THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Environmental Conservation

DIVISION OF ENVIRONMENTAL HEALTH
Environmental Health Laboratory

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July 29, 2021

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

RE: Fairbanks Analytical Testing – Audit Report for Onsite Audit – Review comments for July 23, 2021 Laboratory Submittal

Dear Director Klinkhart:

The attached audit report for the May 2021 audit of Fairbanks Analytical Testing (FAT) is updated to reflect FAT's second response (dated July 23, 2021) since the initial issuance of this report on May 25, 2021. FAT's initial responses through July 2, 2021 closed 7 of 30 findings. This response closes 4 of the 23 remaining findings. A due date of August 13, 2021 is requested for the remaining 19 findings.

FAT has not completely made available documentation demonstrating an ability to defend the validity of their work. Basic questions regarding traceability of reported results and proving through documentation that SOPs are followed, remain unanswered. These questions remain through repeated requests for clarification, both during the onsite audit and communication exchanges post-audit. Select documents, for which availability was requested prior to the audit for the onsite audit, are still unavailable to the audit team over two months later. The tone of the laboratory's 7/23/21 response appears disinterested in nature. The laboratory stated three times (Findings 5, 6, and 13) in the audit response that required actions will not be completed due to a pending operational 2-month shutdown. The laboratory incorrectly cites regulations and past A2LA reviews as justification for not completing Findings 4, 6 and 15. The laboratory did not address all the points of Findings 1, 2, 12, 25, 26, 29, and 30. The extent and nature of the open findings and their continuing unresolved status warrant consideration for suspension until all corrective actions are closed, in the interest of public health and commerce.

If you have any questions or require additional information after reviewing the audit report, please feel free to contact us at declabcert@alaska.gov or (907) 375-8200.

Sincerely,

Shera Hickman
Chemist 4
State of Alaska
Department of Environmental Conservation
Environmental Health Laboratory

Cc: Rick Helms, AMCO Program Coordinator
James Hoelscher, AMCO Enforcement Supervisor
Michael Chiesa, AMCO Investigator
Dylanne Macomber, Fairbanks Analytical Testing
Alex Tackett, Fairbanks Analytical Testing

Alaska Department of Environmental Conservation
Environmental Health Laboratory
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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)

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.

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.

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.

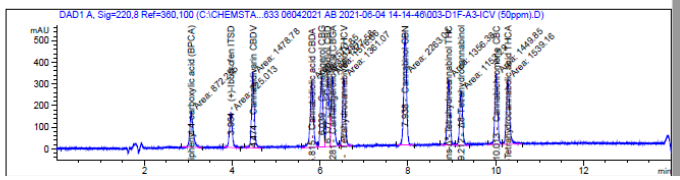
   Action: For each injection in the two logs (53 injections on 6/21/2021 and 31 injections on 6/26/2021), submit an injection summary report containing the data represented below, which is an excerpt of a summary submitted on 6/28/2021. Two of the injection summary reports were submitted, but the request 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 [min]	Type	Area [mAU*s]	Amt/Area	Norm %	Grp	Name
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		

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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?

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.

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.

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.

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.

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.

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.

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.

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 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.

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!

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