10

   Action 1: Submit the integration peak areas for client sample 2103FBA0239.0951, and the Spring 2021 Potency Proficiency Test, **to EHL with the accompanying calculation spreadsheet for each run. Once the plant-based submission is found acceptable, EHL will make an additional request for the same data supporting potency results in at least two other sample matrices, and their accompanying QC (CCVs, LFBs, Method Blank,**

MS/MSD and parent samples) with the final report. The deadline for this second request is two business days from the date of the plant material submission. Additional findings may occur as a result of this data review.

Action 2: Complete a corrective action report (CAR) which provides a timeline of what happened to the data, how it was recovered/replaced, and what measures were taken to mitigate recurrence of the data becoming inaccessible in the future.

2. *Finding:* The laboratory is not preserving the original peak integrations in an accessible format. The issue in Finding #1 was exacerbated by the files not being saved in a format which preserves the original integration. The data file and its matching method revision instead had to be acquired and downloaded from the archive to reintegrate the peaks. Unfortunately, it was displayed why the original integration used to report the results must be saved in a format readable by widely available software, such as PDF. The attempted reintegration of the peaks did not result in the peak areas displayed in the calculation spreadsheet. Observations of sample testing that either support the final result or affect the final result must be recorded.

   Reference: 3 AAC 306.635 (a) (3), LCD, p.8

   Action: After recalibration of potency analysis approved on 5/24/2021, submit two runs of data in the injection summary report format discussed during the audit, with a run log (list of injections in order). Submit the SOP revision describing how to generate the integration summary reports.

3. *Finding:* Some client reports from dates within the regulatory retention requirement were deemed inaccessible by current staff during the audit. EHL sent a request to have certain documents on hand for review more than two weeks prior to the audit visit. Included in the request were one report from August 2020 for all regulated microorganisms, one report from November 2020 for potency, and one report from January 2021 for residual solvents. Once onsite, when the auditor requested the report from November 2020, the Office Manager interviewed said that she has been employed by FAT since March 2021, and any reports before then were too hard to find since she did not understand the filing system previously used for client reports. The Office Manager was able to locate client reports requested for samples received March 23, 2021.

   Reference: 3 AAC 306.620 (b)

   Action: Submit the three requested reports above, one from August 2020 for Microorganism, one from November 2020 for potency, and one from January 2021 for residual solvents. Additional data requests will follow for the data supporting these reports. Additional findings may occur as a result of the related report review.

4. *Finding:* The latest versions of the Quality Manual and SOPs were not yet approved by the board or its contractor. The Potency SOP revision was 12/19/2020, the RSA revision was 1/4/2021, and the Quality Manual revision was 10/20/2020.

   Reference: 3 AAC 306.640 (b)

   Action: Submit the Quality Manual and each SOP individually to AMCO and the EHL requesting review and approval after edits required in this report are completed.

5. *Finding:* The laboratory has thermometers with calibration documentation in all refrigerators, freezers, and incubators, but only 4 of those thermometers show calibration dates within the last twelve months. The laboratory is using the certificate of calibration vendor provides when purchased. Four of the thermometers have calibration dates of September 29, 2020. The remainder have calibration dates of February 28, 2020 or earlier. It was noted during the on-site the calibration certificates from the vendor have the expiration date set at two years, however, the regulation supersedes the vendor applied expiration date.

   Reference: 3 AAC 306.635 (b)

   Action: The laboratory must update their procedure to ensure thermometers are calibrated annually and must provide updated calibration documentation for all thermometers currently in-use. The laboratory may choose to purchase a reference thermometer and perform thermometer calibrations on-site, send the current thermometers off-site for calibration, or purchase new thermometers with current calibrations.

6. *Finding:* The laboratory has not marked the thermometers with calibration information. At a minimum, thermometers should be marked with calibration date, expiration date and Correction Factor (CF).

   Reference: 3 AAC 306.635 (a) (3) (b)

   Action: Submit photo documentation of the marked thermometers. As discussed during the on-site, if unable to mark the thermometers with the required information, the information can be placed on the unit in which the thermometer is used, or on the log sheet.

7. *Finding:* The laboratory is not applying the calibration factor (CF) when taking temperatures.

   Reference: 3 AAC 306.635 (a) (3) (b)

   Action: Update and submit procedure to include applying CF when recording temperatures.

8. *Finding:* Multiple instances of missing temperature or outliers without comment were noted for incubators, refrigerators, and freezers. For example, only one temperature was recorded (minimum two are required) for the incubators on March 29, 2021 and March 31, 2021, and in December of 2020, incidents of the Enrichment Incubator out of the required temperature range were noted on the 7th, 8th, 9th and 14th. No comments were made for the outliers in any of these incidences.

   Reference: 3 AAC 306.635 (b)

   Action: Update and submit procedure to ensure outliers are noted on all temperature logs. Additionally, please submit temperature logs from May 18, 2021 through June 25, 2021.

9. *Finding:* White-out was used on temperature logs for December 14 and 15, 2020. Additionally, instances of overwrites were observed in the temperature logs.

   Reference: 3 AAC 306.635 (b)

   Action: Original documentation must be maintained, and changes cannot obliterate the original information. Any changes must occur with a single line through the original data along with initial and date of the person making the change. **Submit a plan or policy to ensure changes to documents are properly made.**

10. *Finding:* Documentation of annual review for the Microbiology SOP was not available. The date of the current SOP is February 21, 2020.

    Reference: 3 AAC 306.635 (a) (3), LCD pg. 10.

    Action: Submit a plan to ensure annual review and documentation of review of the Microbiology and all other laboratory SOPs.

11. *Finding:* Dates and initials are not consistently used to document laboratory testing activities. Dates were inconsistently used in the sample weight notebook at the top of each page, with some pages missing dates. A date and initials are required for each dry weight measurement separate from the rest of the analyses' sample weights.

    The pipette calculation spreadsheet did not contain the identity of the person who performed the check, or a label to prompt the recording of the information.

    Reference: 3 AAC 306.635 (b)

    Action: Submit a corrective action that describes the activities which will be dated and initialed as a result of this finding. Include documented training on the changes. Also submit three pages of sample weights and a pipette calibration, including the dates and initials.

12. *Finding:* Corrective action was not taken on a proficiency test failure. The laboratory's analysis of delta-9 THC in Hemp Bud for the Emerald proficiency study S2021 had a Not Acceptable rating. The nominal amount for delta-9-THC was 285 µg/g, and the laboratory reported 93.44 µg/g (33% recovery). Documented follow-up to this PT failure in the form of a corrective action and a repeat PT test were not performed.

    Reference: 3 AAC 306.625(d) "The laboratory shall take and document remedial action when it scores less than 100 percent in a PT."

    Action: Submit a CAR which addresses the found root cause and mitigates recurrence. The CAR will show efficacy of the corrective actions with a repeat PT.

13. *Finding:* Internal audits were not available for residual solvents analysis and microbials, and the internal audit for potency is incomplete. An internal audit was submitted for potency, but upon review, it consisted of data presentation only. No summary, findings, action items, or follow ups were observed.

    Reference: 3 AAC 306.635 (a) (3), LCD p.18

    Action: Perform internal audits for all tests and submit an internal audit report that describes exactly what the audit reviewed, and list any findings discovered during the audit. Provide corrective actions addressing the findings or minimally provide correction action plans with definitive action items and timelines for completion.

14. *Finding:* The frequency of measurement uncertainty review is not described in the measurement uncertainty SOP.

    Reference: A2LA P103b, FAT SOP-FA-006, 3 AAC 306.635 (b)

    Action: Update the SOP to indicate the frequency at which the measurement uncertainty for enumerative methods is reviewed for possible updating. Submit the revision to EHL.

15. *Finding:* A k value of 2 was used for a population size of ten (10) measurements in calculating the measurement uncertainty for balance checks. FAT's SOP indicates k=2 can only be used for 50 or more measurements. A2LA policy requires a minimum of 20 or more measurements for k=2.

    Reference: A2LA P103b, 3 AAC 306.635 (b)

    Action: Recalculate and re-submit the measurement uncertainty calculation for balance checks using the k-value appropriate for ten (10) measurements.

16. *Finding:* The laboratory did not have a procedure for professional judgment used during sample reporting. For instance, if THCV is present in the method blank, but all samples in that preparation batch are non-detect for THCV, then the sample results are reportable using professional judgment. Capability convey comments on the final report does not exist; the same is true for internal comments in the laboratory's Confident Cannabis LIMS.

    Reference: 3 AAC 306.635 (a) (3), LCD p.10

    Action: Submit a revision of the Reporting SOP and/or the Quality Manual describing the process in cases where professional judgment may be used, and by whose authority. Add fields in Confident Cannabis LIMS where comments may be entered as a case narrative on the report, discussing, for instance, the use of professional judgment in reporting the data. Submit a client report to demonstrate the existence of this capability.

Observation 1: Observations noted in the pre-audit documents review indicate a need for housekeeping of all lab documents.

- The effective date is missing for SOP Lab-GLP-001 and Laboratory Release of Information Policy. The Policy is also missing the ID number.
- References to a Bio-Med department and Bio-Med review are present in the SOP Lab-GLP-001, an artifact of an SOP from another organization.
- In the Quality Manual, cross reference is made to measurement uncertainty in Section 5.9, but Section 5.9 does not mention measurement uncertainty.
- In the record "Assessment for CCV, AT/AB" spreadsheet, several cells contain broken links (indicated by "REF!"). These cells were not required for the assessment, but were artifacts from the calculation spreadsheet template.
- Two typos were observed in the calculation template for potency and residual solids, which were fixed while the auditor was onsite.

Observation 2: Insufficient Corrective Action Reports. The auditors encountered several occurrences which were opportune candidates for CARs. CARs can aid for quick resolution in cases of repeated occurrences, and general benefit to laboratory operations, demonstrating the laboratory is actively involved in quality control of its activities

Observation 3: Participate in the full scope of proficiency tests before the required date of September 25, 2021. While the laboratory has until September 2021 to run its annual PTs, this is a reminder that annual PTs for Potency, RSA, STEC, *Salmonella*, and *Aspergillus* must be run and scored reports with passing results for all parameters sent to AMCO and the DEC EHL by September 25, 2021. All matrices must be covered for Potency, including concentrates, edibles, and drinks. A repeat PT for delta-9 THCA in plant material must also be completed.

Potency:

17. *Finding:* Alternate compounds used for potency quality control (QC) checks are calibrated separately from the analytes. The laboratory reported the last time the alternate QC compounds had been calibrated was 2/2/2021, but the cannabinoid analytes were not spiked into the calibration solutions and therefore not calculated. The alternate compounds were approved by EHL as a less expensive way to indicate instrument drift for the targeted cannabinoid analytes. If the alternate compound responses drift, thus requiring recalibration, then recalibration is also required for the target analytes. The alternate compounds must never be calibrated separate from the analytes.

    Reference: 3 AAC 306.635 (b)

    Action: Immediate simultaneous recalibration of both the alternate QC compounds and cannabinoid analytes is required for continuation of Potency analysis. The laboratory submitted the integrated chromatograms and the linear regressions of all alternate compounds and analytes by May 24, 2021. Submit the revised SOP instructing analysts to calibrate alternate QC compounds and cannabinoid analytes simultaneously.

18. *Finding:* The HPLC column was changed on 4/13/2021, and the instrument was not recalibrated afterward. Changing an HPLC column is a significant change in the instrument, which requires a recalibration. Different columns will have different retention times and different response ratios. Since the calibration was not done, it cannot be ascertained if the potency test results released to the client and AMCO are accurate since 4/13/2021.

    Reference: 3 AAC 306.635 (b)

    Action: Immediate simultaneous recalibration of both the alternate QC compounds and cannabinoid analytes is required. The laboratory submitted the integrated chromatograms and the linear regressions of all alternate compounds and analytes by May 24, 2021. Submit the revised SOP instructing analysts to recalibrate the instrument after major changes, such as column replacement.

19. *Finding:* The calculation of the sample percent moisture was incorrect for potency reporting of plant material. The calculation in the calculation spreadsheet template used the separate sample weight for the potency plant sample instead of the sample weight that was used for the moisture analysis.

    Reference: 306.645 (b)(1)(B)(i)

    Action: The laboratory submitted a corrected calculation spreadsheet template on May 20, 2021. No further action is required.

20. Finding: The confirmation wavelength is not appropriate, and is not as described in the SOP. The confirmation and primary wavelengths only vary by 5 nm, and that is not enough separation to confirm analyte identities. The SOP lists 360 nm as the confirmation wavelength.

    Reference: 3 AAC 306.635 (b)

    Action: Submit a revision of the calculation template spreadsheet, correcting the alternate wavelength to agree with the SOP (360 nm). The injection summaries of Findings 1 and 2 must also display data from 360 nm.

21. Finding: A gap exists between 150 and 200 ppm between the low and high calibration curves. Gaps in calibration are not allowed, and results based on measurements in the uncalibrated regions are not valid.

    Reference: 3 AAC 306.635 (b)

    Action: The low point on the upcoming high calibration curve must be less than or equal to 200ppm, since the low calibration accepted on 5/24/2021 had 200ppm as the high point. Submit the linear regression of the high calibration completed after 5/24/2021.

Observation 4: The MDLs on the final reports for Potency and Residual Solvents were calculated using the y-intercept of the linear calibration and the standard deviation of the response factors. Estimating the MDL with the y-intercept can incorporate bias into the estimation. For Potency, seven replicates of the CCV were analyzed and an MDL was calculated, but the spike

concentration is too high, rendering the MDLs artificially low. For RSA, seven replicates were analyzed near the lower calibration point, but MDLs were not calculated. **The MDLs most representative of the analysis are going to have a spike level at approximately the lowest calibration point.**

Observation 5: Add the calibration date just above each copied calibration table in the calculation spreadsheet template. The filename could be added also for better traceability. The analyst explained in the 3/24/2021 potency run examined in the audit, the DBCA surrogate appeared to fail in the CCV, but upon further inspection by the analyst and prior to review, it was found that the most recent calibration data was not used. Updating the calibration table resulted in a passing DBCA in the CCV. Addition of the date to the calibration section would enable a quick check for the most recent calibration.

Residual Solvents Analysis:

22. *Finding:* Too many injections are occurring between CCV checks. In the analysis run sequence observed during the audit, 13 injections occurred between CCVs. The 13 injections consisted of 10 client samples, a parent sample (which doubles as the client sample), the matrix spike and matrix spike duplicate. QC samples which undergo the sample preparation should be counted as injections.

    Reference: 3 AAC 306.635 (a) (3), LCD p.14, paragraph 1.

    Action: Submit a run log which shows that prep QC samples are counted as injections.

Microbiology:

23. *Finding:* The laboratory is recording media prep data, enrichment data, and microbiology analysis data on post it notes, gloves, or other locations for later transfer into the microbiology spreadsheet, but does not retain these original documents in any format.

    Reference: 3 AAC 306.635 (a) (3), LCD pg. 8.

    Action: The laboratory must immediately start recording and retaining data as it is created. Submit a plan to ensure data is recorded at the time of prep or observation and the original documentation is retained. This plan is due to the LCP by 5pm Tuesday, June 1, 2021, along with documentation of original data (media prep, enrichment, time in enrichment incubator, time out of enrichment incubator, plating data, time in plate incubator, time out of plate incubator, observations of plates) of all microbiology samples run from May 18, 2021 through May 31, 2021. Additionally, submit documentation of original data (media prep, enrichment, time in enrichment incubator, time out of enrichment incubator, plating data, time in plate incubator, time out of plate incubator, observations of plates) of all microbiology data from June 1, 2021 through June 25, 2021.

24. *Finding:* The lab is not documenting media prep for in-house made media. The laboratory does have a worksheet for Dichloran Rose Bengal Chloramphenicol Agar (DRBC) media prep that contains all the required information except for a unique prep ID, but the laboratory is not using the sheet to document media prep. The laboratory does not have similar worksheets for the other two media made in-house, Sorbitol-MacConkey Agar (SMAC) and Tryptic Soy Broth (TSB).

    Reference: 3 AAC 306.640

    Action: Update and submit the DRBC media prep worksheet to include a unique media prep ID and create and submit media prep worksheets for SMAC and TSB. All in-house made media must be disposed and a new lots made with traceable prep documentation Submit prep documentation for new media. This documentation should also include a note regarding old media disposal along with disposal date. Additionally, submit a plan to ensure the worksheet is used with each batch of media. The laboratory may choose to update the current worksheet to apply to all in-house made media or may create separate forms for each media.

25. *Finding:* While the laboratory's procedure is to run a positive and blank control with every batch, documentation of performing these controls does not exist and therefore QC documentation for the media does not exist. All media must include a positive (target organism), negative (non-target organism), and sterility control on a per lot basis, prior to use. Per lot basis means the manufacturer's lot number for ready to use media purchased from the vendor (Compact Dry SL plates) or the unique media prep ID (see Finding #24) for media made in-house (TSB, DRBC, and SMAC).

    Reference: 3 AAC 306.635 (a) (3), LCD pg. 8, 14 -15.

    Action: Update and submit procedure to ensure media QC is run and documented. Submit QC documentation for new in-house made media and all current lots of the Compact Dry SL plates.

26. *Finding:* Not all prep and analysis information is present. The lab does keep a spreadsheet of microbiology set up and analysis; however, information including the ID of the controls, media lot number (unique prep ID for in-house made media), analysts initials, and written and photo observations are not captured.

    Reference: 3 AAC 306.635 (a) (3), LCD pg. 8, 14 - 15.

    Action: Update and submit plan and any new forms to ensure all required information is documented and retained. Additionally, submit all microbiology data records for the period of May 18, 2021 through June 25, 2021.

27. *Finding:* The laboratory has made changes to their procedures without updating the SOP. Specifically, the laboratory is making SMAC and TSB in-house but has no procedures for this in the SOP. Also, the SOP states to autoclave the media (DRBC) but the laboratory is using a pressure cooker.

    Reference: 3 AAC 306.340.

Action: Submit updated SOP that includes all procedures the laboratory is actually performing. See Finding #30 for further information on SOP updates.

28. *Finding:* The laboratory is using a pressure cooker to sterilize media. While this is highly discouraged, it is not forbidden provided the laboratory can document the conditions required by the media manufacturer for media sterilization are met. This can be accomplished by the use of a data logger device with each run and periodic spore checks. The same proof of conditions being met apply to autoclave use as well.

    Reference: 3 AAC 306.635 (a) (2)

    Action: Submit a plan to ensure manufacturer's sterilization conditions (temperature and sterilization) are met. Additionally, provide documentation of the conditions being met.

29. *Finding:* The laboratory is not following the Micro SOP SOP-FA-003. The SOP reflects the manufacturer's method except as noted in Finding #30; however, during the analyst interviews the following discrepancies between the laboratory's SOP and how the method is actually run were noted.

    - The SOP states the laboratory screens samples for STEC using the Compact Dry Plates. The laboratory has skipped the screening step and is platting all samples on SMAC. This is an acceptable procedure and one the lab has as part of the confirmation step, but the SOP requires update to reflect the actual procedure employed.
    - For SMAC plates and the DRBC plates, the SOP states the laboratory inoculates the plate with 0.1mL of sample and spreads the inoculum. This procedure reflects manufacturer and the Food and Drug Administration's Bacterial Analysis Manual procedures. During the observation, the analyst added an unmeasured amount of a dummy sample using an uncalibrated bulb pipette, topped with agar with a "small amount" of TSB and tilted the plate to coat.
    - For the Compact Dry SL Plates, the SOP states the laboratory inoculated the plate with 1mL of sample. The laboratory is adding 0.1mL of sample and 1mL of sterile water to the plate. The procedure the lab is using matches the manufacturer's instructions, but does not match the SOP.
    - The SOP states to autoclave the media and take the pH but the media is being sterilized using a pressure cooker and the pH is not being taken.
    - The SOP states that for any colony growth on the SMAC each colony will be individually tested with the latex assay. The analyst only transferred one colony during the demonstration. When asked if each colony is individually tested, he stated no. All presumptive colonies on the SMAC plate must be moved on to the latex agglutination verification. The lab may test each colony individually or swab the entire plate for a single test.

    Reference: 3 AAC 306.640.

    Action: Submit a plan to ensure the SOP is followed.

30. *Finding:* The SOP requires updating. Some procedures do not follow the manufacturer's method and other are missing from the SOP.

- The SOP contains portions of the validation study. This is not necessary for the SOP and may lead to confusion. The validation study must be separated into its own document. Additionally, everything past pg. 17 of the current SOP, requires internal evaluation to verify if it is the actual procedure the laboratory uses. Any part of the procedure not in use must be removed.
- The SOP requires LCS/LCMS for each batch, but instructions are not given on how to prepare the LCS/LCMS, nor what to do if it fails.
- The SOP does not provide prep instructions or QC requirements for TSB.
- The SOP does not list required controls for *Salmonella*, nor describe how to plate the controls.
- The instructions for Compact Dry SL plates for *Salmonella* in the SOP do not match the manufacturer's instructions.
- The Compact Dry EC instructions should be removed from the SOP if the method is not being used.
- The SOP does not provide prep instructions for SMAC.
- The SOP lists negative and sterility controls for SMAC but does not require a positive control, list the frequency of controls, nor describe how to set up the controls.
- The SOP lists a positive control for DRBC but does not require a negative control, list the frequency of controls, nor describe how to set up the controls.
- The SOP contains instructions for preparing DRBC and states the approximate shelf life of the poured plates is 1 week. The DRBC preparation worksheet lists the 2-4 weeks.
- Multiple instances of the *Aspergillus* characteristics section were observed where the text does not match up with the information presented in the table.
- The SOP does not clearly state how control organisms are made and maintained, nor how long they are kept.

Reference: 3 AAC 306.635 (a) (2), 3 AAC 306.640

Action: Submit updated SOP. The SOP requires revision to remove any extraneous information or procedures not used by the lab. The validation study information must be removed from the SOP and put into its own document. The laboratory may choose if they want a separate SOP for each method or a single document for all microbiology methods.

The microbiology SOP should have the following sections only:

- **Scope and Application** (1-2 paragraphs on what organisms the method is looking for and in what type of matrices)
- **Equipment/Supplies** (what equipment (incubator) and supplies (loops/pipette) are needed for this analysis)
- **Reagents and Standards** (what reagents and standards (media/sterile water/control organisms) are needed for analysis)
- **Procedure** (what are the steps, subsampling, enrichment, plating, incubation, what you're looking for, verification steps)
- **Quality Control** (explain the QC (what QC is run, how often, how is it made, how are control organism made a stored, what control organism are used, what are the expected results and what to do if it fails)

- **Health and Safety** (what are health and safety concerns/precautions for running the method)
- **Interferences** (what are known interferences, what are steps to decrease or eliminate them)
- **Qualifications** (what education or training must analyst perform in order to independently perform this analysis) – this may actually go in a separate document on analyst training and that's fine.
- **Examples of the forms used for this method.**
- **Associated Documents and References.**

Conclusion

Submit the corrective actions and other documents described above to the EHL and AMCO by **5 p.m. June 25, 2021, except where earlier due dates are specified in a finding (e.g. finding 23)**. If you have any questions or require additional information regarding the contents of this report, you can email declabcert@alaska.gov with a cc: to the appropriate AMCO contacts, or call Shera Hickman or Kelly Snyder at 907-375-8210 or 907-375-8209, respectively.

Thank you for your cooperation during the audit!

Shera Hickman
Chemist IV
State of Alaska
Department of Environmental Conservation
Environmental Health Laboratory

Department of Commerce, Community, and Economic Development

DIVISION OF CORPORATIONS, BUSINESS & PROFESSIONAL LICENSING

LICENSE DETAILS

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Status: Expired

Issue Date: 10/01/2017

Expiration Date: 12/31/2020

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FAIRBANKS, AK 99701

Physical Address: 1521 stacia st, A
9076876745
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Owners

FAIRBANKS ANALYTICAL TESTING LLC

Activities

Line of Business	NAICS	Professional License #
54 - Professional, Scientific and Technical Services	541711 - RESEARCH AND DEVELOPMENT IN BIOTECHNOLOGY	

Endorsements

No Endorsements Found

License Lapse(s)

If this business license lapsed within the last four years the lapsed periods will appear below. Lapsed periods are the unlicensed period between an expiration date and renewal date.

Start Date	End Date
1/1/2020	1/1/2020