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

MEMORANDUM

TO: Marijuana Control Board

DATE: September 20, 2021

FROM: Glen Klinkhart, Director

RE: Notice of Probation Provision and further suspension of license

BACKGROUND:
As you may be aware, Fairbanks Analytical Testing ("FAT") was audited on May 18-19, 2021 by the Alaska Department of Environmental Conservation (DEC) 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. The audit revealed substantial violations of quality control, quality assurance, and testing protocols.

Prior to the May 18-19, 2021 audit, FAT as the Respondent, agreed as part of a Mediated Settlement Agreement 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.

At the August 18th, 2021 Marijuana Control Board meeting in Nome, the board voted to uphold the suspension, and made the suspending for 30 days which began immediately. During the meeting the board asked FAT the following and took the following actions:

Chairmen Miller asks FAT's Dylanne R. Macomber, "If the Board were to adopt a 30-day suspension is that sufficient time for you to correct all of these deficiencies respond properly to DEC?" Dylanne R. Macomber responded, "I don't foresee that being an issue."

Board Member Eliza Muse seconds. None opposed, motion carries. Board Member Christopher Jaime amends to include tab 10 documents in support of the decision. Eliza seconds. None opposed, motion carries.

On August 18th, 2021 when the board upheld probation suspension the FAT audit had 18 finding still open. As of the writing of this memorandum, September 20, 2021 FAT has 15 findings still open.

According to the ongoing audit findings by the audits for DEC, during this ongoing audit and in conjunction with the past 30 days of license suspension, FAT has not properly responded to audit requests. Additionally, it appears FAT has continued in not correcting errors detailed in the audit report, at least three of which DEC has deemed to be ongoing "critical findings".

FAT's failure to timely respond to audit information requests, report findings, and FAT's failure to correct errors/violations detailed in the audit report within thirty calendar days constitute violations of FAT's probation. Accordingly, as a result of these probation violations, Fairbanks Analytical Testing, LLC - License 15124 suspension of an additional 30-day license suspension is hereby revoked, and 30-day suspended time is imposed pursuant to the Mediated Settlement Decision and Order.

REQUESTS OF THE BOARD:

The AMCO Director is requesting that the MCB review the information provided, the witnesses available to speak and to answer questions, and to uphold the decision to have Fairbanks Analytical Testing's license to operate suspended as of midnight onTuesday, September 21, 2021, for a period of 30 additional days; until Noon, Thursday, October 21, 2021.

Glen Klinkhart
Director
Alcohol & Marijuana Control Board
550 W 7th Ave #1600, Anchorage, AK 99501
Office (907) 269-0350

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

September 17, 2021

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

Lance Christine Wells
Law Offices of Lance Christian Wells, LLC
733 W. 4th, Suite 308
Anchorage, Alaska 99501

Delivered via email and hand delivered

Re: End of 30-day license suspension and additional suspension consideration by the Marijuana Control Board.

Dear Dylanne Macomber & Ronald Eads:

The following notice is provided to inform you your Testing Facility License (#15124) for Fairbanks Analytical Testing (F.A.T.) is being returned to you. On August 18, 2021 the Marijuana Control Board (MCB) held discussions regarding the possible suspension of you license under the accepted probation agreement between F.A.T. and the Marijuana Control Board (OAH No. 20-0972-MCB/MACO AM20-720). At that time the board upheld a 30-day suspending of your license (#15124) which will end on September 18, 2021.

At the time of the board's decision it was the expressed hope of the Marijuana Board that F.A.T. would be able to meet the remaining required portions of the ongoing audit which would then close out the audit. As of the writing of this communication it appears audit requests & requirements have not yet been completed by your organization, that

possible violations of your probation agreement continue, and that the audit itself still remains open.

The circumstances of the situation dictate this be brought before the board where they will consider the probation situation and they will be asked to consider extending the suspension of your license (#15124).

This letter is a director's decision to impose the remaining period of your license suspension and should be considered as such; it is set to take effect at 5 PM on September 21, 2021. Your attendance at the zoom hearing will be considered an appeal to the Marijuana Control Board under 3 AAC 306.095. Your failure to appear may be considered a waiver of your right to appeal under 3 AAC 306.095. Should you not appear, you are ordered to cease operations for a period of thirty (30) days beginning 5 PM on September 21, 2021.

September 21, 2021 at 3:00 pm

Zoom Meeting
https://amco-alaska-gov.zoom.us/j/82479403697?pwd=TC9iVm1YaGs2MnYwVm1DVGNEYTgwZz09

Meeting ID: 824 7940 3697
Passcode: 340949

Dial by your location
+1 346 248 7799 US
+1 669 900 6833 US

Regards,

ALCOHOL & MARIJUANA CONTROL OFFICE

By: Glen Klinkhart
Executive Director, AMCO

Fairbanks Analytical Testing

Date of Audit	5/18-19/21	
Report Date	5/25/21	30 findings open
30-day Due Date	6/25/21	30 findings open
Last Test Date (est.)	8/13/21	18 findings open
Suspension Start Date	8/18/21	18 findings open
Suspension End Date	9/17/21	15 findings open

Critical Findings

1. Microbiology SOP (STEC, *Salmonella, Aspergillus*)
2. Potency Data Defensibility/Traceability
3. Proficiency Testing Scored Results

Unknown Quantity

1. 12/3/18 – 10/2/20
   All calculations for potency testing of plants, concentrates, and edibles are incorrectly calculated. These data are in METRC. (5/18/21 audit uncovered plant calculation error.)

2. 12/3/18 - Present
   - Microbiology SOP and documentation are not defensible or traceable. These data are in METRC.
   - Potency data are not defensible or traceable. These data are in METRC. Approximately 3 months lapsed before data were received.

Marijuana Control Board Meeting
September 21, 2021
Steve Crupi, DEC EHL Quality Manager

Public Health Concern

> Data in METRC and on client reports that are inaccurate and/or indefensible.
> Data are not quickly or easily retrievable, if even retrievable.

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

EHL Response Date July 9, 2021
(Based on June 1 -2, June 28, and July 2, 2021 Fairbanks Analytical Testing submittals)

EHL Response Date July 29, 2021
(Based on July 23, 2021 Fairbanks Analytical Testing submittals)

EHL Response Date August 26, 2021
(Based on August 13 and 17, 2021 Fairbanks Analytical Testing submittals)

EHL Response Date September 15, 2021
(Based on August 18 and 27, 2021; September 9 and 14, 2021 Fairbanks Analytical Testing submittals)

EHL Response Date September 20, 2021
(Based on September 15, 16 and 17, 2021 Fairbanks Analytical Testing submittal)

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 Angelonis – Office Manager

Quality Control and Quality Assurance:

EHL Response to 7/23 Submission: The laboratory submitted a memo titled "Response to the first entry by Mr. Crupi regarding finding 23". The memo doesn't appear to apply to Finding #23, which has to do with documentation of microbiology data and use of the microbiology spreadsheet. Please clarify to which finding this applies.

EHL Response to 8/13 and 8/17 Submissions: No response was submitted so this memo hasn't been reviewed as a response to any of the open audit findings.

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.

EHL Response to 6/28/2021 Submission: A CAR was received describing what happened to the data, for which recovery of originally integrated data was not possible, and measures planned for the future to mitigate recurrence. A local computer services firm (Computer Works) was used for the attempted recovery. Was Agilent, the vendor for the instrument data system, also consulted? The CAR does not provide a timeline for the data loss. During the audit, it was stated the loss occurred a day or two before the audit (May 14?).

Data files were submitted for the sample (0951) and the PT test. The sample (0951) data file indicates the data was integrated/processed on 6/23/21. The PT test data file indicates a processed date of 5/18/21.

Calculation worksheets were submitted for the sample (0951), the PT test, and the associated ICV. The revision date for the sample (0951) tab is 6/25/21, but there is no revision date for the ICV and PT test because those fields contain a formula that defaults the date to the current date. The Date of Analysis for the ICV and PT test also default to the current date. The Date of Analysis for the sample is 6/25/21; it should be 3/25/21.

The area counts compared between the sample (0951) and PT test data files and the calculation worksheet tabs do not compare. For example, for the PT test, the CBDA area in the data is 5056.8613 and the calculation worksheet area is 4974.9. For the sample (0951), the CBDA area in the data is 107.3485 and the calculation worksheet area is 80.

Action: Update the CAR to indicate a timeline/date for the data loss. Provide an updated spreadsheet that reflects the correct dates of analysis and the correct revision date(s) vs. the current date. Explain the difference in area counts between the data files submitted and the calculation worksheet tabs. Once these items are addressed, the 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 corresponding final reports.

EHL Response to 7/23/2021 Submission: The CAR was handwritten instead of revising the digital CA generated in the 6/28/2021 response. This document is not fully readable. The written response to the audit report states the "spreadsheet seems very monotonous, overreaching and is not necessary. Automatic dates have been removed from the spreadsheet and new template. All spreadsheets are saved with the respective dates the samples were analyzed." The submission of the corrected spreadsheets is necessary because the spreadsheets are part of the traceable record and are still under audit evaluation.

An explanation for the difference in area counts between the data files submitted (6/28/21 submission) and the calculation worksheet tabs was not provided in this response. The EHL request for data for other matrices is pending this explanation.

Action: Explain the difference in area counts between the submitted instrument injection summaries and the calculation worksheet tabs for the PT and sample 0951. Please submit the explanations in typewritten form vs. handwritten.

EHL Response to 8/13/2021 Submission: There was no direct response by the laboratory for this Finding between 7/29/2021 and 8/13/2021. On 8/17/21, the procedure for backing up and preserving the chromatography analysis data was submitted, but that procedure was actually requested with Finding 2, and already reviewed. A report was described in the front matter of the 8/17/21 submission, but that report was not found in the accompanying files. The Action above is still required; the explanation can be in a memo format.

9/15/21 – Response from FAT is pending.

EHL Response to 9/17/2021 Submission: See Finding #2 below. Closure of this finding is dependent on closing finding #2.

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.

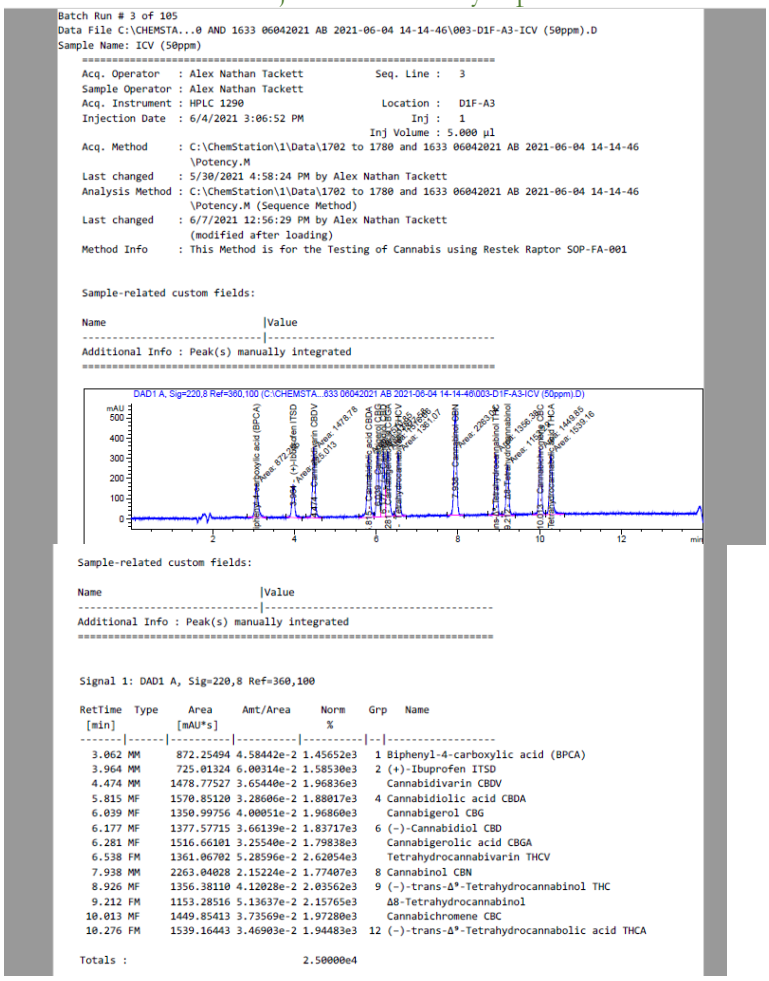
   EHL Response to 6/28/2021 Submission: The laboratory submitted the requested SOP update and data for two injections, an ICV and a CCV. However, two runs were requested in the original Action request vs. two injections.

   Action: Submit two complete analytical runs post-5/24/2001 of data in the injection summary report format discussed during the audit, with a run log (list of injections in order).

   EHL Response to 7/23/2021 Submission: The run logs were submitted, but not the injection summaries containing the actual data, as requested.

   Action: For each injection in the two logs (53 injections on 6/21/2021 and 31 injections on 6/26/2021), submit an injection summary report containing the data represented below, which

is an excerpt of a summary submitted on 6/28/2021. Two of the injection summary reports for QC samples were submitted, but the request was to supply all 84 injection summary reports. Please submit all 84 injection summary reports.



```
Batch Run # 3 of 105
Data File C:\CHEMSTA...0 AND 1633 06042021 AB 2021-06-04 14-14-46\003-D1F-A3-ICV (50ppm).D
Sample Name: ICV (50ppm)
    ======================================================================
    Acq. Operator   : Alex Nathan Tackett           Seq. Line :   3
    Sample Operator : Alex Nathan Tackett
    Acq. Instrument : HPLC 1290                     Location :   D1F-A3
    Injection Date  : 6/4/2021 3:06:52 PM               Inj :   1
                                                  Inj Volume : 5.000 µl
    Acq. Method     : C:\ChemStation\1\Data\1702 to 1780 and 1633 06042021 AB 2021-06-04 14-14-46
                      \Potency.M
    Last changed    : 5/30/2021 4:58:24 PM by Alex Nathan Tackett
    Analysis Method : C:\ChemStation\1\Data\1702 to 1780 and 1633 06042021 AB 2021-06-04 14-14-46
                      \Potency.M (Sequence Method)
    Last changed    : 6/7/2021 12:56:29 PM by Alex Nathan Tackett
                      (modified after loading)
    Method Info     : This Method is for the Testing of Cannabis using Restek Raptor SOP-FA-001


    Sample-related custom fields:

    Name                          |Value
    ------------------------------|---------------------------------------
    Additional Info : Peak(s) manually integrated
    ======================================================================
```



```
    Sample-related custom fields:

    Name                          |Value
    ------------------------------|---------------------------------------
    Additional Info : Peak(s) manually integrated
    ======================================================================


    Signal 1: DAD1 A, Sig=220,8 Ref=360,100

    RetTime  Type     Area      Amt/Area     Norm    Grp   Name
     [min]          [mAU*s]                   %
    -------|------|----------|----------|----------|--|------------------
      3.062 MM      872.25494 4.58442e-2 1.45652e3   1 Biphenyl-4-carboxylic acid (BPCA)
      3.964 MM      725.01324 6.00314e-2 1.58530e3   2 (+)-Ibuprofen ITSD
      4.474 MM     1478.77527 3.65440e-2 1.96836e3     Cannabidivarin CBDV
      5.815 MF     1570.85120 3.28606e-2 1.88017e3   4 Cannabidiolic acid CBDA
      6.039 MF     1350.99756 4.00051e-2 1.96860e3     Cannabigerol CBG
      6.177 MF     1377.57715 3.66139e-2 1.83717e3   6 (-)-Cannabidiol CBD
      6.281 MF     1516.66101 3.25540e-2 1.79838e3     Cannabigerolic acid CBGA
      6.538 FM     1361.06702 5.28596e-2 2.62054e3     Tetrahydrocannabivarin THCV
      7.938 MM     2263.04028 2.15224e-2 1.77407e3   8 Cannabinol CBN
      8.926 MF     1356.38110 4.12028e-2 2.03562e3   9 (-)-trans-Δ⁹-Tetrahydrocannabinol THC
      9.212 FM     1153.28516 5.13637e-2 2.15765e3     Δ8-Tetrahydrocannabinol
     10.013 MF     1449.85413 3.73569e-2 1.97280e3     Cannabichromene CBC
     10.276 FM     1539.16443 3.46903e-2 1.94483e3  12 (-)-trans-Δ⁹-Tetrahydrocannabolic acid THCA

    Totals :                  2.50000e4
```

EHL Response to 8/13/2021 Submission: There was no response by the laboratory for this Finding between 7/29/2021 and 8/13/2021. There was an attempt to submit data from 7/29/21 on 7/30/21, but the EHL could not open the pdfs of the chromatograms because of the size and the propriety format of adjoining files. The EHL replied with a request for the laboratory to remove the files in the proprietary format and resend only the pdf files, and to submit the data from 6/21/21 and 6/26/21. On 8/18/21, EHL re-sent the request to Ms. Macomber, who it was discovered was not included in the 7/30/21 email. Later that day, the chromatograms were received by EHL for the 31 injections on 6/26/21. Also received were 53 links to Google Docs files stated to be from analyses on 6/21/21. Review of the 31 emailed files will be complete once the calculation spreadsheet associated with the data is received with the calibration and calculations from the 6/26/21 data (23-47-42). This spreadsheet was requested via email on 8/18/2021. The 6/26/21 data along with the spreadsheet is anticipated to be sufficient to review data traceability capability for the laboratory. Resubmission of the 6/21/21 data is not necessary at this time.

Action: Submit the spreadsheet file containing all tabs for the 23-47-42 analyses, analyzed on 6/26-27/2021. (The injections in an analytical run are in a single file with a separate tab for each injection.)

EHL Response to 8/18/21 and 8/27/2021 submissions: The integrated peak areas for the 23-47-42 (6/26/2021) run on the spreadsheets submitted 8/27/21 do not match those on the chromatograms submitted 8/18/2021. The injection report shows results from the data acquisition method from the 8/9/2021 run, not the 6/26-27/21 run. By using an inappropriate acquisition method version, the laboratory is not demonstrating that the reported result can be traced back to its integration, or the calibration integrations. This information, including the below Action, was shared in a phone call with Dylanne Macomber on 9/2/2021.

Action: Generate the same chromatograms on the 23-47-42 (6/26/2021) run using the acquisition method version which originally integrated the data. The data traces are: peak areas from the chromatogram must match the peak areas in the spreadsheet, and the spreadsheet results must match the results reported to the client. If all the data traces match, resubmit the spreadsheets, and submit the reprocessed chromatograms and client reports for the 23-47-42 (6/26/2021) run. If the 23-47-42 data traces do not match, find a potency run from another day which includes client samples and has matching data traces, and submit chromatograms, spreadsheets and client reports for it. If no analytical run has matching data traces, complete a corrective action describing how traceable sample and calibration integrations will be preserved using the chromatogram report like those submitted on 8/18/2021.

EHL Response to 9/17/21 Submission: The corrective action report contains two options for documenting a change to the auto-generated pdf file. EHL clarifies that in the case of integration changes, the second option must be performed. Both the original and manual integrations must be retained and annotated. Peak area changes must not be handwritten, but generated through a report. To ascertain that full traceability is achieved by this new process, an example is needed to be evaluated by EHL.

Action: Provide an example of the current integration data preservation procedure for potency analysis. Further details of the example will be communicated in a separate email to the laboratory.

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.

EHL Response to 6/28/2021 Submission: The laboratory submitted reports for samples 2008FBA0228.0803, 2011FBA0433.1631, and 2101FBA0049.0189. The microbials section of the first two reports addresses the STEC requirement by reporting "E. Coli", which is incorrect. The report should express the result as "E. Coli O157". The first report (2008FBA0228.0803) indicates the sample was received 8/31/20 and the report created on 9/3/20. For *Aspergillus*, per the lab SOP, a sample in enrichment broth is incubated for 24 hours. It is then plated on DRBC and incubated for minimally 72 hours. (See step 4 in the DRBC procedure section of the Micro SOP that states, "Examine for growth after 3-, 4- and 5-days incubation.") Given those parameters, the earliest the report could be created for *Aspergillus* is 9/4/20, one day after the actual Report Created date on the report.

Action: Submit the raw data for each of the three samples to include the associated sample preparation and instrument quality control samples and the instrument calibration. Provide two corrective action reports, one for correcting the result expression on the report for the STEC requirement to include a copy of an updated report format and one for addressing the DRBC incubation period being shorter than the period stipulated in the SOP for sample 2008FBA0228.0803.

EHL Response to 7/23/2021 Submission: The corrective action addressing the DRBC incubation period explains that report creation happens before the result is known. The report date is intended to be the date that the result is sent to the client. Regardless of report date semantics, per the microbiology log submitted on 6/28/2021, sample 0803 was placed into enrichment 8/31/2020 at 15:05. Sample 0803 was subsequently plated onto DRBC and placed into the incubator for a 3-5 day incubation on 9/1/2020 at 14:34. The DRBC plate was removed on 9/2/2020 at 13:26 after less than one day, which is only allowed if the sample itself is positive. The sample result was negative, which means it must minimally stay in the incubator until 9/4/2020, the day after the actual report date.

The corrective action addressing the report format must have supporting documentation. The corrective action report states an email was sent to Confident Cannabis to correct the results label on the report. The corrected report must be submitted before the corrective action is resolved. Once this action is acceptable, the raw data submission from 2011FBA0433.1631 and 2101FBA0049.0189 will be requested.

Action: Edit the DRBC corrective action report to address that the sample was removed from the incubator before the time stipulated in the SOP. Create a new corrective action report to correct the report date to be the date that the report is sent to the client. Submit the two corrective action reports along with supporting data.

EHL Response to 8/13/2021 Submission: There was no response by the laboratory for this Finding between 7/29/2021 and 8/13/2021. The Action above is still required.

EHL Response to 8/17/2021 Submission: FAT stated in the 9/15/21 phone call that the date on the report is the date the report was sent to the client. The corrective actions for the microbial have been resolved. Since it has already been established in Finding #2 that the data

from all past analyzed potency samples is not traceable to their integrated peak areas, the raw data from 2011FBA0433.1631 is not requested, instead this Finding will stay open until Finding #2 is closed. The raw data from the residual solvent analysis sample in report 2101FBA0049.0189 is being requested as mentioned above (underlined).

Action: Submit the integrated chromatograms, peak areas, and the spreadsheet of calculations for the residual solvent analysis sample in report 2101FBA0049.0189 and associated QC.

EHL Response to 9/17 Submission: Two chromatograms were submitted, one for the sample and one for the CCV at 50 ppm. The sample was nondetect for all analytes; the CCV is being used to evaluate integration traceability. A spreadsheet was not submitted for the analytical run, so EHL compared it to the spreadsheet tab submitted 7/26/21. The tab submitted was labeled ICV, not CCV. The integrated areas do not match the data in the spreadsheet tab, but it is not known whether the traceability gap is due to not having the CCV spreadsheet vs the ICV, or integration changes. Regardless of the source, there is a traceability gap in the residual solvent data similar to that of the Potency data.

Action: Provide an example of the current integration data preservation procedure for residual solvent analysis. Further details of the example will be communicated in a separate email to the laboratory.

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.

   EHL Response to 6/28 Submission: The Quality Manual and SOPs were submitted to the EHL for review. However, the fact remains the documents were put into service prior to the audit without the approval by the board or the EHL, as required by regulation.

   EHL Response to 7/23/2021 Submission: The laboratory states, "A2LA the same accrediting body that approved the EHL testing scope approved our procedures. From here on out we will ensure to send the Sop to EHL as well for review." Any approval A2LA may have lent to procedures are based on document versions generated before those documented in this finding. Approval of prior document versions does not extend to updates. No further action required, at this time.

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.

EHL Response to 6/28 Submission: The laboratory sent an updated Quality Manual with a plan to calibrate all thermometers annually against a NIST traceable thermometer, and also stated the NIST thermometers are sent to the manufacturers annually for recalibration. Since the lab did not own NIST reference thermometers at the time of the audit, it is unclear if in-use thermometers will be sent out for calibration or reference thermometers purchased to perform calibrations in-house. The CAR submitted by the laboratory states data loggers have been purchased but makes no mention of purchasing NIST thermometers to perform in-house calibrations. A plan of use will need to be submitted for the data loggers (e.g. location(s), data storage, calibration).

Action: Submit an updated detailed procedure explaining how the lab will ensure temperature monitoring devices (thermometers and data loggers) are calibrated annually. Additionally, please submit a plan of use for the data loggers, data storage/management, and calibration protocols for the new data loggers.

EHL Response to 7/23 Submission: The updated calibration plan meets the necessary requirements, however, the plan for the data logger use still needs to addressed. The laboratory still needs to describe how they will store and manage the data from the data loggers (i.e. Is there an automatic download from the loggers to a database or spreadsheet that will be maintained? Does the data have to be downloaded manually, if so how and where is that done and how often will the data be downloaded.?

Action: Submit an updated plan of use for the data loggers, to include data storage/ management and calibration protocols for the new data loggers.

EHL Response to 8/13 Submission: The lab has submitted an updated data logger plan that addresses how often reports are sent to the laboratory director's email. The laboratory still needs to address storage of the temperature logs. (e.g. Are the reports saved from email? Where are they stored and for how long? Is this plan in an SOP?)

Action: Submit an updated plan describing storage of temperature records. Once the plan is complete, this plan needs to be put into an SOP or the Quality Manual to ensure it is followed consistently. **Submit updated SOP or Quality Manual with the data logger plan.**

EHL Response to 9/9 Submission: The updated plan and Quality Manual have added data storage and are acceptable. No further action is required.

Expired thermometers in use: The COAs, Thermometer Tracking Sheet and the thermometer photos submitted indicate that thermometer 9980, which was due for calibration 2/28/21, was

moved to the standards freezer in response to the audit finding. The lab's audit response states this action was taken since no samples have required freezing. Frozen standards have required temperatures and as such require a calibrated thermometer. Another expired thermometer was moved to a drying oven in response to an audit finding, since it has a digital readout. Digital readouts on units are not acceptable for use unless they can be calibrated. Expired thermometers in these locations must be calibrated or replaced.

Action: Submit documentation showing that all temperature measuring devices in use have current calibrations.

EHL Response to 7/23 Submission: The response to this second part of the finding is acceptable. The laboratory should note though that the Manufacture's calibration date on the spreadsheet is in the future. The spreadsheet should be updated, but since the manufacturer's calibration documentation has been reviewed and is acceptable, the spreadsheet does not need to be resubmitted.

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.

   EHL Response to 6/28 Submission: The laboratory submitted photo documentation of the marked thermometers, however it was noted in review of the photos that the Correction Factor (CF) noted on the thermometers in the pictures was not correctly expressed. All thermometers were marked with ± .5°C for the correction factor. The correction factor is the difference between the True Temperature (the value of the NIST Reference Thermometer) and the Observed Temperature (the value of the in-use thermometer). For example, when calibrating a thermometer, if the NIST reads 37.6°C and the in-use thermometer reads 37.4°C, the correction factor is 37.6°C – 37.4°C = +0.2°C. Likewise, if the NIST reads 37.6°C and the in-use reads 38.0°C, the correction factor is 37.6°C – 38.0°C = -0.4°C. This correction factor is then applied to the temperature reading when recording unit temperatures. For example, if the in-use thermometer in the unit reads 37.2°C and the correction factor is +0.2°C, the temperature reading is recorded on the temperature log as 37.4°C.

   Action: Please update CF on all temperature measuring devices and submit photos of the updates.

   EHL Response to 7/23 Submission: 21 CFR 58.63 (a) states "…Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated and/or standardized." Applying the CF to a thermometer meets that requirement. The procedure to calculate the CR is described above in the EHL response to 6/28 submission.

Action: Please update CF on all temperature measuring devices and submit photos of the updates.

EHL Response to 8/13 Submission: Photos of the thermometers were submitted, however it is unclear how the laboratory determined the CF. The CF values do not match the manufacturer's COA submitted earlier, but the expiration dates do match the COAs. The thermometers also have a date of 8/11/21, but the calibrations listed on the COA took place in 2020. Is 8/11/21 the date they were labeled, or were new calibration checks completed on the thermometers? No documentation of data loggers marked with CF was submitted.

Action: Please submit documentation showing how and when the laboratory determined the CFs listed on the thermometers. Additionally, submit documentation of data loggers marked with the correction factor. If the laboratory plans to add correction factors to the data logger, such as through the data logger software, that needs to be added to the data logger plan and submitted with the data logger plan as part of finding #5.

EHL Response to 9/9 Submission: Multiple documents were submitted, however there are still some questions about the procedure. For easier readability, only the last four digits of the thermometer serial numbers are used below.

- Manufacturer's calibration documents and photos were submitted for thermometers 7092, 7097, 7100 and 7101. For 7100 and 7101, the thermometers used in the dryers used the CF at 40°C. 7092 and 7097 are on the refrigerator. 7097 used the CF at 0°C, but 7092 used the CF at 40°C. If multiple CFs exist at different points, there needs to be consistency of which CF is used. The most reasonable and suggested method is to use the CF at or closest to the temperature of use; 40°C for the dryers and 0°C for the refrigerators.
- For the in-house calibrations, the lab provided a log of the calibrations, however there are questions and missing documentation.
    - Thermometers 4210, 9980 and 9982 have calibration data, but no photos showing the CF.
    - The Calibration Date column lists future dates. Is this the Calibration Due Date? Assuming this column is the calibration due date, it is unclear why the dates are different if all thermometers were calibrated on the same day (8/11/21).
    - Was the 0C CF for the reference thermometer accounted for in the reference temperature?
    - The CF calculation is the difference between the reference reading (true value) and the working thermometer reading. The correction factors listed on the log do not follow this equation.
    - It is also unclear if the Reference temperature is rounded. If that is the case, what are the lab's rounding rules and where are they documented?

Action: Correct above discrepancies, and resubmit the calibration documentation/photo documentation. It is recommended EHL and the lab discuss these discrepancies and the CF process either at the 9/15/21 meeting or at another, agreed upon time.

EHL Response to 9/15 Submission: The choice of calibration factor was discussed 9/15/21 and is no longer a finding. Thermometer 7092 is used for the freezer and not the refrigerator. The applied CF comes from the -20°C calibration. This is acceptable and no action is required. The remaining action items above have not been addressed.

Action: Correct the remaining above discrepancies, and resubmit the calibration documentation/photo documentation.

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.

   EHL Response to 6/28 Submission: The laboratory updated the QAM to include applying correction factor to all temperature recordings, however, this finding cannot be closed until the laboratory can demonstrate proper documentation and application of correction factors. See finding 6 for additional information on determining the correction factor.

   EHL Response to 7/23 Submission: Closure of this finding is dependent on closing finding #6.

   EHL Response to 8/13 Submission: Closure of this finding is dependent on closing finding #6.

   EHL Response to 9/9 Submission: Closure of this finding is dependent on closing finding #6.

   EHL Response to 9/17 Submission: Closure of this finding is dependent on closing finding #6.

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.

   EHL Response to 6/28 Submission: Temperature records for the Plate Fridge/Freezer requested for May 2021 were not received with the submission. The laboratory provided an updated QAM that states to "document the outlier appropriately on the bench sheet and adjust the temperature accordingly…" The instructions do not define what is appropriate. The laboratory also provided a CAR for the missing documentation. The CAR found the root cause to be insubordination/not listening to management and stated the action as employment for those employees has ended. The CAR did not address how the laboratory plans to prevent this in the future, nor does review of the temperature logs submitted with the CAR support this as the root cause.

Review of the temperature logs submitted showed that in addition to the many outliers without comment for refrigerators, freezers and incubators 5/18/21 through 6/24/21 (date of last initials/signature for the two analysts no longer employed), on 6/25/21 the Standards Freezer was out of range without comment with management initials. On 6/25/21, the Aspergillus and STEC (O157) incubators were out of range, high, without comment and with management initials. It was also noted that while the logs for the standards and sample refrigerators/freezers have a line for review, none of the submitted documents indicated review had been completed.

Action: Submit an updated QAM that defines appropriate documentation of temperature outliers, and how the laboratory will ensure this documentation is being completed.

EHL Response to 7/23 Submission: The updated QAM is sufficiently defines appropriate documentation, but the laboratory hasn't addressed how they will ensure documentation is being completed as required. The original CAR stated the root cause as insubordination and related employees no longer employed at the lab, but never addressed how management will ensure future employees follow the procedure.

Action: Please submit an updated QAM or CAR to ensure the procedure for documenting temperature outliers is followed.

EHL Response to 8/17 Submission: The updated QAM adds training of employees and the performance of periodic records review to ensure temperature outliers are properly documented. Response is acceptable. No further action required.

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.**

   EHL Response to 6/28 Submission: The laboratory updated the procedure and submitted documented training forms from 6/24/21 for Alex Boyle (last day employed), Alex Tackett, Alicia Lenze (last day employed) and Jessica Angelonis. Training documentation was not provided for Dylanne Macomber, but she did sign the updated policy. While the policy is appropriate, based on review of records submitted for other findings, the submittal indicates the plan is not effective. Overwrites and obliterations by all staff were noted on temperature logs, media prep logs and autoclave run log prior to the 6/24/21 training. Additionally, overwrites and obliterations were noted on the temperature logs for 6/24/21 and 6/25/21. Documentation errors will occur in laboratory operations. Subsequent corrections must preserve original recordings in the interests of data traceability and defensibility.

   Action: Submit a plan or policy to ensure changes to documentation are properly made.

   EHL Response to 7/23 Submission: Response is acceptable. No further action is required.

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.

    EHL Response to 6/28 Submission: Response is acceptable. No further action required.

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.

    EHL Response to 6/28 Submission: The submittal included documented policy training, three pages of sample weight documentation, and a pipette calibration, all with dates and initials. However, the policy is limited to notebook documentation, when the original finding included the spreadsheet for pipette calibration.

    Action: Update and re-submit the corrective action report to include the activities which will be dated and initialed. The update can simply state that, for the following activities that may not be an all-inclusive list, initials and dates will be recorded: whenever observations or data are recorded, for any type of sample processing, reagent preparation, calibration work, and analytical activities performed, whether in a notebook, hardcopy benchsheet or electronically in any form, whether spreadsheet, database, or instrument data system.

    EHL Response to 7/23 Submission: Response is acceptable. No further action is required.

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.

EHL Response to 6/28/2021 Submission: The laboratory did not provide a root cause for the PT failure. The investigative notes on the CAR are vague and appear cursory (e.g. no comments about chromatography, performance of associated prep and instrument quality control, possibility of interference from prior analyses). The corrective action stated a secondary PT was ordered as part of the investigation, but evidence of the order was not supplied.

Action: Supply evidence that a secondary PT was ordered. Update the CAR to include additional investigative observations and a root cause for the outlier.

EHL Response to 7/23/2021 Submission: Acknowledged that a repeat Potency in Hemp Bud PT was ordered on 6/25/2021. The laboratory reports that the PT results have been submitted, and scored results are expected soon. A passing PT result is not enough to resolve a PT failure; the corrective actions taken to address the root cause of the failure must be submitted.

Action: 1) Update the CAR to include a root cause for the outlier and submit corrective actions taken. 2) Submit the PT result scoring.

EHL Response to 8/13/2021 Submission: There was no response by the laboratory for this Finding between 7/29/2021 and 8/13/2021. The 8/17/21 response was a "fish bones" table which is a useful tool to investigate the causes of a corrective action, but does not communicate a root cause conclusion, nor does it describe the corrective actions taken to address the root cause. The Action above is still required.

9/15/21 – Response from FAT is pending.

EHL Response to 9/17 Submission: The 9/17 response described unsuccessful efforts to obtain a repeat PT result scoring, but a revised corrective action containing a root cause and corrective actions taken was not submitted.

Action: 1) Update the CAR to include a root cause for the outlier and submit corrective actions taken. 2) Submit the PT result scoring.

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.

EHL Response to 6/28/2021 Submission: The laboratory submitted internal audits that do include findings, but no corrective actions or corrective action plans were submitted.

Action: Submit corrective actions or corrective action plans for the internal audit checklists submitted for this finding.

EHL Response to 7/23/2021 Submission: A document was submitted which addressed each action item identified. The laboratory notes that Internal Audit corrections are still underway, some of which are financially pending due to a 2 month shut down. Note that a shutdown does not remove the need for corrective action. The internal audit noted items are almost identical to those included in this external report, and they will be tracked separately instead of attached to this finding. During the next onsite audit, additional internal audit reports generated by the laboratory's internal audit process will be reviewed.

Action: Submit pending completed corrective actions related to the internal audit.

EHL Response to 8/13/2021 Submission: There was no response by the laboratory for this Finding between 7/29/2021 and 8/13/2021. The Action above is still required.

EHL Response to 9/14/21 Submission: Generally the corrective actions are listed in the same document as the internally reported deficiencies. The submitted plan is a list of the deficiencies without reference to the original report or the date at which the deficiencies were found. The first item contains enough detail, but it is preferable that dates of the activities be included. The rest of the items (excluding the two items deemed to be deficient in error) need to be written in complete sentences with dates, document references, equipment IDs, etc. included. The external audit report can be referenced, but the reference should not comprise the entire response because the report is only a summary and will not describe the activities that took place prior to submission.

Action: Revise the Internal Audit Plan to include more detail, specific references, and complete sentences.

EHL Response to 9/16 Submission: For select findings, the internal audit relies on efforts of another audit (i.e. May 2021 DEC EHL audit) when it must stand on its own. This boundary does mean efforts completed for another audit require repeating in the audit report; however, this requirement is for implementation of future internal audits vs. requiring an update to the submitted corrective action report.

Microbiology internal audit findings 1, 3, and 4 require additional work.

Actions:

Finding 1: **Data loggers are available for insertion into an autoclave to monitor the temperature. The temperature measurements taken by the data logger are later downloaded to a computer through a docking station. There are no leads extending through the autoclave door to cause a concern with maintaining a seal. Calibrated and certified maximum readable thermometers (MRTs) are also available. Sterilization strips are not sufficient documentation as part of the media prep processes. Investigate**

and proceed with one of these two options, providing evidence of purchase and calibration.

Finding 3: The response indicates spore strips were purchased. Confirm date of receipt of the spore strips and provide documentation of use for an autoclave cycle that would be used for at least one type of media.

Finding 4: The response indicates a timepiece has been purchased. Confirm date of receipt of the timepiece and provide documentation of use for an autoclave cycle that would be used for at least one type of media.

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.

    EHL Response to 6/28 Submission: The response is accepted. No further action is required, at this time.

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.

    EHL Response to 6/28 Submission: The response included an updated version of SOP-FA-006 for measurement uncertainty. The SOP contains an error is section 6.2.B.7, where it states that, for 20 data points at 95% confidence level, to use a k-value of 2.1. The correct k-value is 2.09. The spreadsheet included in the submittal uses a k-value of 1.63 for 10 data points, which is incorrect. The k-value increases as the number of data points decreases, so the k-value for 10 data points is less than the k-value for 20 or more data points. For 10 data points, the k-value is actually 2.23. Generally speaking for measurement uncertainty, the k-value will never be less than 2.

    Action: Correct the error in the SOP and update the spreadsheet calculation and resubmit both documents.

    EHL Response to 7/23/2021 Submission: The spreadsheet calculation is still using k=2 for the uncertainty calculation for sets of both n=20 and n=10. The use of k=2 low-biases the uncertainty, causing an overconfidence in the measurement accuracy.

    The SOP-FA-006 in 6.2.A.4 correctly describes the value to be used for the coverage factor k: "for 95% and 50 points, use 2; for less than 50 points, use the appropriate t statistic for 95%". But section 6.2.B.7 says to use k=2 via A2LA P103b .The instruction in the A2LA P103b document states "If fewer than 20 LCS results are available, the coverage factor should be the

appropriate t statistic for 95% confidence for the associated number of degrees of freedom (10=2.228, 20=2.086, 30=2.042, 40=2.021, 60=2.000, 120=1.980 & ∞=1.960, NIST SP260-100: 1993 Table B.3.4). Therefore, the statement in SOP section 6.2.B.7 is incorrect.

Action: Correct the error in the SOP, update the spreadsheet calculation and resubmit both documents.

EHL Response to 8/13/2021 Submission: The same documents were submitted on 8/13/21 and 8/17/21 as with the 7/23/2021 response, with no observable changes made. Therefore, no response was made by the laboratory for this Finding between 7/29/2021 and 8/13/2021. The Action above is still required.

EHL Response to 9/14/21 Submission: The SOP-FA-006 document is acceptable.

The scale verification spreadsheet has some errors which must be corrected. The number of points for the U.S. Solid measurements is 10, so the k value used should be 2.228 instead of 2.086.

The standard deviation calculation for the U.S. Solid columns references cells 5-15, not 5-25. While correct for this application, if the spreadsheet is used for future verification, the standard deviation would be calculated incorrectly if more than 10 measurements were used. Likewise the k value must be changed in the cells of row 30 for additional use of this spreadsheet.

Action: Submit the revised spreadsheet with the correct k value adjusted for the number of measurements in each column.

EHL Response to 9/16/21 Submission: The revised spreadsheet is acceptable. This finding is now closed.

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.

    EHL Response to 6/28 Submission: The response is accepted. No further action is required, at this time.

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 25, 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.

    EHL Response to 6/28 Submission: The response is accepted. No further action is required, at this time.

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.

    EHL Response to 6/28 Submission: The response is accepted. No further action is required, at this time.

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.

    EHL Response to 6/28 Submission: The response is accepted. No further action is required, at this time.

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.

    EHL Response to 6/28 Submission: The laboratory states, "I believe there may be some confusion here, we are using 215nm as a verification wavelength for the target analyte on 220nm, our equipment uses 360 as a spectral reference." However, the SOP does not mention the use of the 215nm wavelength for verification.

    Action: Update the SOP to include the use of the 215nm wavelength for verification, which should include the parameter(s) required to be met to verify the presence of a parameter.

EHL Response to 7/23/2021 Submission: The laboratory submitted the 7/15/2021 revised Potency SOP, clarifying that retention times of the analytes must be within 2.5% of one another in the 220nm primary chromatogram and the 215nm secondary chromatogram. This finding is closed.

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.

    EHL Response to 6/28 Submission: The response is accepted. The laboratory indicated that, initially, the gap will be closed by taking the current high calibration curve out of use and reanalyzing samples at a dilution for concentrations greater than the high point of the low curve. According to FAT, a high calibration curve that closes the gap is expected to be developed and implemented by 7/31/21.

    EHL Response to 8/27/2021 Submission: The high calibration curve from 2.5 mg/L to 500 mg/L is acceptable. This finding is still closed.

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.

    EHL Response to 6/28 Submission: The response satisfies the initial finding, but the submittal creates a new finding in the process. The run log submitted for this finding indicates:

    - Samples 1970, 1971, and 1972 all coming from vial 6;
    - Samples 1974-A, 1974-B1, 1974-B2, 1975-LCS, 1975 LC-MS, and 1975 LCS-MSD all coming from vial 11; and
    - Samples CCV (50 ppm) and a second CCV (50 ppm) both coming from vial 14.

    Action: For this analysis, a vial can only be sampled from once. Please explain, correct, or clarify the multiple analyses taken from a single vial.

    EHL Response to 7/23/2021 Submission: The laboratory stated "We appreciate this catch, upon further investigation FAT has concluded there must [analyst name] must have made a typo, looking at the chromatographs of each samples the peaks signify that they are most definitely not from the same vial. This Shall not happen in the future and appreciate this being brought to our attention." However, a corrective action is necessary to demonstrate how the incorrect documentation of the vials used will not recur.

    Action: Please submit a corrective action report demonstrating how incorrect documentation of the vials used will not recur.

    EHL Response to 8/13/2021 Submission: The laboratory did submit a corrective action report on 8/13/21 and the same version on 8/17/21, but there were no details in the report of:

    - which batch/run and which vials were mislabeled;
    - how the laboratory came to the conclusion that the vials were mislabeled; and
    - when the review of the run labels will occur, and how the review will be documented.

    Action: Please submit a revised corrective action report including the details described above. Submit supporting documentation of the reviews described in the CAR.

    9/15/21 – Response from FAT is pending.

    EHL Response to 9/16/21 Submission: The response is acceptable. The correct labeling and vial assignment for RSA samples and QC will be examined during the next audit visit. This finding is now closed.

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.

    EHL Response to 6/28 Submission: The laboratory submitted a plan and data June 2, 2021. Per the June 2, 2021 EHL email to FAT, the plan was acceptable to meet the June 1, 2021 deadline. The same email also stated that the plan and the spreadsheet required corrections to comply with the June 25, 2021 submission. However, no update to the plan was submitted. The original plan was to enter data into the spreadsheet on the computer in real time. The spreadsheet documenting all data from May 18, 2021 through June 25, 2021 was submitted on June 28, 2021. Review of the spreadsheet indicates the laboratory is unable to secure the data in the spreadsheet and all data is suspect. A list of issues can be found in Finding #26.

    Action: The laboratory must immediately stop use of the spreadsheet and record all data in a hard copy form on a bench sheet or lab notebook until the issues with the spreadsheet can be corrected and the updated version is approved by the EHL. In order for the spreadsheet to be approved, the laboratory must also submit a plan to insure the spreadsheet is controlled to prevent unauthorized or accidental changes to the original data and correct the review findings in Finding #26 below.

    EHL Response to 7/23 Submission: The updated plan only states the lab has locked and password protected the spreadsheet and are in the process of setting up a LIMS. Does this mean individual cells are locked or just the spreadsheet document? If a cell needs to be changed how is that accomplished and documented? Is any type of review of the data/spreadsheet taking place? The LIMS system is a good plan for the future but the use of a spreadsheet cannot be granted on the promise it will be fixed in the future.

    Action: The spreadsheet is not approved and the laboratory is not allowed to switch back to using the spreadsheet at this time. The laboratory must continue recording data in a hard copy format. Submit a detailed plan describing how the laboratory will control the spreadsheet. This plan needs to include what is locked, who has access, who is authorized to change what, how are changes to the data tracked in the spreadsheet?

EHL Response to 8/13 Submission: The laboratory stated in their submission that the use of bench sheets and bar codes have been implemented and to see the attached Micro SOP for the new process. The SOP showed examples of the bar codes and made a brief mention of the bench sheet but did not explain how either are used. The new bench sheet was also submitted for recording data while testing but there are still items that need to be updated. The bench sheet doesn't have a location to record observations or results. It is lacking space to record the latex agglutination test for STEC and microscopic exam for Aspergillus. Finally, there is no space to record the analyst who removes/reads out plates.

Action: Please submit a detailed explanation of how the bench sheets will be used. Additionally, please update and submit a copy of the bench sheet(s) along with data (bench sheets and photos) for all batches run from 8/13/21 through 8/26/21.

9/15/21 – Response from FAT is pending.

EHL Response to 9/17 Submission: The response detailed how the lab will use the bench sheets and QR codes, but did not submit data for all batches from 8/13/21 – 8/26/21. They did state they were not accepting samples as of 8/7/21 so did not have data. They also did not submit the updated bench sheet as required in EHL's response to 8/13 submission (EHL's response sent 8/26/21). Based on the explanation, a few things still need to be clarified. It seems a hard copy of the latex bench sheet will be filled out in real time and then that information entered in to the system somehow. How is the information put into the system? How is the hard copy maintained and associated with samples? It also appears from the explanation that media prep is recorded in real time on the media prep log and that information is added to the system. How is the hard copy of the media prep log maintained? The plan also states the time in and out of the incubator will be scanned in real time into the log for that sample, but doesn't address how observations and results are recorded when they are read out. Is a hard copy bench sheet still used or are the results entered into Confident Cannabis in real time? If a hard copy bench sheet is used how is that maintained and associated with the sample? If they are entered in in real time how does the system ensure results are not inadvertently changed.

Action: Please clarify how the above information will be scanned into Confident Cannabis and how the real time recordings will be maintained. Additionally, please submit updated bench sheets with the missing information from EHL's 8/26/21 request.

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.

EHL Response to 6/28 Submission: The plan submitted states a new checklist in the Microbiology manual will be used to ensure the prep sheets are used, however there are issues with the checklist (see finding 29). Documentation of the disposal of old media without IDs was also not submitted. The laboratory did submit an updated media prep worksheet that contains all three in-house made media and documentation of new lots of media, except, the prep logs were missing for lots made 6/24/21.

The laboratory is recording the media prep on the Preparation for Agar and Broth Record Log sheets as well as electronically in the Micro Log Spreadsheet. Review of the spreadsheet and prep logs indicated documentation issues. The laboratory is using the form to record all types of media made in a day on a single form. So one form will have data for DRBC, TSB and SMAC. It is highly recommend each form is only used for a single batch and the type of media. If the lab wishes to continue to use the single sheet for all three made at once, some changes will need to be made to the form. Each line that records individual information for each media needs to somehow identify which media matches which data. For example there is a single line for Agar/Broth Lot# and the three lots are record on this line, but it's not clear which lot corresponds with which type of media. This can also be seen in the weight line, the pH line, the number of plates poured lines and the time in storage line. Confusion is also possible if sterilization for one of the batches isn't successful since it is only a yes/no option. Also, required information is still missing. The form doesn't list the analyst that pours the plates or the time/date they are poured or documents disposal of the media if it fails any of the QC. Additionally, the lab needs to document the media QC check outcomes on the prep log.

Action: Please submit an updated form. In addition, please submit a plan to ensure errors, like those listed below are caught and corrected.

- In addition to the issues with the form template, the following issues with the batches from 6/21/21 were observed upon comparison of the handwritten logs with the Micro Log Spreadsheet
- The Micro Log Spreadsheet has an individual tab for all in-house made media (TSB, DRBC and SMAC). Both the TSB and DRBC tabs contain a header of "Tryptic Soy Broth" written across the top of the spreadsheet.
- Multiple overwrites, obliterations, and line-throughs without initials/date were noted on the Prep Logs for both batches A and B.
- The Prep Log for batch A lists the amount of dehydrated TSB as 30.0051g, but the Micro Log Spreadsheet lists 30.0062 (no units included in the spreadsheet). For TSB for batch B, the Prep Log lists the amount as 300.75g, while the Micro Log Spreadsheet lists 30.007
- The SOP and manufacturer's instructions list the amount of DRBC to add to 1L of water as 31.6g, but the Prep Log lists 30.0045g for batch A and 30.1565 for batch B.

- The SOP and manufacturer's instructions list the amount of SMAC to add to 1L of water as 50g, but the Prep Log lists 30.00X2g (write over, illegible) for batch A and 30.00709g for batch B.
- Amount of purified water added to the media for the A batches appears to read 1mL or 1uL, but it isn't legible on the log.
- The SOP lists the pH for TSB as 7.3±0.2 (pH units). The pH recorded on the Prep Log is 7.0 for both batches A and B. There is no indication the media was disposed or remade, and in fact it is recorded on the Micro Log Spreadsheet for sample data as being used for enrichment for batches run from 6/21/21 through 6/23/21.
- Time in Storage is listed as 8:40/8:20/8:20 (though it is unclear if this is a.m. or p.m. and which time applies to which media) for both batches A and B.
- Date in storage is listed as 6/24/21. There is no comment explaining why plates weren't placed in storage for 3 days (i.e. from 6/21/21 to 6/24/21), or what date the plates were actually poured.
- The ID given to the media on the Prep Log doesn't match the ID in the Micro Spreadsheet. For example batch A of the Prep Log lists the ID as DRBC.62121ATA, the ID in the spreadsheet is DRBC.6212021.AT.

EHL Response to 7/23 Submission: The following required additions were not added to the prep logs as requested: initials of who pours the plates, time and date the plates are pours, QC check and disposal data. Additionally the following issues were observed with the forms:

- The updated plan in this submission states the forms have been updated to include the manufacturer's parameters, but the manufacturer pH requirements were not added to the DRBC or the SMAC logs. Also for all three forms, the amount of media is listed as ~XXg. If a range is going to be used, it needs to be specific and match what is listed in the SOP.
- The time of storage has "(min)" listed by it. What does this mean? Is this "min" from coming out of the autoclave or from starting to pour the plates, or does it mean something else?
- The prep log for SMAC notes boiled for 1 minute, but not more than 3. The manufacture only allows for a 1 minute boiling time. This must be updated in the SOP and the prep sheet.
- For the DRBC and the SMAC logs, what is date of validation? If this is the media QC (positive, negative and sterility controls), why is the date of validation only recorded for new lots? Media QC is required on all lots or batches of media.
- For TSB the require pH is listed as ~7.3 ± 0.2. The range must be exact, not an estimate.
- For the TSB log, there is a question of whether the broth cooled within an acceptable range. What does that mean? Is this the range where it is placed in the refrigerator?

Action: Update and submit media prep logs with the above corrections.

EHL Response to 8/17 Submission: The lab submitted updated prep logs for the media. The DRBC log lists the tempering temperature (cooled within an acceptable range) as 40-50°C, but the SOP lists the temperature as 50-55°C.

Action: Please update to ensure the prep log and SOP agree.

9/15/21 – Response from FAT is pending.

EHL Response to 9/15 Submission: Updated prep logs were submitted. The prep log for SMAC doesn't match the prep log example in the SOP. The SMAC prep log example in the SOP doesn't match the SMAC prep section in the SOP.

Action: Update and resubmit SOP. The lab may choose to update the prep log examples in the SOP to the most current prep logs, or alternatively they may add a comment to the SOP that examples are not necessarily the most current form, and to use the most current form. Along with that statement the location of the current forms must be listed.

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.

EHL Response to 6/28 Submission: The laboratory is running controls with each run, which can meet the media QC checks if documented properly. Media ID documentation has also been added to the logs, allowing for QC check traceability for SMAC and the DRBC (exceptions noted for missing documentation for the media made on 6/9/21 and 6/21/21 (see Findings #24 and #26)). TSB and SAL QC check documentation is still missing. No results are recorded for the TSB as part of the microbiology raw data, so QC cannot be considered complete. The QC check is being run for each batch for the SAL media, but there is no lot number information for the SAL plates so the QC check documentation is not traceable. There is a new Media QC log in the updated SOP, but no mention of it or documentation of it being used was received as part of the audit response submission.

Action: Update procedure to ensure TSB QC results are recorded and the lot number for the SAL plates is recorded to make QC traceable. Submit QC documentation for all lots of TSB and SAL media in-house.

EHL Response to 7/23 Submission: No response from lab.

Action: Submit the procedure updated for the noted items (above) and the requested QC documentation.

EHL Response to 8/17 Submission: A photo of the 7/28 positive and blank control for Salmonella was submitted, but no associated data with run information was included. No negative control for Salmonella or QC for TSB was submitted.

Action: Update procedure to ensure TSB QC results are recorded and the lot number for the SAL plates is recorded to make QC traceable. Submit QC documentation for all lots of TSB and SAL media in-house.

9/15/21 – Response from FAT is pending.

EHL Response to 9/17 submission: The response does contain QC for TSB and Salmonella. However, based on the SOP submitted 9/15/21, the QC for the TSB was not run correctly and will need to be re-run. The Salmonella QC is acceptable.

Action: Update procedure to ensure TSB QC is properly run and recorded (see SOP for corrections that need to be made for TSB QC). Submit QC documentation for all lots of TSB media in-house.

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.

EHL Response to 6/28 Submission: See response to Finding #23 for immediate action. No updated plan was submitted to ensure required information is documented, as discussed in Finding #23. The Microbiology Spreadsheet was initially submitted by FAT on June 1 and June 2 and reviewed and commented on in a June 2 email. FAT implemented further updates and resubmitted the worksheet on June 28. Following are findings from review of the two submittals:

Review findings for the June 1 and 2 submittals:

- The spreadsheet only lists the analyst that preps the enrichment step and the analyst that runs the latex agglutination test; however, all tests must have analyst initials at all steps they complete. Steps missing initials include:
  - the analyst that prepping samples for enrichment,
  - the analyst performing the DRBC plating,
  - the analyst removing the DRBC plates from the incubator and reading them,
  - the analyst performing the macroscopic and microscopic examination for growth on the DRBC plates,
  - the analyst plating and incubating the SMAC plates,
  - the analyst reading the SMAC plates,
  - the analyst performing the latex agglutination test,
  - the analyst plating and incubating the SAL plates, and
  - the analyst reading the SAL plates.

Action: Update spreadsheet to include analyst identification for all steps of micro testing.

- No pictures or written documentation of samples with growth were submitted.

Action: Submit photos of samples showing any growth when the spreadsheet is resubmitted for approval.

- The laboratory did add the observations (Growth/No Growth) to the spreadsheet as requested. However, observations are listed under the results tab, but no results are listed. Also missing is indication if the Growth is from the target organism when a 'Growth' is used.

Action: Update the spreadsheet to include observations and results. The results must indicate if the target organism is present or absent and the species identified for Aspergillus.

Review findings for the June 28, 2021 submission:

- The June 2, 2021 submission didn't contain any data prior to 5/13/21, but the new submission has data from 5/14/20 through 6/28/21. Where does the data for 5/14/20 through 5/12/21 come from? Since this spreadsheet was created on or near 5/13/21, the addition of preceding data from another storage location requires documentation, specifically to indicate if this data still exists in the original storage location.

- Elements of the spreadsheet data in the submitted June 2, 2021 were altered (without comment or audit trail) in creating the June 28, 2021 submission. Changes to data for multiple samples were noted. Sample 1509 (lab assigned ID) data, compared between the two submissions, was used to provide examples of noted alterations for this report:
    - June 2 submission lists the lot number for DRBC as VM824166816. June 28 submission lists the lot number as 17147 which is a catalog number for Dichloran Rose Bengal Agar (Base) not for DRBC and not a lot number.
    - June 1 submission lists the date out of the incubator for DRBC as 5/17/21. June 28 submission lists the date out as 5/20/21. (Note: Both submissions list the date in the incubator as 5/14/21, if incubation ended 5/20/21, that is outside the method incubation period.)
    - June 2 submission lists incubator readings for DRBC as 23.8°C, 23.9°C, and 24.3°C. June 28 submission lists the incubator readings for DRBC as 23.0°C, 23.1°C, and 23.1°C.
    - June 2 submission lists the lot number for SMAC as BCCC7252. June 28 submission lists the lot number for SMAC as 54082. 54082 is actually the catalog number for this media and is not a lot number.
    - June 2 submission lists the date/time of the sample into the SMAC incubator as 5/14/21 at 14:56. June 28 submission lists the date/time of the sample into the SMAC incubator as 5/15/21 at 14:56.
    - June 2 submission lists the date/time of the sample out of the SMAC incubator as 5/15/21 at 13:24. June 28 submission lists the date/time of the sample out of the SMAC incubator as 5/19/21 at 13:24, which represents an

exceedance of the incubation period when paired to the in time, whether 5/14/21 or 5/15/21.

- June 2 submission lists the SMAC incubator temperatures as 36.1°C, 35.9°C, and 35.8°C. June 28 submission lists the SMAC incubator temperatures as 35.7°C, 35.7°C, and 35.6°C.
- Similar anomalies were observed in the data for the latex agglutination test and the SAL testing.

- TSB used from 5/20/21 through 5/28/21 is listed as TSB.5212021.AT on the Micro Log Spreadsheet, but on the Media Prep Log, it is listed as TSB.05202021.AT. Sterilization data shows the media sterilization took place on 5/21/21, so how was it used to set up sample on 5/20/21?
- Per the Micro Log Spreadsheet, sample 1983 was placed into the enrichment incubator on 6/23/21 and removed on 7/1/21; however, the data documenting this activity was submitted three days earlier, on 6/28/21. Properly documenting data includes entry at the time of occurrence vs. projecting forward.
- DRBC is listed on the Media Prep Log as DRBC.05202021.AT, but on the Micro Log Spreadsheet as DRBC.5212021.AT. This media had a documented expiration date of 5/28/21, but was used to set up samples on 6/1/21. A similar anomaly exists for the SMAC media.
- All three types of media made on 6/9/21 are identified as XXX61121AT on the Media Prep Log and XXX6092021AT in the Micro Log Spreadsheet.
- SMAC.6022021AT was used to set up the sterility samples run on 6/10/21. However, the client samples were run with SMAC.6092021.AT, which means SMAC.6092021.AT was used without running a sterility check prior to use.
- DRBC.6162021.AT (recorded on the Media Prep Log as DRBC.61621.AT), prepped 6/16/21 was used to run sample 1851 on 6/14/21, per the Micro Log Spreadsheet.
- The laboratory is including a latex agglutination test lot number for samples that are not being run for that method. The lot number being recorded also does not consistently match the lot number used to run the control samples. Lot numbers between a batch's control samples are also mismatched, at times. An example of the latter is for 6/18/21, the negative control was run with lot C19248, while the positive control was run with lot C19252. The lot numbers recorded for the samples that day (although none of the samples were put through to the latex agglutination test, so lot numbers should not have been recorded) were C19253, C19254, C19255…..C19302) NOTE: There are multiple instance of latex agglutination lot number or dates or times for other methods that appear the lab has copied down from one cell to the next with values incrementing by 1 from cell to cell.
- Samples are recorded on the Micro Log Spreadsheet as going into the DRBC incubator 5/20/21 at 15:47; however, they are not recorded as coming out of the enrichment incubator, a preceding step, until 5/20/21 at 16:03. (The enrichment is what is used to plate onto the DRBC.) Other instances of DRBC going into the incubator prior to the sample being removed from enrichment also occurred 5/21/21, 5/27/21, 6/14/21, and 6/25/21.
- Sample are recorded on the Micro Log Spreadsheet as going into the SMAC and SAL medias incubators the same time they come out of an incubator for the preceding enrichment step. Again, the enrichment is what is plated onto the SMAC and SAL

media. The timing suggests the enrichment is removed from the incubator, plated onto multiple media, and put into the next incubator in less than one minutes.

Action: Reconcile and explain the noted discrepancies. Although, please note that data in the spreadsheet cannot be changed without documenting reason(s) for the change.

EHL Response to 7/23 Submission: A LIMS system is useful, but, until it is implemented it is not an acceptable corrective action while the lab is still running samples. The laboratory must either fix the issue with a temporary solution until the LIMS is running and verified, or the defensibility of the testing may continue to be in question until the LIMS is running and verified.

Action: All actions listed above for EHL's response to the 6/28 submission for finding #25 still requires a response. And the updated spreadsheet needs to be submitted for review.

EHL Response to 8/17 Submission: The laboratory stated in their submission that the use of bench sheets and bar codes have been implemented and to see the attached Micro SOP for the new process. The SOP showed examples of the bar codes and made a brief mention of the bench sheet but did not explain how either are used. The new bench sheet was also submitted for recording data while testing but there are still items that need to be updated. The bench sheet doesn't have a location to record observations or results, it is lacking space to record latex agglutination test for STEC and microscopic exam for Aspergillus, and there is no space to record the analyst who removes/reads out plates. Photos of control from 7/28 were also submitted.

Action: Please submit the revised bench sheets, and a detailed explanation of how these bench sheets will be used. Additionally, please update and submit a copy of the bench sheet(s) along with data (bench sheets and photos) for all batches run from 8/13/21 through 8/26/21.

9/15/21 – Response from FAT is pending.

EHL Response to 9/17 Submission: The response detailed how the lab will use the bench sheets and QR codes, but did not submit data for all batches from 8/13/21 – 8/26/21. They did state they were not accepting samples as of 8/7/21 so did not have data. They also did not submit the updated bench sheet as required in EHL's response to 8/13 submission (EHL's response sent 8/26/21). Based on the explanation, a few things still need to be clarified. It seems a hard copy of the latex bench sheet will be filled out in real time and then that information entered in to the system somehow. How is the information put into the system? How is the hard copy maintained and associated with samples? It also appears from the explanation that media prep is recorded in real time on the media prep log and that information is added to the system. How is the hard copy of the media prep log maintained? The plan also states the time in and out of the incubator will be scanned in real time into the log for that sample, but doesn't address how observations and results are recorded when they are read out. Is a hard copy bench sheet still used or are the results entered into Confident Cannabis in real time? If a hard copy bench sheet is used how is that maintained and associated with the sample? If they are entered in in real time how does the system ensure results are not inadvertently changed.

Action: Please clarify how the above information will be scanned into Confident Cannabis and how the real time recordings will be maintained. Additionally, please submit updated bench sheets with the missing information from EHL's 8/26/21 request.

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.

    EHL Response to 6/28 Submission: A rough draft of the SOP was submitted with a note that it would be edited, completed and submitted by Friday, July 2, 2021. The draft submitted 7/2/21 was reviewed. See finding 30 for review findings requiring updates.

    EHL Response to 7/23 Submission: A rough draft of the SOP was submitted with a note that it would be edited, completed and submitted by Friday, July 2, 2021. The draft submitted 7/2/21 was reviewed. See finding 30 for review findings requiring updates.

    Action: This finding remains open until finding 30 is satisfied.

    EHL Response to 8/13 Submission: This finding remains open until finding 30 is satisfied.

    9/15/21 - This finding remains open until finding 30 is satisfied.

    EHL Response to 9/15 Submission: This finding remains open until finding 30 is satisfied.

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.

    EHL Response to 6/28 Submission: The laboratory submitted a statement that the pressure cooker has been taken out of use and an autoclave is being used. However, no plan to ensure SOP prescribed sterilization conditions for the autoclave are met was submitted, nor was any documentation submitted showing the conditions are met with each run. The laboratory did

submit an autoclave run log showing the maximum temperature but it was unclear if a temperature measuring device was used or if this was recorded from the autoclave gauge. No calibration documentation for a temperature measuring device or the autoclave gauge was submitted.

Action: Submit a plan to ensure media manufacturer's sterilization conditions (temperature and sterilization) are met. Additionally, provide documentation of the time and temperature conditions being met with each run. Include in the plan the autoclave settings for both media and waste, the meaning of 'start time' (the time when autoclave reaches temperature and pressure or when items are placed in the autoclave), the meaning of 'end time' (end of an autoclave cycle or when items are removed from the autoclave), and is the 'run duration' the cycle time or the total time in the incubator.

EHL Response to 7/23 Submission: Even if the laboratory is using an autoclave, the lab still needs to show they are meeting the manufacturer's sterilization conditions. The thermometer gauge on the autoclave is not calibrated and therefore cannot be used to determine the temperature. SOP-FA-MIC-AS- Autoclaving and Sterilization section of the Microbiology SOP states to "record the date, contents, maximum temperature reached, pressure, time in sterilization mode and total run time (may be recorded as time in and time out) and analyst's initials." This citation doesn't answer the question of what is meant by "start time" or "end time" on the run logs. Review of the autoclave run logs shows some issues with autoclave time. These definitions are needed to determine if the issue is occurring in documentation or operation.

Action: Submit a plan and any updated documentation to ensure media manufacturer's sterilization conditions (temperature and sterilization) are met. Additionally, provide documentation of the time and temperature conditions being met with each run. This could include and update to the forms or SOP along with calibration documentation for autoclave temperature monitoring device. Include in the plan the autoclave settings for both media and waste, the meaning of 'start time' (the time when autoclave reaches temperature and pressure or when items are placed in the autoclave), the meaning of 'end time' (end of an autoclave cycle or when items are removed from the autoclave), and is the 'run duration' the cycle time or the total time in the autoclave.

EHL Response to 8/17 Submission: The lab submitted an updated autoclave use/ maintenance log but the log had no data. The updated log does define the start and stop time as the total time in the autoclave, but since the autoclave section of the SOP was removed for this submission, the log cannot be evaluated against the SOP and may therefore not be adequate to document all information required by the SOP. The lab still needs to define the cycle time as well. If Waste or Agar are set cycles that have timing checks, those just need to be defined in the SOP, if they are not set cycles, the cycle (sterilization) time must also be included on the log. Additionally, no calibration documentation for a temperature monitoring device was received.

Action: Please submit a copy of the log in use, showing autoclave runs. Additionally, please submit an updated SOP that describes autoclave use, documentation of a temperature monitoring device in the autoclave, and calibration documentation for the device.

9/15/21 – Response from FAT is pending.

EHL Response to 9/16 Submission: The lab has submitted an updated SOP, but did not submit the autoclave run logs since they haven't run the autoclave during the shutdown. The lab also stated they do not have a temperature measuring device for the autoclave since they say they can't properly seal the autoclave with a data logger in it. They are using the temperature gauge on the autoclave instead, and using autoclave tape for every run to ensure the autoclave meet the minimum temperature. The temperature of the autoclave must be monitored while making media. The autoclave temperature cannot exceed 121°C when making media or the media will be degraded. The temperature gauge on the autoclave is not calibrated and therefore not acceptable to use to monitor the temperature of the autoclave during the run. Autoclave tape turns color at the minimum temperature and does not reflect the high temperature of the run. Additionally, the lab's SOP states "Demonstration of sterilization temperature is to be provided by use of a continuous temperature-recording device or by use of a maximum registering thermometer with every cycle." There are data loggers that are made to go completely in the autoclave, or the lab can also use what is called a maximum registering or read thermometer, which is a special thermometer made to go in the autoclave. The updated SOP does have other issues in the autoclave section as discussed in response to finding #30 that also need to be addressed.

Action: Media cannot be made in-house until the lab is able to ensure the media is sterilized at the correct temperature. Please submit documentation of a temperature monitoring device in the autoclave, and calibration documentation for the device. Additionally, please submit an updated SOP as discussed in finding #30.

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.

EHL Response to 6/28 Submission: The laboratory submitted a plan stating a checklist will be developed. The updated Micro SOP contained the checklist but there is no description on how the checklist will be used (i.e. frequency, protocol for responding to findings, what positions are authorized).

Action: Submit an updated plan or SOP explaining how the checklist will be used. This needs to include frequency, protocol for responding to findings, who is authorized to use it and how, and what exactly is inspected. See the SOP with comments for more on how to update the checklist.

EHL Response to 7/23 Submission: The laboratory only addressed one of the four elements required. The laboratory still needs to address the protocol for responding to findings, who is authorized to use the checklist and how, and what exactly is inspected. Additionally, the laboratory did not address the comments made by EHL in the SOP itself for updating the checklist.

Action: Submit an updated plan or SOP explaining how the checklist will be used. This needs to include frequency, protocol for responding to findings, who is authorized to use it and how, and what exactly is inspected. See the Microbiology SOP document with comments for more on how to update the checklist.

EHL Response to 8/13 Submission: The laboratory submitted an updated SOP, but the checklist has been removed from this version and no new plan was submitted describing how the laboratory will ensure SOPs are followed.

Action: Submit plan to ensure the SOPs are followed. If the lab still plans to use the checklist, submit an updated plan or SOP which explains how the checklist will be used. The plan must include frequency, protocol for responding to findings, who is authorized to use it and how, and what exactly is inspected.

9/15/21 – Response from FAT is pending**.**

EHL Response to 9/17 Submission: The checklist and plan are more complete and understandable, and are a great addition to help ensure everything was done for the day. However, it is highly recommended the laboratory also add a monthly or quarterly records review by management to ensure all QC data is accurate and acceptable. The finding is acceptable, but subject to review at the next audit. No further action is required.

The following instances of the SOP not being followed were observed during review of the records submitted June 28, 2021.

- The laboratory isn't following incubation times in the SOP

- Enrichment incubation time is listed in the SOP as 20-24 hours. Multiple instances exist of a sample being in the incubator for slightly outside that range, such as in the incubator at 15:18 on 6/24/21 and out at 18:33 on 6/25/21 (3 hours & 15 minutes beyond the 24-hour limit). Of greater concern are examples such as 6/11/21 and 6/23/21 showing samples in the Enrichment incubator for multiple days. On 6/11/21 (Friday) the sample was placed in the enrichment incubator at 15:49 and was removed and plated on 6/14/21 (Monday) at 17:05. This also occurred with sample 1781 which was put into enrichment 6/3/21 (Thursday) and out on 6/7/21 (Monday). The risk is a possibility of a high enough organism count or reproduction rate that consumes all the nutrients in the broth, resulting in a die off of organisms, resulting in false negative results.
- Per the Micro Log Spreadsheet, samples were placed into the DRBC incubator on 6/1/21 at 16:41 and removed on 6/3/21 at 16:06. This also occurred with samples placed into the incubator on 6/22/21 and being taken out on 6/24/21. Per the SOP, DRBC is incubated for 3, 4 or 5 days.
- The sterility blank for *E.coli* O157 was placed into the SMAC incubator 5/20/21 at 16:03 and came out 5/21/21 at 16:12 per the Micro Log Spreadsheet. Per the SOP the laboratory is incubating the SMAC sterility blanks for 48 hours. EHL noted in the SOP review comments that the sterility blank should be incubated for the same time as the samples and not exceed 24 hours.
- On 5/20/21 samples were put into the SMAC incubator at 16:03 and removed 5/21/21 at 16:12. Per the SOP SMAC incubation is 20-24 hours, but not to exceed 24. Incubation of more than 24 hours for SMAC was seen multiple times including 5/21/21, 5/27/21, 6/3/21, 6/4/21, 6/18/21, 6/22/21, and 6/24/21. The dates and times were observed for samples in the SAL incubator which also has a 20-24 hour incubation time per the SOP. Prolonged incubation may result in *E.coli* O157 colonies losing their characteristic colorless appearance, which results in a false negative.
- On 6/25/21 samples were put into the SMAC incubator at 18:30 and removed at different times without explanation per the Micro Log Spreadsheet, on 6/26/21 at 02:24 or 09:36 depending on the sample.

- The laboratory isn't following the SOP in regards to the amount of dehydrated media used.
  - Per the SOP (and manufacturer's instructions), 30±1 g of TSB, 31.6g of DRBC or 50g of SMAC is rehydrated in 1L of water. Amounts listed in the Micro Log Spreadsheet, for media made 6/2/21 through 6/24/21, shows the lab used varying amounts of DRBC between 30.0045g to 31.565g (vs. 31.6g prescribed), and varying amounts of SMAC between 30.0018g and 30.0075g (vs. 50g prescribed) into 1L of water. As noted in the EHL response to finding #26, these amounts don't necessarily match the amounts on the Media Prep worksheets for the corresponding batches.
- Per the SOP, photos are taken of Positive and Negative controls on SMAC but no photos were submitted with the laboratory response.

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 for which the method is looking 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.**

EHL Response to 6/28 Submission: The SOP still contains procedures not used by the lab, thereby not accurately reflecting the procedures used at the lab. An example SOP template that includes general document guidance is included as an attachment to this report. This template is to give the lab a framework to create a stepwise SOP for microbial analysis. This template is suitable for defining an SOP's structure. A commented copy of the updated SOP, submitted by the lab, is also attached. If the lab wishes to continue using its current SOP, the comments provide the basis for making required corrections to yield an SOP that accurately describes activities currently being performed.

Action: Submit an updated SOP reflecting only the protocols used at the laboratory.

EHL Response to 7/23 Submission: No response from lab. The laboratory did submit an updated SOP which fixed some spelling and grammatical errors and updated the frequency for the checklist as required in finding #29. However, since no other updates required by findings #29 or #30 (to include the SOP annotated with updates by EHL) were apparent in the re-submitted document, the finding remains open.

Action: Submit an updated SOP reflecting only the protocols used at the laboratory. Changes noted in the annotated SOP sent from EHL July 9, 2021 (attached again for reference in MS-Word format) must be addressed.

EHL Response to 8/13 Submission: The lab submitted a shortened version of the SOP, but it is unclear if the full SOP was submitted or just the first 25 pages since the documents ends but no references or sections such as the appendix were present. The majority of the procedures the lab had in the previous SOP which they do not perform, were not present in the version submitted; however, the submitted version also lacked in-depth descriptions of all the procedures the laboratory does perform, or should perform. A copy of the updated SOP with specific notes from EHL will be sent to the laboratory by 5pm Friday, August 27, 2021. It would also be useful to set up a call between EHL and the laboratory the week of August 30th to discuss the notes and required changes that need to be made to the SOP.

Action: Submit a new microbiology SOP that describes in-depth all the procedures the laboratory performs, and only the procedures the laboratory performs.

EHL Response to 8/30 Submission: A phone discussion took place on 8/30/21 with EHL and FAT to discuss EHL's comments on the Microbiology SOP and what changes need to be made, but no updated SOP has been received as of 9/13/21.

Action: Submit a new microbiology SOP that describes in-depth all the procedures the laboratory performs, and only the procedures the laboratory performs.

EHL Response to 9/15 Submission: An updated SOP has been resubmitted. Not all required instructions have been added and clarifications still need to be made. Additionally, there are issues with the new procedures that have been added. A word document copy of the updated SOP with specific notes from EHL is enclosed with this response.

Action: Update the SOP in accordance with the enclosed notated copy and resubmit.

SUMMARY – EHL 7/09/2021 Response to 6/01/2021, 6/02/21, 6/28/21 and 7/02/20 Submissions: The findings stemming from the review of the four submittals demonstrate data defensibility concerns, inconsistencies in documentation practices, and technical validity concerns resulting from SOP deviations. A response to the findings of this review are requested by 5 p.m. on July 23, 2021.

SUMMARY – EHL 7/29/2021 Response to 7/23/2021 Submissions: The findings stemming from the review of this submittal continue to demonstrate data defensibility concerns, inconsistencies and gaps in documentation practices, and unaddressed SOP deviations. Documents, availability of which were requested ahead of the audit to be available during the audit, are still unavailable to the audit team over two months later. The tone of the findings responses appears, at times, disinterested in nature. The extent and nature of the open findings and their continued unresolved status warrant consideration for suspension until all corrective actions are closed. A response to the findings of this review are requested by **5 p.m. on August 13, 2021**.

SUMMARY – EHL 8/26/2021 Response to 8/13/2021 and 8/17/2021 submissions: The response was incomplete; some findings were not addressed by either of these two submissions. The EHL and FAT discussed a path forward during a phone call on 8/25/21, a path including a goal to close out all open findings by 9/18/2021. Follow-up status calls are scheduled for 9/2/21, 9/7/21, and 9/15/21.

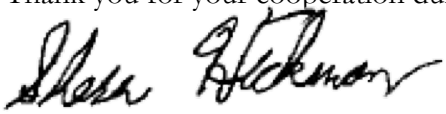
SUMMARY – EHL 9/15/2021 Response to 8/18/2021, 8/27/2021, 9/9/2021 and 9/14/2021 submissions: Responses were received for Findings 2, 5, 6, and 21 only. Finding 5 (half) is now closed. Finding 21 was already considered closed, but the additional calibration is acceptable. Seventeen total Findings 1, 2, 3, 6, 7, 12, 13, 15, and 22-30 are still open.

SUMMARY – EHL Response to 9/15, 16, 17/2021 submissions: Responses were received for Findings, 1, 2, 3, 5, 6, 7, 12, 13, 15, and 22-30. Findings 5 (other half), 15, 22, and 29 are now closed.

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

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

DEPARTMENT OF LAW
OFFICE OF THE ATTORNEY GENERAL
ANCHORAGE BRANCH
1031 W. FOURTH AVENUE, SUITE 200
ANCHORAGE, ALASKA 99501
PHONE: (907) 269-5100

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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Timeline of F.A.T. audit issues

Prepared by Director Klinkhart, AMCO
September 20, 2021

Highlighted Dates	Description
May 26, 2020	AMCO requested audit for new equipment at FAT
June 11, 2020	EHL audit agenda sent to FAT
June 23, 2020	Audit at FAT occurs
July 6, 2020	EHL requested responses from FAT audit results
July 8, 2020	Including, but not limited to: A) From 7/3/2020 to 9/14/2020 FAT missed approximately 16 deadlines to respond or to correct errors/issues B) FAT has been using incorrect potency calculations for concentrates since 2018 C) FAT has been using incorrect calculations for plant sample weights, which affected potency results D) FAT has been using incorrect calculations for edibles which affected potency results.
September 14, 2020	Last missed deadline
October 9, 2020	FAT Served with AMCO Accusation, NOV and notice of defense Attachment A - FAT Complaint and NOV Inv Rukes 10092020 FINAL
November 30, 2020	FAT case referred and case file provided to AOH
December 3, 2020	FAT legal representative responds to AMCO

February 1, 2021	AMCO, SOA AG, and FAT meet several times in OAH mediation Mediated Settlement Agreement reached
March 31, 2021	MCB Members meet with OAH Mediated agreement with FAT is approved by the board *Two (2) year probation agreement by FAT includes:* *$2500 fine (which FAT has paid)* *An audit by EHL on FAT, to be paid for by FAT (up to $5000)* *Failure to respond and/or correct an error/violation found by an audit within 30 days is a probation violation* *Violation is up to two (2) months of license suspension*
May 5, 2021	Final agreement signed by MCB Nick Miller
May 25, 2021	May 2021 EHL conducts an Audit of FAT Multiple issues are discovered EHL Audit requests/corrections/errors still not properly addressed by FAT
June 3, 2021	FAT given notice by AMCO of Audit violations to be corrected within 30 days
July 2, 2021	FAT given notice of Probation violationsn and notice of suspendtion of operations for two (2) months *Only 7 of 30 findings of the June 3, 2021 demand to address have be responded to and/or corrected by FAT*
July 8, 2021	Notice from FAT legal representative requesting a stay of suspention *AMCO stays the suspendion and invites FAT to the MCB August 18th meeting where it will be discussed*
July 29, 2021	EHL May 25th Audit requests/corrections/errors still not properly addressed by FAT *19 findings remain open and have yet to be fully addresed/responded to and/or corrected by FAT*
August 18, 2021	MCB meets to hear the Probationary violation *18 findings remain open and have yet to be fully addresed/responded to and/or corrected by FAT* MCB upholds 30 Day suspension of FAT license

September 18, 2021 FAT 30-day Supention ends

15 findings remain open and have yet to be fully addresed/responded to and/or corrected by FAT

September 21, 2021 MCB Special meeting to consider additional suspension of FAT license

Klinkhart, Glen Edward (CED)

From: Dylanne macomber <fairbanksanalytical@gmail.com>
Sent: Friday, September 17, 2021 6:31 PM
To: Lwells; Klinkhart, Glen Edward (CED)
Subject: Deficiency submits
Attachments: CORRECTIVEPREVENTIVE ACTION Manural Intigrated Peaks.pdf; Micro Checklsit Plan.docx; Media Quality Control Record.pdf; ATCC Positive Control Form Explained.docx; Explination of how to use QR Codes.docx; Daily Microbiology Checklist.docx; 0189 TO 0192 2021-01-21 09-50-18 Alex Boyle_006F0601.pdf; 0189 TO 0192 2021-01-21 09-50-18 Alex Boyle_003F0301.pdf

Def. 1&2 Please see attached typed Corrective Action Form

Def. 3 Please see attached GC reports used for Sample 189 and CCV (50PPM) report.

Def. 4 Approved 7/23/2021

Def. 5 (two part) Approved 7/23/2021 and 9/9/2021

Def. 6 shall be submitted 9/18/2021

Def. 7 Close depending on Finding 6

Def.8 approved 8/17/2021

Def. 9 Approved 7/23/2021

Def. 10 Approved 6/28/2021

Def. 11 Approved 7/23/2021

Def. 12 9/17/2021 FAT emailed Absolute standards to check on results seeing as it was stated to us that the results should be 48 hours. They informed us that they had not received any results from what was entered 9/14. Results have been re entered and we are hoping to have results Monday. FAT sent a follow up email after entering results to verify that the results were obtained by Absolute and have not received an email back.

Def. 13 Submitted 9/14/2021 resubmitted for approval 9/16/2021

Def. 14 Approved 6/28/2021

Def. 15 Submitted 9/14/2021 resubmitted for approval 9/16/2021

Def. 16 Approved 6/28/2021

Def. 17 Approved 6/28/2021

Def. 18 Approved 6/28/2021

Def. 19 Approved 6/28/2021

Def. 20 Approved 7/23/2021

Def. 21 Approved 8/27/2021

Def. 22 Submitted 9/16/2021

Def. 23 Please see attached explanation of how the bench sets are utilized in the lab. FAT suspended accepting samples 5 days prior to the AMCO meeting (8/12/2021) so we have no Microbial data for the 8/13-8/26 time frame, but we are more than willing to submit the completed bench sheets after our reopening.

Def. 24 Submitted 9/15/2021

Def. 25 Please see attached QC documentation for Salmonella and TSB, we have re-run the QA/QC on the inhouse lots just to ensure proper ethics and documentation.

Def. 26 Please see attached explanation of the new bench sheets and how they will be used. FAT suspended accepting samples 5 days prior to the AMCO meeting (8/12/2021) so we have no Microbial data for the 8/13-8/26 time frame, but we are more than willing to submit the completed bench sheets after our reopening.

Def. 27 Open until finding 30 is resolved

Def. 28 Submitted 9/16/2021

Def. 29 Please see attached Improved Checklist as well as the new plan for ensuring the Checklist is completed and how we will do so.

Def. 30 Submitted 9/15/2021

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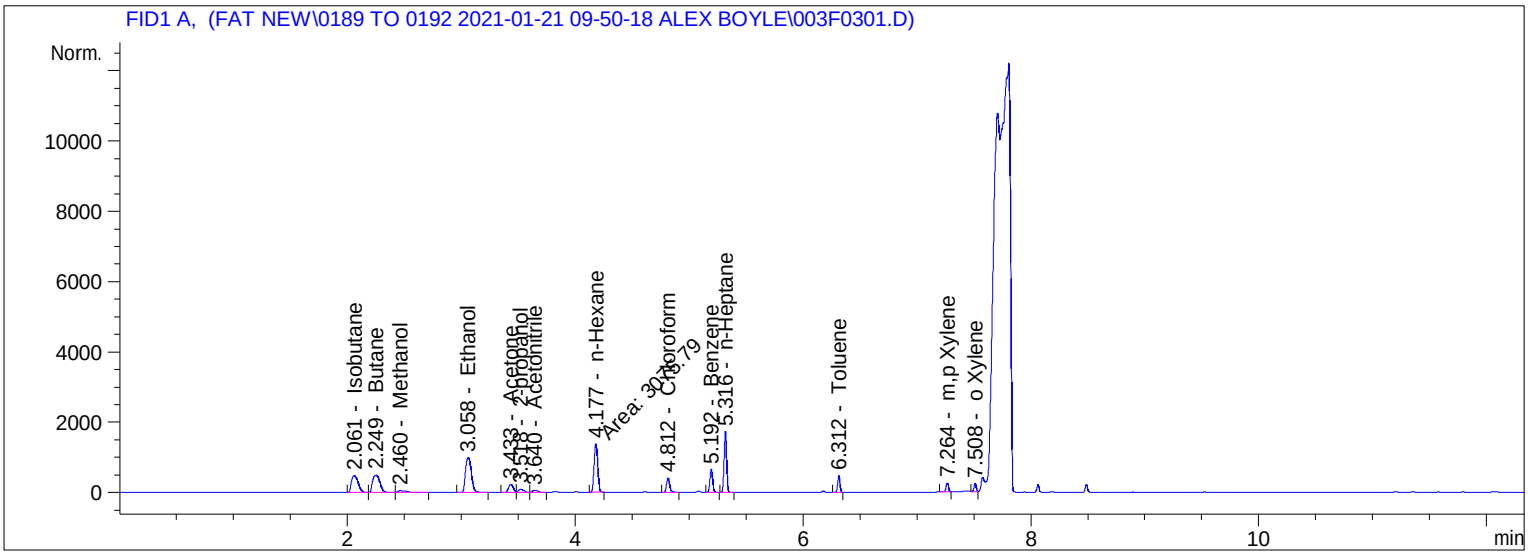
Dylanne Macomber
Chief Executive Officer
Fairbanks Analytical Testing
fairbanksanalytical@gmail.com
907-479-1259

Data File C:\CHEM32\1\DATA\FAT NEW\0189 TO 0192 2021-01-21 09-50-18 ALEX BOYLE\003F0301.D
Sample Name: CCV(50ppm)

Acq. Operator	: Alex Boyle	Seq. Line	: 3
Acq. Instrument	: Agilent 6890N	Location	: Vial 3
Injection Date	: 1/21/2021 11:13:43 AM	Inj	: 1
		Inj Volume	: Manually
Acq. Method	: C:\CHEM32\1\DATA\FAT NEW\0189 TO 0192 2021-01-21 09-50-18 ALEX BOYLE\RSA_GC_10162020.M		
Last changed	: 10/26/2020 4:24:53 AM by Alex Boyle		
Analysis Method	: C:\CHEM32\1\METHODS\RSA.M		
Last changed	: 6/28/2021 4:27:39 PM by Alex Boyle		
Method Info	: RSA Method for SOP-FA-002		

Sample-related custom fields:

Name	Value
Additional Info	: Peak(s) manually integrated



External Standard Report

Sorted By	:	Retention Time	
Calib. Data Modified	:	6/28/2021 4:27:24 PM	
Multiplier:	:	1.0000	
Dilution:	:	1.0000	

Use Multiplier & Dilution Factor with ISTDs

Signal 1: FID1 A,

RetTime [min]	Sig	Type	Area [pA*s]	Amt/Area	Amount [ug/g]	Grp	Name
2.061	1	BB	1927.08984	2.27345e-2	43.81137	1	Isobutane
2.249	1	BV	2146.19214	1.91670e-2	41.13600	2	Butane
2.460	1	VB	220.61188	1.26281e-1	27.85905	3	Methanol
3.058	1	BB	3550.22095	1.26675e-2	44.97238	4	Ethanol
3.433	1	BV	653.48145	9.16015e-2	59.85986	5	Acetone
3.518	1	VB	267.53177	1.66824e-1	44.63062	6	2-propanol

Data File C:\CHEM32\1\DATA\FAT NEW\0189 TO 0192 2021-01-21 09-50-18 ALEX BOYLE\003F0301.D
Sample Name: CCV(50ppm)

Acq. Operator : Alex Boyle Seq. Line : 3
Acq. Instrument : Agilent 6890N Location : Vial 3
Injection Date : 1/21/2021 11:13:43 AM Inj : 1
Inj Volume : Manually
Acq. Method : C:\CHEM32\1\DATA\FAT NEW\0189 TO 0192 2021-01-21 09-50-18 ALEX BOYLE\RSA_GC_10162020.M
Last changed : 10/26/2020 4:24:53 AM by Alex Boyle
Analysis Method : C:\CHEM32\1\METHODS\RSA.M
Last changed : 6/28/2021 4:27:39 PM by Alex Boyle
Method Info : RSA Method for SOP-FA-002

Sample-related custom fields:

Name	Value
Additional Info	Peak(s) manually integrated

RetTime [min]	Sig	Type	Area [pA*s]	Amt/Area	Amount [ug/g]	Grp	Name
3.640	1	BB	162.05487	2.37931e-1	38.55792	7	Acetonitrile
4.177	1	MM	3075.78882	1.70582e-2	52.46746	8	n-Hexane
4.812	1	BB	796.81207	7.48925e-2	59.67523	9	Chloroform
5.192	1	BB	1077.03418	5.17395e-2	55.72518	10	Benzene
5.316	1	BB	2662.64795	2.00332e-2	53.34146	11	n-Heptane
6.312	1	BV	632.21710	8.10705e-2	51.25418	12	Toluene
7.264	1	BB	389.48080	1.17107e-1	45.61080	13	m,p Xylene
7.508	1	VB	300.67783	1.80003e-1	54.12305	14	o Xylene

Totals : 673.02456

Group summary :

Group ID	Use	Area [pA*s]	Amount [ug/g]	Group Name
1	G	1927.08984	43.81137	Isobutane
2	G	2146.19214	41.13600	Butane
3	G	220.61188	27.85905	Methanol
4	G	3550.22095	44.97238	Ethanol
5	G	653.48145	59.85986	Acetone
6	G	267.53177	44.63062	Isopropyl Alcohol
7	G	162.05487	38.55792	Acetonitrile
8	G	3075.78882	52.46746	Hexane
9	G	796.81207	59.67523	Chloroform
10	G	1077.03418	55.72518	Benzene
11	G	2662.64795	53.34146	Heptane
12	G	632.21710	51.25418	Toluene
13	G	389.48080	45.61080	meta-para-Xylene
14	G	300.67783	54.12305	ortho-xylene

1 Warnings or Errors :

Warning : Calibration warnings (see calibration table listing)

Data File C:\CHEM32\1\DATA\FAT NEW\0189 TO 0192 2021-01-21 09-50-18 ALEX BOYLE\003F0301.D
Sample Name: CCV(50ppm)

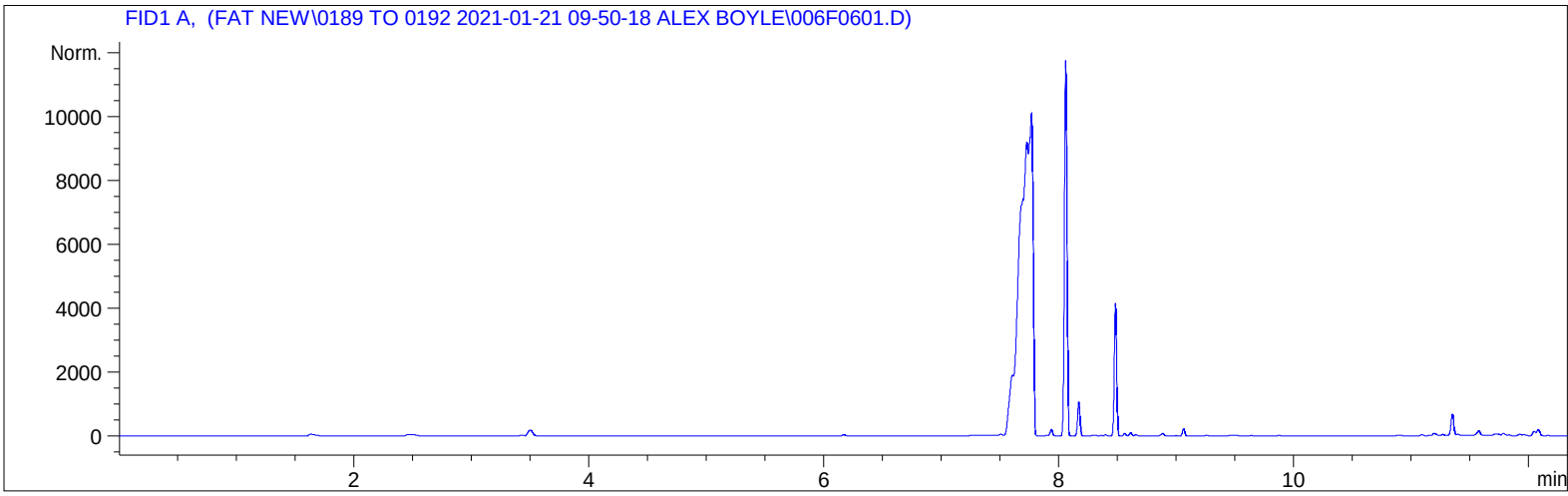
```
    ======================================================================
    Acq. Operator   : Alex Boyle                     Seq. Line :   3
    Acq. Instrument : Agilent 6890N                   Location : Vial 3
    Injection Date  : 1/21/2021 11:13:43 AM                Inj :   1
                                                   Inj Volume : Manually
    Acq. Method     : C:\CHEM32\1\DATA\FAT NEW\0189 TO 0192 2021-01-21 09-50-18 ALEX BOYLE\RSA_
                      GC_10162020.M
    Last changed    : 10/26/2020 4:24:53 AM by Alex Boyle
    Analysis Method : C:\CHEM32\1\METHODS\RSA.M
    Last changed    : 6/28/2021 4:27:39 PM by Alex Boyle
    Method Info     : RSA Method for SOP-FA-002


    Sample-related custom fields:

    Name                          |Value
    ------------------------------|-------------------------------------
    Additional Info : Peak(s) manually integrated
    ======================================================================

     ======================================================================

    Compound-related custom fields:
                              *** End of Report ***
```

Data File C:\CHEM32\1\DATA\FAT NEW\0189 TO 0192 2021-01-21 09-50-18 ALEX BOYLE\006F0601.D
Sample Name: 189

Acq. Operator	: Alex Boyle	Seq. Line	: 6
Acq. Instrument	: Agilent 6890N	Location	: Vial 6
Injection Date	: 1/21/2021 12:24:51 PM	Inj	: 1
		Inj Volume	: Manually
Acq. Method	: C:\CHEM32\1\DATA\FAT NEW\0189 TO 0192 2021-01-21 09-50-18 ALEX BOYLE\RSA_GC_10162020.M		
Last changed	: 10/26/2020 4:24:53 AM by Alex Boyle		
Analysis Method	: C:\CHEM32\1\METHODS\RSA.M		
Last changed	: 6/28/2021 4:27:39 PM by Alex Boyle		
Method Info	: RSA Method for SOP-FA-002		

Sample-related custom fields:

Name	Value
Additional Info	: Peak(s) manually integrated



External Standard Report

Sorted By	: Retention Time
Calib. Data Modified	: 6/28/2021 4:27:24 PM
Multiplier:	: 1.0000
Dilution:	: 1.0000

Use Multiplier & Dilution Factor with ISTDs

Signal 1: FID1 A,

RetTime [min]	Sig	Type	Area [pA*s]	Amt/Area	Amount [ug/g]	Grp	Name
2.100	1		-	-	-	1	Isobutane
2.270	1		-	-	-	2	Butane
2.490	1		-	-	-	3	Methanol
3.058	1		-	-	-	4	Ethanol

Data File C:\CHEM32\1\DATA\FAT NEW\0189 TO 0192 2021-01-21 09-50-18 ALEX BOYLE\006F0601.D
Sample Name: 189

Acq. Operator : Alex Boyle Seq. Line : 6
Acq. Instrument : Agilent 6890N Location : Vial 6
Injection Date : 1/21/2021 12:24:51 PM Inj : 1
Inj Volume : Manually
Acq. Method : C:\CHEM32\1\DATA\FAT NEW\0189 TO 0192 2021-01-21 09-50-18 ALEX BOYLE\RSA_GC_10162020.M
Last changed : 10/26/2020 4:24:53 AM by Alex Boyle
Analysis Method : C:\CHEM32\1\METHODS\RSA.M
Last changed : 6/28/2021 4:27:39 PM by Alex Boyle
Method Info : RSA Method for SOP-FA-002

Sample-related custom fields:

Name	Value
Additional Info	Peak(s) manually integrated

RetTime [min]	Sig	Type	Area [pA*s]	Amt/Area	Amount [ug/g]	Grp	Name
3.433	1		-	-	-	5	Acetone
3.500	1		-	-	-	6	2-propanol
3.610	1		-	-	-	7	Acetonitrile
4.108	1		-	-	-	8	n-Hexane
4.752	1		-	-	-	9	Chloroform
5.200	1		-	-	-	10	Benzene
5.300	1		-	-	-	11	n-Heptane
6.254	1		-	-	-	12	Toluene
7.209	1		-	-	-	13	m,p Xylene
7.455	1		-	-	-	14	o Xylene

Totals : 0.00000

Group summary :

Group ID	Use	Area [pA*s]	Amount [ug/g]	Group Name
1	G	0.00000	0.00000	Isobutane
2	G	0.00000	0.00000	Butane
3	G	0.00000	0.00000	Methanol
4	G	0.00000	0.00000	Ethanol
5	G	0.00000	0.00000	Acetone
6	G	0.00000	0.00000	Isopropyl Alcohol
7	G	0.00000	0.00000	Acetonitrile
8	G	0.00000	0.00000	Hexane
9	G	0.00000	0.00000	Chloroform
10	G	0.00000	0.00000	Benzene
11	G	0.00000	0.00000	Heptane
12	G	0.00000	0.00000	Toluene

Data File C:\CHEM32\1\DATA\FAT NEW\0189 TO 0192 2021-01-21 09-50-18 ALEX BOYLE\006F0601.D
Sample Name: 189

Acq. Operator : Alex Boyle Seq. Line : 6
Acq. Instrument : Agilent 6890N Location : Vial 6
Injection Date : 1/21/2021 12:24:51 PM Inj : 1
Inj Volume : Manually
Acq. Method : C:\CHEM32\1\DATA\FAT NEW\0189 TO 0192 2021-01-21 09-50-18 ALEX BOYLE\RSA_GC_10162020.M
Last changed : 10/26/2020 4:24:53 AM by Alex Boyle
Analysis Method : C:\CHEM32\1\METHODS\RSA.M
Last changed : 6/28/2021 4:27:39 PM by Alex Boyle
Method Info : RSA Method for SOP-FA-002

Sample-related custom fields:

Name	Value
Additional Info	Peak(s) manually integrated

13	G	0.00000	0.00000	meta-para-Xylene
14	G	0.00000	0.00000	ortho-xylene

2 Warnings or Errors :

Warning : Calibration warnings (see calibration table listing)
Warning : Calibrated compound(s) not found

Area Percent Report

Sorted By : Retention Time
Calib. Data Modified : 6/28/2021 4:27:24 PM
Multiplier: : 1.0000
Dilution: : 1.0000
Use Multiplier & Dilution Factor with ISTDs

Peak #	RetTime [min]	Sig	Type	Area [pA*s]	Area %	Name
1	2.100	1		0.00000	0.00000	Isobutane
2	2.270	1		0.00000	0.00000	Butane
3	2.490	1		0.00000	0.00000	Methanol
4	3.058	1		0.00000	0.00000	Ethanol
5	3.433	1		0.00000	0.00000	Acetone
6	3.500	1		0.00000	0.00000	2-propanol
7	3.610	1		0.00000	0.00000	Acetonitrile
8	4.108	1		0.00000	0.00000	n-Hexane
9	4.752	1		0.00000	0.00000	Chloroform
10	5.200	1		0.00000	0.00000	Benzene
11	5.300	1		0.00000	0.00000	n-Heptane

Data File C:\CHEM32\1\DATA\FAT NEW\0189 TO 0192 2021-01-21 09-50-18 ALEX BOYLE\006F0601.D
Sample Name: 189

Acq. Operator : Alex Boyle Seq. Line : 6
Acq. Instrument : Agilent 6890N Location : Vial 6
Injection Date : 1/21/2021 12:24:51 PM Inj : 1
Inj Volume : Manually
Acq. Method : C:\CHEM32\1\DATA\FAT NEW\0189 TO 0192 2021-01-21 09-50-18 ALEX BOYLE\RSA_GC_10162020.M
Last changed : 10/26/2020 4:24:53 AM by Alex Boyle
Analysis Method : C:\CHEM32\1\METHODS\RSA.M
Last changed : 6/28/2021 4:27:39 PM by Alex Boyle
Method Info : RSA Method for SOP-FA-002

Sample-related custom fields:

Name	Value
Additional Info	Peak(s) manually integrated

Peak #	RetTime [min]	Sig	Type	Area [pA*s]	Area %	Name
12	6.254	1		0.00000	0.00000	Toluene
13	7.209	1		0.00000	0.00000	m,p Xylene
14	7.455	1		0.00000	0.00000	o Xylene

Totals : 0.00000

2 Warnings or Errors :

Warning : Calibration warnings (see calibration table listing)
Warning : Calibrated compound(s) not found

Compound-related custom fields:

*** End of Report ***

SOP: FA-SOP-003 **Place Barcodes for each ATCC on Back of Page**

Barcode

FAIRBANKS ANALYTICAL TESTING

ATCC Positive Control Form – QA/QC Batch

Date: Personal: Company:

Organism		*Observations/Result Comments*
S. Typhimurium	ATCC: Lot: Expiration Date: Item: Prep Date: Personnel:	
0157:H7 E. coli	ATCC: Lot: Expiration Date: Item: Prep Date: Personnel:	
A. *fumigatus*	ATCC: Lot: Expiration Date: Item: Prep Date: Personnel:	
A. *niger*	ATCC: Lot: Expiration Date: Item: Prep Date: Personnel:	
A. *flavus*	ATCC: Lot: Expiration Date: Item: Prep Date: Personnel:	

Comments/Notes

Reviewed by Laboratory Director Date

Fairbanks Analytical Testing 1521 Stacia St Suite A, Fairbanks, AK 99701 Phone: (907) 687-6745 Email:fairbanksanalytical@gmail.com

Commented [RE1]: Add Barcodes for Each organism ATCC which was cultured. This allows for the tracking of each organism which is used for QA/QC.

Commented [RE2]: Barcode label that is generated for tracking purposes. See SOP for instructions i

Commented [RE3]: This is the Date the form was filled out

Commented [RE4]: This is the person that fills out the form

Commented [RE5]: This is the company which preformed the test -m example: Fairbanks Analytical Testing

Commented [RE6R5]:

Commented [RE7]: Salmonella organism control information:

ATCC Number of Derived Organism from Microbiologics
Lot: Lot number of organisms
Expiration Date of product
Prep Date: Stock culture or secondary culture preparation date

Personnel: Person who made the control culture

Commented [RE8]: Overall Comments relating to organisms used for controls

Commented [RE9]: Signature from laboratory director

Commented [RE10]: Date of signature from laboratory director

CORRECTIVE/PREVENTIVE ACTION

Fairbanks Analytical Testing.

FAIRBANKS ANALYTICAL TESTING

☒ Corrective Action ☐ Preventive Action ☐ Opportunity for Improvement

Source	Reference	Comments
☐ Internal Audit		
☒ External Audit		
☐ Customer Complaint		
☐ Product Deficiency		
☐ Other:		

Fairbanks Analytical cannot provide exact integrated peak matches for data submitted on spreadsheets due to manual integration reports not being annotated or saved properly.

Initiator:	Dylanne Macomber	Signature:	Date:	9/14/21

Assigned to:	Reply Due Date:	

Root Cause: The computers for both the GC and HPLC print out the pdfs which are automatically saved into a defined folder. reports do not include manual integration, only original peak areas acquired by the equipment.

Actions Taken or Planned: Sample is ran and the HPLC and GC print a report for the sample - the data is automatically copied into the excel file. Data is then sent to the LIMS.

In the event that an anomaly is identified by the analyst, the correction is made, and the laboratory will do one of two things:

1) The lab will fix the anomaly and annotate the original report that was generated

2) The laboratory will fix the anomaly and regenerate a report (which will be updated in excel and the LIMS) Both reports will be annotated to include a file ID (i.e. 23-47-42) and dated comment with the analyst initials. The goal is to show the derivatization of the results from the chromatogram.

			Planned Completion Date:	9/14/21
Submitted by:	Dylanne Macomber	Signature:	Date:	9/14/21

Comments by Approval Authority:

Approved by:	Dylanne Macomber	Signature:	Date:	9/14/21
Followed Up by:		Signature:	Date:	
Effective? ☐ Yes ☐ No		Evidence:		
Closed Out by:		Signature:	Date:	

Daily Microbiology Checklist

Check Daily	Comments	Initials
☐ pH meter		
☐ NIST Thermometers		
☐ Scale		
☐ Micro pipettes		
☐ Control Organisms		
☐ Incubators		
☐ Autoclave		
☐ Laminar Flow Cabinet		
Housekeeping, General Safety and Hygiene	**Comments**	**Initials**
☐ Work areas are clean and free of spilled material		
☐ Bio-hazardous waste processed properly		
☐ Items are stored, labeled, and recorded properly		
☐ PPE Available (Gloves, Lab Coat, Glasses, Footies)		
Organism Control Maintenance	**Comments**	**Initials**
☐ E.coli (0157:H7) ☐ S. Typhimurium ☐ A.fumigatus ☐ A.Flavus ☐ A. niger		
☐ Barcode IDs updated		
Forms to Complete	**Comments**	**Initials**
☐ Preperation of Tryptic Soy Broth		
☐ Preperation of DRBC Record Log		
☐ Latex Assay Form		
☐ ATCC Positive Control Form - QA/QC Batch		
☐ Standard Fridge/Freezer Log		
☐ Autoclave Use/Maintenance Log		
☐ Incubator Log		
☐ Thermometer Record Log		
☐ Quality Control Log for New Media Lot		
☐ Sample Batch Log		
☐ Preperation of SMAC Record Log		
Laboratory Compliance	**Comments**	**Initials**
☐ Positive Controls ☐ Negative Controls ☐ Sterility Blank		
☐ Media QA/QC for new lots		
☐ Samples ran with duplicates and controls		
☐ Positive cultures photographed and recorded on batch sheet		
☐ Incubators within defined ranges		

Last Name	First Name	Middle Initial

Date

City	State	Zip

FAIRBANKS ANALYTICAL TESTING

ilac-MRA A2LA ACCREDITED

FAIRBANKS ANALYTICAL TESTING

Fairbanks Analytical Testing LLC

QR code and Bench sheet explanation.

ATCC Positive Control Form- Please Reference bench sheets for information specific the bench sheet, this form shall be filled out with every batch of samples ran. All encompassing QR code labels shall be placed on the back of the sheet from here on out.

Latex Bench Sheet- The latex bench sheet shall be filled out with every batch of samples ran to confirm the positive control as well as a samples confirmation test for presumptive growth of E. coli 0157.

Plates- Once plates are poured, they shall receive a label with two QR Codes one on top one on the bottom the Preparers initials of the plate as well as the date and Plate number associated with that batch of media before they are placed in the fridge. The top QR code when scanned will read the Media ID number, which will correlate with the Media Prep Sheet specific for that Media ID for additional information (i.e media preparer, lot number) The top QR code after sample has been plated and is ready to put in incubator shall be scanned into the "log" section of Confident Cannabis for that specific sample. When scanned it shall read the media name media ID and "plated and placed in Incubator" once this has been scanned into Confident cannabis logs section it is now tracked and unable to be changed, it will also provide a time stamp and will state the name of the person scanning the plate. For Salmonella plates the barcode shall read the lot number of the Dry compact plates being used as well "plates put in incubator.

The bottom QR code shall be scanned once they are pulled from the Incubator to be analyzed it shall state "plate pulled from incubator" and will again have a time stamp and a name associated with the personnel pulling and analyzing the plate.

If further review/analysis or microscopy is necessary, then it shall be typed into the logs by the reviewer for COC.

QR code will also be made with each batch of TSB and placed on the plates to be scanned in as well as all stock solutions used for controls for the samples. These will also be scanned into Confident Cannabis.

Form

FAIRBANKS ANALYTICAL TESTING

Media Quality Control Record

G = Growth
NG = No Growth

Name	Date	Media ID	Lot Number	pH	Control Results			Validated
					Positive	Negative	Sterility	
TSB	2/3/21	TSD-PB12, RT	VM19411 30089	7.3	G	NG	NG	Yes
SAL DC	2/3/21	T4085	C0052102	NA	G	NG	NG	

Reviewed by

08/3/21
Date

Form

FAIRBANKS ANALYTICAL TESTING

Preparation for Tryptic Soy Broth

Exp. 9/21/21 (Three wks)

Preparer: Alex Tackett Date: 8/31/21

Media ID: TSB.OP312021.AT

Storage Temperature: 23 (C) Temperature within range?: ☑ Yes ☐ No

Broth Lot#: VM941159039 Expiration Date: 09/02/2025 median

Amount of broth weigh out: 17.001 (g) 30.0g ± 0.1 g

Amount of Purified water added: 500 mL (L) 1L

Was solution brought to a boil for a minimum of 1 min not to exceed 3 min?: ☑ Yes ☐ No

Did the broth dissolve?: ☑ Yes ☐ No

pH of broth: 7.3 (7.3 ± 0.2)

Was broth solution sterilized using the autoclave?: (15 minutes @ 121°C) ☑ Yes ☐ No

Was the autoclave log Completed?: ☑ Yes ☐ No

Sterilization successful?: ☑ Yes ☐ No

Was broth cooled within an acceptable range before Placed in Fridge?: 40 – 50 (°C) ☑ Yes ☐ No

How much was made?: 760 (mL)

Time of storage: 0821

Date of storage: 8/31/21

Was date and initials written on plates when stored?: ☑ Yes ☐ No

Use broth within a week. Dispose of waste per Microbiology Manual DO NOT POUR DOWN DRAIN!

T S B Culture in Culture out Initials: AT Date: 8/31/21 Fairbanks Analytical Testing, LLC

Tryptic Soy Broth
ID: TSB.08312021.AT
Batch Date: 08312021
Exp Date: 9/21/21
Item: TSB
Lot: VM941159039
Enrichment Broth
Prep: Alex Tackett

500 mL
Batch Stock

Fairbanks Analytical Testing LLC.

Microbial Checklist Plan

9/15/2021

Scope: This plan shall be used to ensure that the Microbial SOP is being followed within Fairbanks Analytical Testing's day to day operations.

Plan: Attached is Fairbanks Analytical Testing's new revised microbial checklist, this checklist will be filled out every day, and encompasses all aspects of microbial procedure. This checklist shall be completed by the Director or Lab Manager, or a trained technician performing the microbial duties that day and reviewed by the director or manager. The check list is expected to be 100% complete daily.

Any findings that are discovered while performing the checklist shall be brought to the immediate attention of the director or the Lab Manager and shall have a Corrective action put into place immediately. A root cause must be determined, and the lab manager or director will implement the preventive measures.