FLORIDA DEPARTMENT OF Environmental Protection

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2600 Blair Stone Road
Tallahassee, FL 32399-2400

Ron DeSantis
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Secretary

VIA EMAIL
Read receipt requested

August 1, 2019

Eric Smith
ALS Laboratories, Inc., Jacksonville, FL
9143 Phillips Highway, Suite 200
Email: Eric.Smith@alsglobal.com

Re: Final Audit Report for Microbiology Lab Records and Quality System Audit

Dear Mr. Smith:

Thank you for responding to the preliminary report and subsequent review of the draft final report for the Microbiology Lab Records and Quality System Audit of ALS Laboratories, Inc. (ALS), Jacksonville. The Florida Department of Environmental Protection (department or DEP) has reviewed your response and proposed corrective actions.

Attached is the final audit report detailing the audit procedure, audit findings, and the department's audit conclusions. This final audit report will also be posted on the department's website at http://www.dep.state.fl.us/labs/cgi-bin/reports/search.asp. As noted in the report, the department concluded that the laboratory procedures and laboratory documentation used by ALS have not met the QC criteria required by the approved methods, NELAC 2003 standards, Chapter 62-160, Florida Administrative Code (F.A.C.), and/or DEP contract requirements. The critical finding for the laboratory is the frequency of outside of range or missing temperatures on incubator logs.

Due to this critical finding, results for fecal coliform, Enterococci and *E. coli* generated by ALS before the corrective action implementation date may be considered by DEP as estimated for certain uses of the data. DEP auditors determined other QC deficiencies as well, as outlined in the report. The laboratory's implementation of corrective actions described in this report will lead to an improved quality system. DEP may verify the implementation of corrective actions with future requests for QC documentation.

Under Chapter 120 of the Florida Statutes, ALS, and any other person whose substantial interests are affected by the department's agency action, may challenge the attached final audit report, including the corrective actions and the data usability analysis. The process to challenge any portion of this agency action is described below in the Notice of Rights section.

If you have any questions or concerns about this final audit report, please feel free to contact Nia Wellendorf at (850) 245-8190 or Kristen Sapp at (850) 245-8686.

Notice of Rights

This action is final and effective on the date mailed (via e-mail) unless a sufficient petition for an administrative hearing is timely filed under sections 120.569 and 120.57 of the Florida Statutes as provided below. If a sufficient petition for an administrative hearing is timely filed, this agency action becomes only proposed agency action, subject to the result of the administrative review process. Therefore, on the filing of a timely and sufficient petition, this action will not be final and effective until further order of the department. Because an administrative hearing may result in the reversal or substantial modification of this action, the petitioner is advised not to proceed until the deadlines noted below for filing a petition for an administrative hearing or request for an extension of time have expired.

Petition for Administrative Hearing

A person whose substantial interests are affected by the Department's action may petition for an administrative proceeding (hearing) under Sections 120.569 and 120.57, F.S. Pursuant to Rules 28-106.201 and 28-106.301, F.A.C., a petition for an administrative hearing must contain the following information:

(a) The name and address of each agency affected and each agency's file or identification number, if known;
(b) The name, address, any e-mail address, any facsimile number, and telephone number of the petitioner, if the petitioner is not represented by an attorney or a qualified representative; the name, address, and telephone number of the petitioner's representative, if any, which shall be the address for service purposes during the course of the proceeding; and an explanation of how the petitioner's substantial interests will be affected by the agency determination;;
(c) A statement of when and how the petitioner received notice of the agency decision;
(d) A statement of all disputed issues of material fact. If there are none, the petition must so indicate;
(e) A concise statement of the ultimate facts alleged, including the specific facts that the petitioner contends warrant reversal or modification of the agency's proposed action;
(f) A statement of the specific rules or statutes that the petitioner contends require reversal or modification of the agency's proposed action, including an explanation of how the alleged facts relate to the specific rules or statutes; and
(g) A statement of the relief sought by the petitioner, stating precisely the action that the petitioner wishes the agency to take with respect to the agency's proposed action.

The petition must be filed (received by the Clerk) in the Office of General Counsel of the Department at 3900 Commonwealth Boulevard, Mail Station 35, Tallahassee, Florida 32399-3000, or via electronic correspondence at Agency_Clerk@dep.state.fl.us. Also, a copy of the petition shall be mailed to ALS at the address indicated above at the time of filing.

Time Period for Filing a Petition

In accordance with Rule 62-110.106(3), F.A.C., petitions for an administrative hearing by the applicant and persons entitled to written notice under Section 120.60(3), F.S., must be filed within 21 days of receipt of this written notice. Petitions filed by any persons other than the applicant, and other than those entitled to written notice under Section 120.60(3), F.S., must be filed within 21 days of publication of the notice or within 21 days of receipt of the written notice, whichever occurs first. The failure to file a petition within the appropriate time period shall constitute a waiver of that person's right to request an administrative determination (hearing) under Sections 120.569 and 120.57, F.S., or to intervene in this proceeding and participate as a party to it. Any subsequent intervention (in a proceeding initiated by another party) will be only at the discretion of the presiding officer upon the filing of a motion in compliance with Rule 28-106.205, F.A.C.

Extension of Time

Under Rule 62-110.106(4), F.A.C., a person whose substantial interests are affected by the Department's action may also request an extension of time to file a petition for an administrative hearing. The Department may, for good cause shown, grant the request for an extension of time. Requests for extension of time must be filed with the Office of General Counsel of the Department at 3900 Commonwealth Boulevard, Mail Station 35, Tallahassee, Florida 32399-3000, or via electronic correspondence at Agency_Clerk@dep.state.fl.us, before the deadline for filing a petition for an administrative hearing. A timely request for extension of time shall toll the running of the time period for filing a petition until the request is acted upon.

Mediation

Mediation is not available in this proceeding.

This determination constitutes an order of the department. Subject to the provisions of paragraph 120.68(7)(a) of the Florida Statutes, which may require a remand for an administrative hearing, the applicant has the right to seek judicial review of the order under section 120.68 of the Florida Statutes, by the filing of a notice of appeal under rule 9.110 of the Florida Rules of Appellate Procedure with the Clerk of the Department in the Office of General Counsel, 3900 Commonwealth Boulevard, Mail Station 35, Tallahassee, Florida, 32399-3000, or via electronic correspondence at Agency_Clerk@dep.state.fl.us; and by filing a copy of the notice of appeal accompanied by the applicable filing fees with the appropriate district court of appeal. The notice of appeal must be filed within 30 days from the date when the final order is filed with the Clerk of the Department.

Executed in Tallahassee, Florida.

STATE OF FLORIDA DEPARTMENT
OF ENVIRONMENTAL PROTECTION

David Whiting, Deputy Director
Division of Environmental Assessment and Restoration
2600 Blair Stone Road
Tallahassee, FL 32399
Tel No.: (850) 245-8191

Attachments:
Final Audit Report

Copies furnished to:

Kenneth Hayman, DEP Office of General Counsel
Cheryl Swanson, DEP Biology Program
File

CERTIFICATE OF SERVICE

The undersigned duly designated deputy clerk hereby certifies that this determination, including all copies, was e-mailed before the close of business on August 1, 2019, to the above listed persons.

FILING AND ACKNOWLEDGMENT

FILED, on this date, pursuant to 120.52(7)
Florida Statutes, with the designated Department Clerk,
receipt of which is hereby acknowledged.

Ashley Phillipo 8/1/19
Clerk Date

Final Audit Report
ALS Environmental Laboratory - Jacksonville
DOH # E82502
Microbiology Laboratory Audit
Conducted December 10-11, 2018

Division of Environmental Assessment and Restoration
Florida Department of Environmental Protection
August 1, 2019

Introduction

This laboratory quality system and records audit of the ALS Environmental Laboratory (ALS) was conducted by the Florida Department of Environmental Protection (DEP or department) Aquatic Ecology and Quality Assurance Section (AEQAS) and Biology Program. The audit was conducted in accordance with Rules 62-160.650 and 62-160.670, Florida Administrative Code (F.A.C.), to verify that ALS is complying with the quality assurance (QA) requirements of DEP contract LAB037 and correctly implementing approved analytical methods, including acceptable quality control, and maintaining adequate laboratory documentation.

This final audit report lists the procedural and documentary deficiencies as determined by the department auditors, responses from the audited party, and the department's response to the corrective actions proposed by the laboratory.

Audit Description

In May 2018, DEP performed a records-only audit for fecal coliform, E. coli, and enterococci samples analyzed under contract LAB037 during 2017 (Table 1). The preliminary report was sent to ALS on June 27, 2018. Policies, practices, documents, or records that did not comply with evaluation criteria for lab analysis were identified, and corrective actions were indicated (Table 2). ALS replied with comments to the corrective actions on August 13, 2018 (Table 2).

The auditors could not determine compliance with the contract requirements based on the laboratory's responses, so DEP scheduled an in-person audit to review additional records and review the lab's quality system for microbiology analyses. DEP auditors Nia Wellendorf and Kristen Sapp from AEQAS and Avril Wood-McGrath from the Biology Program visited ALS on December 10-11, 2018. DEP staff met with Eric Smith, the QA officer, Valerie Spears, the supervisor, and Halee Hernandez, the analyst, and reviewed records for samples that covered a broader analysis date range (Table 3).

Records reviewed included custody chains, laboratory check in logs, analytical runs, laboratory reports, and QA and Quality Control (QC) documentation. The systems portion of the audit included verification of laboratory procedures through review of laboratory analytical and QC records for the microbiological tests, the laboratory Quality Manual and Standard Operating Procedures (SOPs), interviews with laboratory staff, and direct observation. The DEP contract LAB037, the 2003 National Environmental Laboratory Accreditation Conference (NELAC) standards, and the relevant methods listed in Tables 1 and 3 provided the criteria for the audit and all findings.

Preliminary Audit Report and Implementation of Corrective Actions

A preliminary audit report of findings and deficiencies was sent to Eric Smith of ALS on March 7, 2019. Procedures or documentation that did not comply with audit criteria are identified in Tables 4 and 5, along with the department's suggested or required corrective actions. DEP approved a request from ALS for a time extension to provide responses to the findings. Mr. Smith provided responses to the preliminary report with proposed corrective actions and implementation dates for the noted deficiencies on May 3, 2019, and those responses have been included in Tables 4 and 5. Mr. Smith also provided a cause analysis report (Appendix A), which provides additional insight into the causes of deficiencies. The auditors reviewed and accepted

most of the proposed corrective actions. On July 10, 2019, DEP staff requested clarification for two findings: Table 4, Finding 1, and Table 5, Finding 4. Clarifications and supplemental documentation were provided by ALS on July 17. The responses were reviewed and accepted. The auditors' responses are found in the last column of Tables 4 and 5.

Audit Conclusions

Based on the findings from this audit, DEP has determined that the laboratory has not met one critical QC criterion required by the approved methods, NELAC 2003 standards, and/or DEP contract requirements. The critical finding for the laboratory is the frequency of outside of range or missing temperatures on incubator logs. DEP auditors determined other QC deficiencies as well, as outlined in the findings tables.

The laboratory's implementation of corrective actions described in this report will lead to an improved quality system. DEP will verify the implementation of corrective actions with future requests for QC documentation. Due to findings deemed critical by DEP auditors, data analyzed during the date range evaluated under this audit and data affected by the problems identified in the audit may be considered by DEP as estimated values for certain uses of the data.

NOTE: The audit evaluated the indicated data for the use(s) described in this report. The usability of the audited data for other purposes or the usability of data produced by the audited organization for other analytes or other date ranges must be determined separately according to applicable requirements in rule 62-160.670, F.A.C.

Table 1. List of audited samples for the records audit of ALS Environmental Laboratory conducted by DEP's AEQAS and Biology Program, May 2018.

Lab ID	Collection Date	Analyte	Method
J1704846-001	7/17/2017	Fecal Coliform	SM 9222D
J1705546-001	8/14/2017	Fecal Coliform	SM 9222D
J1707172-001	10/23/2017	Fecal Coliform	SM 9222D
J1706481-004	9/26/2017	*E. Coli*	SM 9223B
J1707266-003	10/25/2017	*E. Coli*	SM 9223B
J1708005-003	11/27/2017	*E. Coli*	SM 9223B
J1704584-003	7/6/2017	Enterococci	ASTM D6503
J1705788-002	8/23/2017	Enterococci	ASTM D6503
J1706509-005	9/27/2017	Enterococci	ASTM D6503
J-1707738-002	11/14/2017	Enterococci	ASTM D6503

Table 2. Audit Findings for the lab records audit of ALS Environmental Laboratory conducted by DEP's AEQAS and Biology Program, May 2018.

Finding #	Analyte	Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action (CA)	Laboratory Response	Implementation Date	DEP response, additional corrective actions
1	Fecal Coliform	For confirmations, only one end time is recorded for each sample. There are two tests involved in confirmations that have different incubation times. It is unclear if the start and end times are times in the incubator, and with only one time recorded, we cannot verify that the samples run on EC-MUG were incubated the correct amount of time. The structure of the log sheet makes it appear that EC- MUG results are read at 48 hours, not the method prescribed 24 hours.	J1704846-001, J1705546-001, J1707172-001	**Required:** Record time in and time out of incubator for all tests and read EC-MUG results at 24 hours.	Benchsheet used to record colony verification has been updated and BIO-QC SOP will be updated to provide the clarification.	Benchsheet – Done SOP – 8/31/2018	This CA is acceptable. Please provide a copy of the updated benchsheet.
2	Fecal Coliform	The original result for the samples used for confirmations is not recorded on the confirmation log. This makes it difficult to re-create the analysis and easily confirm that method requirements are followed.	J1704846-001, J1705546-001, J1707172-001	**Recommended:** For each sample used for confirmations, record the original result on the confirmation log.	A place to record original and revised sample result has been added to the benchsheet.	Done	Please provide copies of updated confirmation benchsheet templates, along with the date the updates were effective.
3	Fecal Coliform	Only two analysts are participating in counting variability. Each analyst performing the test shall read the same plate monthly.	J1704846-001, J1705546-001, J1707172-001	**Required:** Have all analysts perform the counting variability test monthly.	ALS Environmental - Jacksonville only has 2 trained analysts.	N/A	Acceptable.

Finding #	Analyte	Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action (CA)	Laboratory Response	Implementation Date	DEP response, additional corrective actions
4	Fecal Coliform	The sample result changed from >6000 Z in the original report to 1 Z in the amended report. Both are incorrect, and the result should have been marked as invalid.	J1705546-001	**Required:** Provide an explanation for changing the result. Review with staff the correct procedure for this type of result and review the policy on amending reports.	Sample was TNTC Neg (1 Z) but was originally reported as TNTC Pos (>6000 Z). Report was updated when the error was discovered.	N/A	The corrected report still does not conform with method requirements. The result is invalid, per PO requirements. The result should be "no result Z." Please send the corrected report according to directions in the PO.
5	Fecal Coliform	No duplicate was run on the benchsheet with this sample.	J1705546-001	**Required:** Submit a benchsheet for a duplicate run within 30 minutes of this sample or provide an explanation for the absence.	Duplicate samples were not being analyzed consistently. Analysts were retrained on the appropriate procedure earlier this year. This has been reviewed again with current microbiological staff.	Done	Acceptable. Please provide a corrective action date. This was further evaluated in the follow up audit (see Table 4, Finding 7).
6	Fecal Coliform	The result appears to be calculated incorrectly. The only valid plate count was 63 (two other dilutions had zero) from the 50 ml dilution. The result should be 126.	J1707172-001	**Required:** Correct the sample result or explain how the result of 100 was calculated.	The report has been revised to report a value of 126 CFU/100mL. **Rationale for original reported result:** The 63 positive colonies from the 50mL dilution is outside of the ideal range of 20-60CFU. The 10mL plate had negative colony counts within the ideal range, yet no positive colonies, therefore all dilutions were used to calculate the reported result. **Note:** Sample was already flagged as estimated due to incubating outside of required temperature, which can cause variability in results. Also, FDEP limit is 4000 CFU/100mL and both results are well below the action limit.	Done	The auditors' interpretation differed from the lab's, but both results are valid. The DEP lab agrees that counting all dilutions is appropriate. The report dated 10-26-17 does not have a J qualifier. Please provide the amended report. Note: ALS should report results based on method requirements, not DEP water quality standards or other limits.

Finding #	Analyte	Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action (CA)	Laboratory Response	Implementation Date	DEP response, additional corrective actions
7	Fecal Coliform	The analyst counting variability test and duplicate sample that correspond with this sample were not provided.	J1707172-001	**Required:** Provide the relevant records or explain the absence.	There are no records from Oct 2017 for fecal colony counting verification. Primary analyst did not initiate, per SOP. Training was provided to current analysts to clarify who is responsible for initiating the verification. This has been reviewed again with current microbiological staff.	Done	Please provide a corrective action implementation date for this finding. Duplicate samples were also not completed for this sample; however, that response was provided for Finding 5 in this table.
8	E. coli	ALS ran two dilutions for this sample but did not explain how they chose which result to report.	J1706481-004	This issue has been previously addressed by ALS to DEP's satisfaction. No corrective action necessary.	NA	NA	Emails show that this issue was resolved in February 2018. ALS agreed to run IDEXX methods at a single dilution of 10 mls.
9	E. coli & Enterococci	The mixing vessel volume check is not performed as required by the PO.	J1706481-004, J1707266-003, J1708005-003, J1704584-003, J1706509-005, J1707738-002	**Required:** Add the mixing vessel volume check to the regular QC performed on each lot of consumables.	Each lot of sterile bottles has been volume checked upon receipt.	See attached example.	Finding was incorrect due to auditor misinterpretation. No corrective action needed.
10	E. coli	The media checks appear to have been done two months after the media was received, and after it had been used for samples.	J1708005-003	**Required:** Conduct media checks before use with samples. For this sample, confirm the analysis date of the media checks. If it was after the sample analysis date, review media check procedures with staff.	Verified clarity in SOP. Analyst from last year no longer works for ALS. Procedure has been reviewed with current microbiological staff.	Done	Please provide a corrective action implementation date for this finding. This finding was further evaluated in the follow up audit; please see Table 4, Finding 10.

Finding #	Analyte	Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action (CA)	Laboratory Response	Implementation Date	DEP response, additional corrective actions
11	all	The incubator and water bath temperature checks are frequently forgotten in the afternoon.	all	**Required:** Review temperature control procedures with staff.	Verified clarity in SOP. Analyst from last year no longer works for ALS. Procedure has been reviewed with current microbiological staff.	Done	Please provide a corrective action implementation date for this finding. This finding was further evaluated in follow up audit. Please see Table 4, Finding 1.
12	all	When the incubator or water bath temperature is out of range, there are no notes about corrective actions or qualifying samples. We did not find any guidance on when/how to qualify samples. Six out of the ten audited samples did not have evidence of passing incubator temperatures. None of them were qualified for out of control testing conditions.	all	**Required:** Institute guidelines for when corrective actions should be taken and when/how to qualify samples. Verify that all incubators are operating correctly and holding the appropriate temperature.	The temperature log and the BIO-QC SOP will be updated to include additional instruction on the corrective action process to follow when the incubator or water bath temperature is out of range, including qualification of samples where necessary.	8/31/2018	This finding was further evaluated in follow up audit. Please see Table 4, Finding 1.
13	all	The sample analysis time reported is the time of filtration/pouring. The time incubation started is required by the PO.	all	**Required:** Ensure that the time incubation started and ended is reported for all microbiology samples	The benchsheets were updated to export the incubation start time as the date/time of analysis. The incubation start time is now the analysis time that appears on the report.	Done	Acceptable. Please provide a corrective action implementation date for this finding.

Table 3: List of audited samples for the records audit of ALS Environmental Laboratory conducted by DEP's AEQAS and Biology Program, December 10-11, 2018.

Lab ID	Collection Date	Analyte	Method
J1508593-001	10/28/2015	Fecal Coliform	SM 9222D
J1607878-008	11/8/2016	Fecal Coliform	SM 9222D
J1702498-002	4/11/2017	Fecal Coliform	SM 9222D
J1806419-003	9/6/2018	Fecal Coliform	SM 9222 D
J1802765-007	4/17/2018	Enterococci	ASTM D6503
J1701402-001	2/27/2017	Enterococci	ASTM D6503
J1800539-003	1/22/2018	Enterococci	ASTM D6503
J1706454-001	9/25/2017	*E. Coli*	SM 9223 B
J1801524-004	3/1/2018	*E. Coli*	SM 9223 B
J1708058-001	11/28/2017	*E. Coli*	SM 9223 B

Table 4: Audit Findings for the lab records audit of ALS Environmental Laboratory conducted by DEP's AEQAS and Biology Program, December 10-11, 2018.

Finding #	Analyte	Standard or Method Reference	Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action	Laboratory Response	DEP Response
1	All	NELAC D.3.8, SM 9020, Table I, NELAC 5.4.10	Incubator temps are often not checked. Out of control temperatures are adjusted without further corrective actions. Specific samples with missing or out of control temperatures are listed here. Checking the temperatures and following up with corrective actions for out of control temperatures was an ongoing issue in most records reviewed from 2015-2018. The corrective action code indicated on the logs (B) is inappropriate if the temperature is out of control. Resetting the thermostat without investigating the cause of the drift does not comply with NELAC standards.	J1706454-001 J1708058-001 J1802765-007 J1800539-003 J1806419-003 J1508593-001 J1607878-008 J1702498-002	**Required:** Provide a corrective action report that details the date range the problem existed, the methods affected, what was done to correct it and when, and an estimate of how many DEP samples were affected. ·Language added to the SOP pursuant to the June 2018 preliminary report was an improvement, but additional language is needed in the SOP to specify which corrective actions to use in different scenarios. ·Add prompts to temperature logs for last thermometer verification and applicable correction factor. ·Include this issue in the cause analysis as directed in this report under Required Response.	Corrective action code "B" is a corrective action after cause has been initially evaluated. Code "B" also indicates to recheck the temperature (after one hour per SOP) to verify that the corrective action was adequate to address the issue. If it is not, then additional corrective action measure would be required. As noted on the temperature log sheet, more than one corrective action code may be applied as needed. At the end of each month, secondary review of the temperature log is performed. If a trend of incubator temperature failures or omittances is identified, an NCAR will be generated. This will elevate the issue to management review. An BIO-QC SOP amendment form has been generated to 1) clarify review of incubator temperature logs for a trending failures that would require an NCAR to be generated, and 2) clarify that investigation of the root cause(s) of an exceedance is required to be performed prior to corrective action. A prompt to record the Correction Factor was added to all temperature log forms effective 1/1/2019. The BIO- QC amendment form is provided as Attachment D. **Implementation date:** 5/3/2019 **7/17/19 Follow up Response:** The BIO-QC SOP has been revised to require supervisor review of the temperature log every time there is a temperature exceedance to confirm that appropriate corrective action was taken. Language regarding taking the equipment out of service if necessary and specific corrective action measures to take was also added to the BIO-QC SOP. The BIO-QC amendment form is provided as Attachment T. **Follow up implementation date:** 7/17/2019	We are not sure this adequately addresses the issues. The SOP instructs the analyst to perform corrective actions but doesn't detail what those actions are. If the temperature cannot be controlled, the instrument should be taken out of use until repaired and this should be detailed in the SOP. If the temperature log is only reviewed monthly, does that mean that ongoing failures will not be addressed until the review happens? That seems to create a high risk of having to qualify a large number of samples if the incubator is malfunctioning. We are looking for assurance that persistent problems are addressed immediately so that further samples are not impacted. Response 7/19/19: Acceptable.

Finding #	Analyte	Standard or Method Reference	Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action	Laboratory Response	DEP Response
2	Enterococci	NELAC 5.4.12.2.1	This sample report was changed twice, but all versions were not linked. The final version, dated 7-20-18, added a J qualifier without a comment explaining the reason, and had no narrative explaining the change from the previous report.	J1802765-007	**Required:** Establish a procedure to link amended reports with the original so changed information and sample history is not lost. Always link a comment when using a J qualifier.	Historically, case narrative forms have been manually added to reports. On April 1st of this year, we implemented a new system that automatically inserts case narrative forms during report generation, which will help to eliminate future errors such as the one that occurred in the revised report for J1802765. A revised report for J1802765 has been generated. The revised case narrative for J1802765 is provided as Attachment E. **Implementation Date:** 4/1/2019	Acceptable
3	Enterococci	ASTM D6503 11.2.4	Documentation was not found of negative control checks for gram negative bacteria.	all	**Required:** Perform a negative control with *Serratia marcescens*.	Negative control checks have regularly been performed using Pseudomonas aeruginosa. A method modification has been added to the BIO-Entero SOP indicating that P. aeruginosa is also a gram negative bacteria, making it a suitable substitute. The BIO-Entero SOP change is provided as Attachment F. **Implementation Date:** 5/3/2019	Acceptable
4	Fecal Coliform	NELAC 5.4.12.1.5	The media checks for these samples have no linkage to the dilution/rinse water used for their preparation.	J1607878-008 J1508593-001 J1702498-002	**Required:** Ensure that all consumables and reagents are linked on the benchsheet.	Media check form had been updated prior to the assessment and is provided as Attachment G. **Implementation Date:** 4/27/2019	Acceptable
5	Fecal Coliform	62-160 F.A.C., table 1, NELAC D.3.1	This sample had a positive fecal result on the blank, but there was no qualifier added for this deviation.	J1607878-008	**Required:** Qualify samples associated with a contaminated blank.	SOPs have been revised to clarify reporting requirements for samples associated with blank contamination. A revised report has been generated for J1607878. Excerpts from the report and an SOP amendment forms for BIO- 9222D, BIO-Entero, and BIO-9223B MPN are provided as Attachment H. **Implementation Date**: 5/3/2019	Acceptable

Finding #	Analyte	Standard or Method Reference	Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action	Laboratory Response	DEP Response
6	Fecal Coliform	NELAC 5.4.10.2, SM 9020	Analyst variability was not conducted for April 2017. These types of errors should be caught during routine QA review and corrective actions taken.	J1702498-002	**Required:** Ensure all quality assurance requirements are completed on time. Include this issue in the cause analysis as directed in this report under Required Response.	Currently, compliance review takes place after QA is submitted, sometimes after the appropriate timeframe, not leaving time to perform the requirement, only reprimand. A calendar reminder has been generated on the third week of the month for the supervisor to check the progress of QA requirements, so that effective corrective action can be taken. BIO-QC has been updated to list this requirement. The Annual Micro QC Checklist (IF-77) has been updated to include a spot to document monthly supervisor review. See Attachment I for copies of the BIO-QC SOP amendment form and Annual Micro QC Checklist (IF-77). **Implementation Date:** 5/3/2019	Acceptable
7	All	DEP Guidance Document, *Laboratory Quality Control Duplicates.*	Duplicates were not run, as required by DEP contract. ALS has stated that duplicates were run inconsistently in the past, but the problem has been corrected. Auditors noted that the most recent samples evaluated were part of batches that contained duplicates.	J1701402-001, J1800539-003, J1508593-001, J1607878-008, J1702498-002	**Required:** Conduct duplicate analysis for 10% of samples. Include this issue in the cause analysis as directed in this report under Required Response. Provide corrective action implementation date for this item.	The E. coli, Enterococci, and Fecal benchsheets have been updated with prompt for the analyst to confirm a sample duplicate is performed. The updated benchsheets and SOP change forms are provided as Attachment J. **Implementation Date:** 5/3/2019	Acceptable
8	Enterococci	DEP Guidance Document, Table 4.	Analysis time is reported as time of prep, not time in incubator. During previous audit, the lab stated this has been corrected but did not provide a date. A sample in 2018 still had the incorrect time.	all	**Required:** Provide date when EDD files were revised to report the correct analysis time (time in incubator). Ensure the correct procedure is being followed.	All benchsheets have been confirmed to be exporting the time in incubator to be the analysis start time. **Implementation Date:** 8/10/2018	Acceptable

Finding #	Analyte	Standard or Method Reference	Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action	Laboratory Response	DEP Response
9	*E. coli* and Enterococci	DEP Guidance Document, *Quality Control Blanks*	Method blanks are run at the beginning of each batch rather than at the end.	all	**Required:** For IDEXX methods, follow each sample set with a sterile, non-buffered water blank processed according to the method. If more than 30 minutes elapse between successive sample sets, a new blank must be run.	SOPs BIO-9223B MPN and BIO-Entero have been updated to indicate a method blank is run after samples. See Attachment K for SOP amendment forms for BIO-9223B MPN and BIO-Entero. **Implementation Date**: 5/3/2019	Acceptable
10	*E. coli*	NELAC D.3.1, SM9020	QC checks were conducted after media was used for sample analysis. This issue was found in the previous audit, but a corrective action date was not supplied.	J1708057-001	**Required:** Provide a date of corrective action implementation. Include this issue in the cause analysis as directed in this report under Required Response.	Supplies were not being ordered in a timely manner, causing media to be used before it was lot checked to prevent samples from expiring. An ordering schedule has been implemented to place orders every other week, with a calendar reminder for the department. Additionally, an inventory guidance document has been created to indicate the quantity that should be ordered when the supply reaches a certain level. A training memo will be generated to stress the importance of maintaining inventory and performing lot checks before use on samples. A copy of the Inventory Guidance document is provided as Attachment L. **Implementation dates:** Ordering schedule: 1/1/2018 Inventory document: 3/29/2019 Training memo: 5/10/2019	Acceptable. DEP acknowledges labs can occasionally run out of prepared media due to large number of unexpected samples and it becomes necessary to prepare additional media on same day as sample analysis. We recommend increased communication between lab and customer to ensure adequate amount of media is prepared.

Table 5: Audit Findings for the lab systems audit of ALS Environmental Laboratory conducted by DEP's Biology Program and AEQAS, December 10-11, 2018.

Finding #	Standard or Method Reference	Finding	Required or Recommended Corrective Action	Laboratory Response	DEP Response
1	NELAC 5.5.3; SM9020B	Documentation was not found for water bath and incubator cleaning. A staff member stated they are cleaned as needed, and auditor noted they did not appear dirty.	**Recommended:** Document all maintenance for a piece of equipment, including cleaning.	The BIO-QC SOP has been updated to indicate the procedure for cleaning an incubator and to record maintenance in the logbook. The BIO- 9233B MPN, BIO- Entero, and BIO-9222D SOPs have been updated to clarify that incubators are to be cleaned quarterly. The See Attachment M for copies of the SOP amendment forms. **Implementation Date:** 5/3/2019	Acceptable
2	NELAC D.3.8 b)6)i)	No documentation was found for temperature uniformity and equilibrium checks for water baths and incubators.	**Required**: Perform these checks at least once for each piece of equipment.	BIO-QC has been verified to require that a temperature distribution study be performed prior to initial use of an incubator or water bath. Temperature distribution studies are provided as Attachment N. **Implementation Date:** 5/3/2019	Acceptable
3	NELAC 5.5.9.2 a)8); NELAC D.3.8 b)6); SM9020B	No thermometer was observed in the lab with the incubators and water baths.	**Recommended:** Monitor each room with an incubator or water bath for appropriate temperature.	The BIO-QC SOP has been updated to require that the room temperature be monitored and recorded twice daily. Temperature log forms have been generated to document those room checks. See Attachment O for copies of the BIO-QC SOP amendment form and temperature log forms. **Implementation Date:** 5/3/2019	Acceptable
4	SM 9020B	A plastic carboy is used for measuring buffer water. Records were not available for how the carboy is cleaned.	**Required:** Use class A glassware for measurements, and document cleaning procedures.	The BIO-QC and BIO- 9222D SOPs have been updated to provide cleaning instructions for the carboy. See Attachment P for a copy of the SOP amendment forms. **Implementation Date:** 5/3/2019 **7/17/19 Follow up Response:** The BIO-QC SOP has been revised to include instructions for volumetrically verifying the plastic carboy against Class A glassware prior to use of the carboy. The BIO-9222D SOP has been revised to indicate the plastic carboy is volumetrically verified and to refer to the BIO-QC SOP for instruction on that verification process. In addition, the plastic carboy has been volumetrically verified. The BIO-QC amendment form is provided as Attachment T. The BIO-9222D SOP amendment form and the record of carboy volumetric verification are provided as Attachment U.	We did not see a corrective action for the fact that measurements are being made without the use of class A glassware. Please explain how you are ensuring precise volume measurements. Response 7/19/19: Acceptable.

Finding #	Standard or Method Reference	Finding	Required or Recommended Corrective Action	Laboratory Response	DEP Response
				Follow up implementation date: 7/17/2019	
5	NELAC D.3.8 b7	The pH check is not being performed on glassware.	**Required**: Check pH with 0.04% bromothymol blue or other suitable indicator before first use or after washing glassware. Include this issue in the cause analysis as directed in this report under Required Response.	Soap is not used. Glassware is "rinsed" between uses and only used for one purpose. The BIO-QC SOP has been updated to include instruction on cleaning glassware. See Attachment Q for the BIO-QC amendment form **Implementation Date:** 5/3/2019	Acceptable. Recommend a cleaning procedure using detergent and conduct pH check. Monitor blanks to ensure a detergent cleaning procedure is not needed.
6	NELAC D.3.2, SM9020B	Valerie Spears does not have up to date Demonstration of Capability (DOC) documentation. Although she is a supervisor in the lab, she also functions as an analyst when necessary.	**Required:** Provide documentation that all analysts have a passing DOC within the last calendar year. Include this issue in the cause analysis as directed in this report under Required Response.	Maintaining CDOCs for tertiary analysts has been difficult due to our current DOC procedure of using PT studies, since they are only routinely performed two times a year. The DOC procedures for microbiology are being revised to allow in- house preparation. DOCs will be performed by Valerie Spears before analyzing samples. DOC documentation for all analysts currently performing these analyses is provided as Attachment R. **Implementation Date:** 5/30/2019	Acceptable
7	SM 9223/Colilert product instructions	A comparator was not used when reading results for *E. coli*. ALS staff told auditors that they would purchase and begin to use one.	**Required:** Provide documentation that a comparator was received by the lab.	A comparator has been purchased and is currently being used by the lab. BIO-9223B MPN Section 12.1.3 was updated prior to the follow up assessment in December. A copy of the Quantitray Comparator and Certificate of Analysis are provided as Attachment S. **Implementation Date:** 11/30/2018	Acceptable
8	DEP Guidance Document, *Laboratory Quality Control Duplicates.* SM 9020B	When calculating precision for a duplicate set with one non-detect, the lab is including the non-detect as zero. This practice artificially inflates precision data.	**Required:** Follow the procedure in SM 9020 for calculating precision ("If either of a set of duplicate results is zero, add 1 to both values before calculating the logarithms.")	The duplicate evaluation sheet will be updated to add 1 to results of 0 before calculating the logarithms. **Implementation Date:** 5/30/2019	Acceptable

Appendix A. Causal Analysis Provided by ALS

The following table summarizes cause analysis and date range. Further summary information is provided below the table.

Table # & Finding #	Finding	Sample(s) Affected (lab ID)	Date Ranges	Required or Recommended Corrective Action	Root Cause analysis	Laboratory Response	Implementation date
Table 4, Finding 1	Incubator temps are often not checked. Out of control temperatures are adjusted without further corrective actions. Specific samples with missing or out of control temperatures are listed here. Checking the temperatures and following up with corrective actions for out of control temperatures was an ongoing issue in most records reviewed from 2015-2018. The corrective action code indicated on the logs (B) is inappropriate if the temperature is out of control. Resetting the thermostat without investigating the cause of the drift does not comply with NELAC standards.	J1706454-001 J1708058-001 J1802765-007 J1800539-003 J1806419-003 J1508593-001 J1607878-008 J1702498-002	September 2017, November 2017, April 2018, January 2018, September 2018, October 2015, November 2016, April 2017	Required: Provide a corrective action report that details the date range the problem existed, the methods affected, what was done to correct it and when, and an estimate of how many DEP samples were affected. ·Language added to the SOP pursuant to the June 2018 preliminary report was an improvement, but additional language is needed in the SOP to specify which corrective actions to use in different scenarios. ·Add prompts to temperature logs for last thermometer verification and applicable correction factor.	Additional guidance on handling secondary review of incubator temperature logs appears to be necessary (i.e. trend analysis and NCAR generation). Further emphasis on root cause analysis would also be beneficial.	Corrective action code “B” is a corrective action after cause has been initially evaluated. Code “B” also indicates to recheck the temperature (after one hour per SOP) to verify that the corrective action was adequate to address the issue. If it is not, then additional corrective action measure would be required. As noted on the temperature log sheet, more than one corrective action code may be applied as needed. At the end of each month, secondary review of the temperature log is performed. If a trend of incubator temperature failures or omittances is identified, an NCAR will be generated. This will elevate the issue to management review. An BIO-QC SOP amendment form has been generated to 1) clarify review of incubator temperature logs for a trending failures that would require an NCAR to be generated, and 2) clarify that investigation of the root cause(s) of an exceedance is required to be performed prior to corrective action. A prompt to record the Correction Factor was added to all temperature log forms effective 1/1/2019. The BIO-QC amendment for is provided as Attachment D.	5/3/19

Table # & Finding #	Finding	Sample(s) Affected (lab ID)	Date Ranges	Required or Recommended Corrective Action	Root Cause analysis	Laboratory Response	Implementation date
Table 4, Finding 6	Analyst variability was not conducted for April 2017. These types of errors should be caught during routine QA review and corrective actions taken.	J1702498-002	April 2017	Required: Ensure all quality assurance requirements are completed on time.	Currently, compliance review takes place after QA is submitted, sometimes after the appropriate timeframe, not leaving time to perform the requirement, only reprimand.	A calendar reminder has been generated on the third week of the month for the supervisor to check the progress of QA requirements, so that effective corrective action can be taken. BIO-QC has been updated to list this requirement. The Annual Micro QC Checklist (IF-77) has been updated to include a spot to document monthly supervisor review. See Attachment I for copies of the BIO-QC SOP amendment form and Annual Micro QC Checklist (IF-77).	5/3/2019
Table 4 Finding 7	Duplicates were not run, as required by DEP contract. ALS has stated that duplicates were run inconsistently in the past, but the problem has been corrected. Auditors noted that the most recent samples evaluated were part of batches that contained duplicates.	J1701402-001, J1800539-003, J1508593-001, J1607878-008, J1702498-002	February 2017, October 2015, November 2016, April 2017	Required: Conduct duplicate analysis for 10% of samples. Provide corrective action implementation date for this item.	Previous analysts on occasion would forget to run a duplicate. Rather than rely on analyst to remember to run a duplicate, addition of a prompt would prevent this error from occurring.	The E. coli, Enterococci, and Fecal benchsheets have been updated with prompt for the analyst to confirm a sample duplicate is performed. The updated benchsheets and SOP change forms are provided as Attachment J.	5/3/2019
Table 4, Finding 10	QC checks were conducted after media was used for sample analysis. This issue was found in the previous audit, but a corrective action date was not supplied.	J1708058-001	November 2017	Required: Provide a date of corrective action implementation.	Supplies were not being ordered in a timely manner, causing media to be used before it was lot checked to prevent samples from expiring.	An ordering schedule has been implemented to place orders every other week, with a calendar reminder for the department. Additionally, an inventory guidance document has been created to indicate the quantity that should be ordered when the supply reaches a certain level. A training memo will be generated to stress the importance of maintaining inventory and performing lot checks before use on samples. A copy of the Inventory Guidance document is provided as Attachment L.	Ordering schedule: 1/1/2018 Inventory document: 3/29/2019 Training memo: 5/10/2019

Finding #	Finding	Required or Recommended Corrective Action	Root Cause analysis	Laboratory Response	Implementation date
5	The pH check is not being performed on glassware.	Required: Check pH with 0.04% bromothymol blue or other suitable indicator before first use or after washing glassware.	Soap is not used. Glassware is "rinsed" between uses and only used for one purpose.	The BIO-QC SOP has been updated to include instruction on cleaning glassware. See Attachment Q for the BIO-QC amendment form.	
6	Valerie Spears does not have up to date Demonstration of Capability (DOC) documentation. Although she is a supervisor in the lab, she also functions as an analyst when necessary.	Required: Provide documentation that all analysts have a passing DOC within the last calendar year.	Maintaining CDOCs for tertiary analysts has been difficult due to our current DOC procedure of using PT studies, since they are only routinely performed two times a year.	The DOC procedures for microbiology are being revised to allow in-house preparation. DOCs will be performed by Valerie Spears before analyzing samples.	5/30/2019

Regarding SOP implementation, the laboratory has both a Training SOP (which describes the analyst training process on an SOP) and a Document Control SOP (which describes how SOPs are rolled out to the laboratory staff). These documents ensure appropriate implementation of an SOP. The laboratory acknowledges that improvements have been identified as necessary to the handling, review, and oversight processes for out of control incubator temperature occurrences and certain other QC activities as identified in the findings above. The additional SOP instruction for trend review of failures or omittances during secondary review of temperature logs will help to reduce frequency of such occurrences by ensuring sufficient root cause and corrective action steps are taken when such issues start to occur. The addition of a monthly supervisor review of the Annual Micro QC checklist (Finding 6 of Table 4) will help ensure other QC activities are monitored by management each month. The SOP and form updates made as part of this audit's root cause investigation and corrective action process provide a significant strengthening of systems to help prevent failures in the future and ensure defensibility of the data.