FLORIDA DEPARTMENT OF Environmental Protection

Bob Martinez Center
2600 Blair Stone Road
Tallahassee, FL 32399-2400

Ron DeSantis
Governor

Jeanette Nuñez
Lt. Governor

Noah Valenstein
Secretary

VIA EMAIL
Read receipt requested

May 6, 2019

Stephen Cantin
Advanced Environmental Laboratories, Inc., Tampa
9610 Princess Palm Avenue
Tampa, FL 33619
Email: scantin@aellab.com

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

Dear Mr. Cantin:

Thank you for responding to the preliminary audit report for the Microbiology Lab Records and Quality System Audit of the Advanced Environmental Laboratory-Tampa laboratory (AEL). 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 concludes that the laboratory procedures and laboratory documentation used by AEL have not met one or more critical Quality Control (QC) criteria required by the approved methods, NELAC 2003 standards, Chapter 62-160, Florida Administrative Code (F.A.C.), and/or requirements outlined in purchase order B1696A. The critical findings are: the inability to confirm incubation temperatures, an inadequate analysis of blanks, and lack of a waterbath cover for proper incubation. DEP auditors found other, non-critical 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 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.

Under Chapter 120 of the Florida Statutes, AEL, 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 Sarah Noble at (850) 245-8533.

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. Mediation is not available.

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 of the Florida Statutes. The petition must contain the information set forth below and 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. The petitioner shall also mail a copy of the petition to AEL at the address indicated above at the time of filing.

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, before the applicable deadline. 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. If a request is filed late, the department may still grant it upon a motion by the requesting party showing that the failure to file a request for an extension of time before the deadline was the result of excusable neglect.

If a timely and sufficient petition for an administrative hearing is filed, other persons whose substantial interests will be affected by the outcome of the administrative process have the right to petition to intervene in the proceeding. Intervention will be permitted only at the discretion of the presiding officer upon the filing of a motion in compliance with rule 28-106.205, F.A.C.

In accordance with rules 28-106.111(2) and 62-110.106(3)(a), F.A.C., petitions for an administrative hearing by the petitioner must be filed within 21 days of receipt of this written notice. Petitions filed by any persons who were not entitled to written notice under section 120.60(3) of the Florida Statutes must be filed within 21 days of publication of the notice, if published, or within 21 days of receipt of the written notice, whichever occurs first. Under section 120.60(3) of the Florida Statutes, however, any person who has asked the department for

notice of agency action may file a petition within 21 days of receipt of such notice, regardless of the date of publication. The failure of any person to file a petition for an administrative hearing 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 of the Florida Statutes.

A petition that disputes the material facts on which the department's action is based 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, and telephone number of the petitioner; 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 are or 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.

A petition that does not dispute the material facts on which the department's action is based shall state that no such facts are in dispute and otherwise shall contain the same information as set forth above, as required by rule 28-106.301, F.A.C. Under paragraphs 120.569(2)(c) and (d) of the Florida Statutes, a petition for administrative hearing must be dismissed by the agency if the petition does not substantially comply with the above requirements or is untimely filed.

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; 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 May 10, 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 Phillips 5/10/19
Clerk Date

Final Audit Report
Advanced Environmental Laboratories Tampa
(DOH #E84589)
Microbiology Lab Systems and Records Audit
Conducted September 19-20, 2018

Division of Environmental Assessment and Restoration
Florida Department of Environmental Protection
May 6, 2019

Introduction

This laboratory systems and records audit of Advanced Environmental Laboratories (AEL-Tampa) located in Tampa, Florida, was conducted by the Florida Department of Environmental Protection's (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 AEL-Tampa is complying with the quality assurance (QA) requirements of DEP purchase order No. B1696A 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

On September 19-20, 2018, DEP staff conducted a quality system review at the AEL-Tampa lab, and reviewed analytical and quality control records for twelve samples analyzed for fecal coliform, *Escherichia coli* (*E. coli)*, and enterococci, under purchase order during the year prior to the audit (Table 1). The systems audit included verification of laboratory procedures through review of laboratory analytical and Quality Control (QC) records for the microbiological tests, the laboratory Quality Manual and Standard Operating Procedures (SOPs), interviews with laboratory staff, and direct observation. Records reviewed included custody chains, laboratory check in logs, analytical runs, laboratory reports, and QA and quality control (QC) documentation. The DEP purchase order No. B1696A, the 2003 National Environmental Laboratory Accreditation Conference (NELAC) standards, Chapter 62-160, F.A.C., and the relevant methods (Table 1) provided the criteria for the audit and all findings. Auditors present were Michael Blizzard, Jennifer Claypool, Sarah Panek, and Avril Wood-McGrath. AEL-Tampa staff present were: Michael Cammarata, Lab Manager; Stephen Cantin, Quality Assurance Officer (QAO); and Alaina Vuocolo, Microbiologist.

Preliminary Audit Report and Implementation of Corrective Actions

A preliminary audit report of findings and deficiencies was sent to Stephen Cantin (AEL-Tampa QAO) on January 4, 2019. Procedures or documentation that did not comply with audit criteria are identified in Tables 2 and 3, along with the department's suggested or required corrective actions. Mr. Cantin replied on February 15, 2019 with proposed corrective actions for the noted deficiencies, which have been included in Tables 2 and 3. The AEQAS auditor reviewed the proposed corrective actions, and the corrective actions have been implemented as of the dates indicated in Tables 2 and 3. Response to one non-critical findings was found not to be

acceptable, and additional required corrective actions or other clarifications are indicated in the AEQAS response column.

Audit Conclusions

Based on the findings for the records and systems audit, DEP has determined that AEL-Tampa has not met one or more critical QC criteria required by the approved methods, NELAC 2003 standards, and/or DEP purchase order requirements. The critical findings are the inability to confirm incubation temperatures, an inadequate analysis of blanks, and lack of a waterbath cover for proper incubation. 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 lab records audit of AEL-Tampa conducted by DEP on September 19-20, 2018.

Lab ID	Collection Date	Analyte	Method
T1712250001	7/20/2017	Enterococci	SM 9230C (2013)
T1713867003	8/15/2017	Enterococci	SM 9230C (2013)
T1715179001	9/6/2017	Enterococci	SM 9230C (2013)
T1716974001	10/5/2017	Enterococci	SM 9230C (2013)
T1721243002	12/11/2017	Enterococci	SM 9230C (2013)
T1713060001	8/3/2017	*E. coli*	EPA 1603 (2009)
T1712267001	7/20/2017	*E. coli*	EPA 1603 (2009)
T1715806003	9/18/2017	*E. coli*	EPA 1603 (2009)
T1717727009	10/17/2017	*E. coli*	EPA 1603 (2009)
T1720495001	11/29/2017	*E. coli*	EPA 1603 (2009)
T1703672001	3/1/2017	Fecal Coliform	SM 9222D (2015)
T1803814001	3/7/2018	Fecal Coliform	SM 9222D (2015)

Table 2. Findings for the lab records audit of AEL-Tampa conducted by DEP on September 19-20, 2018.

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
1	Enterococci	SM 9020B 7c, NELAC 5.5.8.3.2	Matrix listed as Surface Water on AEL Sample Receipt, but listed as Waste Water on AEL bench sheet.	T1712250001	**Required:** Ensure information is correctly recorded and check for transcription errors. If incorrect, a corrective action report should be generated.	Change in Micro personnel completed by management. Current Micro staff trained on proper documentation/review of correct sample matrix on the bench form, as it relates to the AEL sample receipt. The report went out correctly. **Implementation Date:** 01/01/2018	Acceptable
2	Enterococci, *E. coli*	NELAC 5.5.8.3.1 a)1) and b)	Prompt for verification of temperature $\leq$ 10°C or received on ice not completed on lab Chain of Custody (COC).	T1712250001, T1713867003, T1715179001, T1721243002, T1716974001, T1717727009, T1720495001, T1713060001, T1715806003	**Required:** Check and record the temperature of all samples received and record.	Issue previously resolved. Retrained login staff on Chain of Custody temperature verification requirements. **Implementation Date:** Late 2017	Acceptable

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
3	*E.coli*, Fecal coliform	Guidance document, pages 2 and 10*; NELAC 5.4.12.2.5.3 b), 5.5.10.2 g)	Analysis Time (1814) on Electronic Data Deliverables (EDD) is not the same Analysis Time recorded on Benchsheet (1750) for *E. coli* sample from 10/17/2017. Date and Time Prepared not recorded on EDD, and Analysis Date and Time were recorded as Time Filtration Start on EDD for 2017 Fecal coliform sample.	T1717727009, T1703672001	**Required:** Record Preparataion Date and Time as Incubation Start Time and Analysis Date and Time as Time Out of Incubator on EDD. Ensure information is correctly recorded and check for transcription errors. If incorrect, a corrective action report should be generated.	Issue previously resolved. AEL is now recording the Preparation Date and Time as Incubation Start Time and Analysis Date and Time as Time Out of Incubator on EDD, per client request. A corrective action report will be generated as required. **Implementation Date:** Late 2017	Acceptable
4	Enterococci	NELAC 5.D.3.1 a)1), 5.4.12.2.1 SM 9020B 9d	For samples prior to 9/6/2017, auditors could not trace individual media batches used for samples. Media batches were properly linked for samples on and after 9/6/2017.	T1712250001, T1713867003	**Required:** Ensure all documentation meets NELAC and method requirements. All consumables should be traceable to individual samples.	Issue previously resolved. Lab is ensuring all documentation meets NELAC and method requirements. All consumables are traceable to individual samples. **Implementation Date:** October 2017	Acceptable

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
5	Enterococci	NELAC 5.D.3.8 b)6)i, NELAC 5.4.12.1.5 f); 5.4.12.2.3, SM 9230C 3b2	Incubator ID recorded on the bench sheet is T1AJ. From the Temperature Log Book, this incubator is kept at 35.0 ± 0.5°C. The correct temperature for this method is 41.0 ± 0.5°C.	T1721243002	**Required:** Explain the discrepancy. Ensure the correct incubator ID is recorded. If the sample was incubated at the wrong temperature, a non-conformance report should be issued, and the results flagged.	The incorrect incubator ID was documented on the benchform in error. The samples were analyzed at the correct temperature. Micro data reviewers have been retrained on proper procedures for verifying the incubator IDs are correct. **Implementation Date:** 2/12/2019	Acceptable
6	Enterococci, *E. coli*, Fecal coliform	NELAC 5.4.12.2.5.3 b)	All incubation times are exactly the required number of hours apart, to the minute, which suggests that exact times are not being recorded.	ALL	**Required:** Enter incubation beginning and ending times exactly, without rounding and without estimating. **Recommended:** Use the same timepiece for all samples to ensure accuracy.	The analysts have been retrained on documenting incubation beginning and ending times exactly, without rounding and without estimating. A single timepiece is already in use. **Implementation Date:** 2/12/2019	Acceptable
7	Enterococci, *E. coli*, Fecal coliform	EPA 1603 9.7 and 12.0, Guidance Document, page 5*, SM 9230 C 5, SM 9222D 3f	There are no sample IDs associated with verification of positives. No indication of Test Result adjustment because verifications of positives are not linked to Sample IDs.	ALL	**Required:** Link Sample IDs with verification of positive analyses.	Sample IDs will be linked with verification of positive analyses going forward. **Implementation Date:** 2/12/2019	Acceptable

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
8	Enterococci	SM 9230 C 5	There was no brain-heart infusion (BHI) broth verification of positives incubated at 45 ± 0.5°C for 48 ± 3 hrs.	ALL	**Required:** In addition to the other verification tests, perform BHI verification of positives incubated at 45 ± 0.5°C for 48 ± 3 hrs.	BHI verification of positives, incubated at 45 ± 0.5°C for 48 ± 3 hrs, will be performed going forward. **Implementation Date:** 2/12/2019	Acceptable
9	Enterococci	SM 9230 C 5	Bile esculin agar (BEA) Broth verification of positives only incubated 24 hours.	T1716974001	**Required:** Incubate BEA broth verification of positives at 35 ± 0.5°C for 48 ± 3 hrs.	Issue previously resolved. BEA broth verification of positives are now being incubated at 35 ± 0.5°C for 48 ± 3 hrs. **Implementation Date:** November 2017	Acceptable
10	Enterococci	SM 9230 C 5, NELAC 5.D.3.8 b)6)i, NELAC 5.4.12.1.5 f); 5.4.12.2.3	Incorrect Incubator ID (T1AN) was recorded for BHI growth @ 10 ± 0.5°C on verifications sheet.	T1712250001, T1713867003, T1715179001, T1721243002	**Required:** Explain the discrepancy. Ensure the correct incubator ID is recorded. If the sample was incubated at the wrong temperature, a non-conformance report should be issued and the results flagged.	Issue previously resolved. The incorrect incubator ID was documented on the benchform in error. The sample verifications were analyzed at the correct temperatures. **Implementation Date:** January 2018	Acceptable

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
11	Enterococci	SM 9230 C 5, NELAC 5.4.12.1.5 f); 5.4.12.2.3	BHI agar verification of positives temperature recorded at 35.0°C on verifications sheet on 9/20/2017, 9/22/2017, and 11/2/2017. Samples should be incubated at 10 $\pm$ 0.5°C.	T1715179001, T1716974001	**Required:** Explain the discrepancy. Ensure that errors in documentation are resolved appropriately.	Issue previously resolved. The incorrect temperatures were documented on the verification sheets in error. The sample verifications were analyzed at the correct temperatures. **Implementation Date:** Late 2017	Acceptable
12	Enterococci	SM 9230 C 5, NELAC 5.4.12.1.5 f); 5.4.12.2.3	No results recorded for BHI growth on 11/2/2017 on verifications sheet.	T1716974001	**Required:** Ensure results are recorded at the time they are made.	Issue previously resolved. Change in Micro personnel completed by management on 12/2017. New micro staff trained on properly recording the results at the time they are made. **Implementation Date:** January 2018	Acceptable
13	Enterococci, *E. coli*	Guidance document, Page 7*, NELAC 5.D.3.1 a)2)	End blanks not performed.	ALL	**Required:** Each sample set shall be associated with a beginning and ending filtration blank for each filtration unit.	Micro staff retrained and each sample set is now being associated with a beginning and ending filtration blank for each filtration unit. **Implementation Date:** October 2018	Acceptable

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
14	Enterococci, *E. coli*	Guidance document, Page 7*, NELAC 5.D.3.1 a)2)	Blanks not performed for each filtration unit used.	ALL	**Required:** The laboratory shall conduct blanks for each laboratory filtration unit used.	Micro staff retrained. And the laboratory is now conducting blanks for each laboratory filtration unit used. **Implementation Date:** October 2018	Acceptable
15	Enterococci, *E. coli*	SM 9230 C 7, EPA 1603 9.6, NELAC 5.D.3.1 a)1)	Samples were analyzed before media control tests were completed.	T1721243002, T1717727009	**Required:** Check media sterility prior to use with samples.	Media sterility will be checked prior to use with samples going forward. **Implementation Date:** 2/12/2019	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.
16	Enterococci, Fecal coliform	NELAC 5.D.3.1 a)5); SM9020 B 5f	Dilution water lot number was not recorded; therefore, no traceability to dilution water or autoclave sterility checks.	T1712250001, T1713867003, T1721243002, T1703672001, T1803814001	**Required:** Link all consumables and prepared reagents to individual sample IDs.	Issue previously resolved. Micro analysts were retrained. All consumables are now traceable to individual samples. **Implementation Date:** April 2018	Acceptable

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
17	Enterococci, *E. coli*	SM 9020B 9a, NELAC 5.D.3.2, EPA 1603 9.12	Analyst counting variability not performed.	ALL	**Required:** Counting variability tests must be conducted monthly with one positive sample read by each analyst within 10% difference or a duplicate count by one analyst within 5% difference.	Counting variability tests are now being conducted monthly with one positive sample read by each analyst within 10% difference or a duplicate count by one analyst within 5% difference. **Implementation Date:** 2/12/2019	Acceptable
18	Enterococci, *E. coli*	SM 9020B 9c, Guidance document, page 8*	Duplicate (Precision) samples not performed.	ALL	**Required:** Perform duplicate analyses at least monthly or more frequently as needed, e.g., 10% of samples when required by the analytical method or regulations, one sample per test run, or one sample per week for a laboratory that conducts less than 10 tests/week.	Issue previously resolved. Duplicate analyses are performed at least monthly or more frequently as needed, e.g., 10% of samples when required by the analytical method or regulations, one sample per test run, or one sample per week for a laboratory that conducts less than 10 tests/week. **Implementation Date:** May 2018	Acceptable
19	*E. coli*	EPA 1603 12.4	For Simmons citrate agar (SCA) confirmation, sample was only incubated for 3 days.	T1713060001	**Required:** Incubate the SCA for 4 days at 35 $\pm$ 0.2°C in an aerobic atmosphere.	The SCA is now being incubated for 4 days at 35 $\pm$ 0.2°C in an aerobic atmosphere. **Implementation Date:** October 2018	Acceptable

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
20	*E. coli*	EPA 1603 12.4.1	SCA result not as expected. On this medium there should be no growth, but according to verification results, all 10 samples had growth, but all other subsequent verifications were as expected.	T1715806003	**Required:** Confirm verifications were performed correctly and results recorded correctly. Ensure that errors in documentation are resolved appropriately.	Change in Micro personnel completed by management on 12/2017. Current Micro staff trained on properly confirming verifications were performed correctly and results recorded correctly. **Implementation Date:** 2/12/2019	Acceptable
21	*E. coli*	EPA 1603 12.4.2 c	Ending temperature for EC broth incubation recorded at 35.0°C. Incubation temperature should be 44.5 $\pm$ 0.5°C. Correct temperature verified in Temperature Log Book.	T1715806003, T1720495001	**Required:** Ensure that errors in documentation are resolved appropriately.	Change in Micro personnel completed by management on 12/2017. Current micro staff trained on proper documentation criteria. **Implementation Date:** January 2018	Acceptable
22	*E. coli*	EPA 1603 9.10, Guidance document, page 7*	No blanks recorded on bench sheet.	T1717727009	**Required:** Perform a filtration blank before and after sample filtrations. Sample needs data qualifier (J) and corrective action report generated.	An opening MB was performed for the sample, but may have not been associated to the unit it was filtered on based on the bench form. Each sample set is now being associated with a beginning and ending filtration blank for each filtration unit. The data is being qualified and a report will be amended. **Implementation Date:** 2/15/2019	Acceptable

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
23	*E. coli*	EPA 1603 section 9.8 & 9.11	Daily checks are not performed for filter and media sterility.	ALL	**Required:** Conduct daily checks of the filters and media used for sample analysis.	Daily checks of the filters and media used for sample analysis will be conducted going forward. **Implementation Date:** 2/22/2019	Acceptable
24	*E. coli*	EPA 1603 9.5 and 14	No record of matrix spikes (MS) until August 2017.	T1713060001, T1712267001, T1717727009	**Required:** Run after every 20 field or MS samples, or once a week when samples are analyzed, whichever is more frequent.	The laboratory will now analyze an MS consistently after every 20 samples, or once a week when samples are analyzed, whichever is more frequent. **Implementation Date:** 2/13/2019	Acceptable. Please note matrix spikes are required for wastewater samples only.
25	*E. coli*	EPA 1603 9.2 and 9.4	No record of ongoing precision and recovery (OPR) samples were found in the audit records.	T1713060001, T1712267001, T1717727009	**Required:** The laboratory should analyze one OPR sample after every 20 field and matrix spike samples or one per week that samples are analyzed, whichever occurs more frequently.	The laboratory will now analyze one OPR sample consistently after every 20 samples, or one per week that samples are analyzed, whichever occurs more frequently. **Implementation Date:** 2/13/2019	Acceptable

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
26	Fecal coliform	SM 9222D 3a, NELAC 5.4.12.1.5 and 5.4.12.2.3	Laboratory reported result does not match DEP EDD file result. AEL noted an amended report was issued with the updated result.	T1703672001	**Required:** Please explain why the original result was changed. Use the appropriate calculation for the method employed by the laboratory. Ensure that errors in documentation are resolved appropriately and generate a corrective action report.	Issue mostly resolved, but the EDD was not updated with the amended report. See attached NCF-T17129. Retrained covering PM on importance of amending both the final report and EDD where necessary. **Implementation Date:** 2/13/2019	Acceptable
27	Fecal coliform	NELAC 5.D.3.1 a)2), SM 9020B 9d1 Guidance document, page7*	Blanks not performed every 10 samples.	T1703672001	**Required:** Insert a sterility blank after every 10 samples.	The laboratory will now consistently run a sterility blank after every 10 samples per filtration unit, before continuing on. **Implementation Date:** 2/13/2019	Acceptable

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
28	Enterococci, *E. coli*, Fecal coliform	NELAC 5.D.3.1 a)2), Guidance document, page7*	Ending blank has same Time Start Filtration as beginning blank. For the two fecal coliform samples, time from start filtration to start incubation is greater than 30 minutes.	T1712250001, T1713867003, T1715179001, T1721243002, T1716974001, T1703672001, T1803814001	**Required:** Ensure exact filtration start and end times are recorded. If more than 30 minutes elapses between successive sample filtrations, a new set of beginning and ending filtration blanks must be performed.	Issue was previously resolved. All samples and blanks are now placed into the incubator within 30 minutes of filtration time and samples that are added to the batch real time are documented with the updated filtration time. Any samples added after the 30 minute filtration to incubator requirement are processed as a new batch altogether. **Implementation Date:** Mid 2018	Acceptable
29	Enterococci, Fecal coliform	SM 9020B 12c	No 2nd level reviewer listed to verify results are correct and entered correctly.	T1712250001, T1713867003, T1715179001, T1721243002, T1716974001, T1703672001	**Required:** Include a verification step during the data entry process to minimize occurrence of transcription errors.	Issue was previously resolved. Regular secondary review is being completed. **Implementation Date:** January 2018	Acceptable

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
30	Fecal coliform	SM 9222D 3f	For verification of positives, there is no indication if colonies verified were typical or atypical.	ALL	**Required:** At a minimum, verify at least five typical and five atypical colonies per membrane. Document which colonies are verified.	The verification form was modified to indicate which samples have typical and which are atypical colonies. Verifying 5 atypical colonies per month is not possible due to them being rare. At least 10 colonies per month will be verified, but they will be mostly typical in type. Every attempt is made to collect atypical colonies for verification. **Implementation Date:** 2/12/2019	Acceptable
31	Fecal coliform	SM 9222D 3f	Lauryl tryptose broth (LTB) confirmation incubated for 46 hours on 3/23/2017 and 24 hours on 3/15/2018. EC confirmation incubated for 22 hours on 3/23/2017.	T1703672001, T1803814001	**Required:** Ensure LTB confirmation incubated for 48 hours and EC confirmation incubated for 24 hours.	The verification on 3/15/18 is a finding. The other two are within control criteria. The analysts have been retrained on the correct incubation times for LTB (48 +/- 3 hrs) and EC (24 +/- 2hrs). **Implementation Date:** 2/13/2019	Acceptable. Auditors acknowledge 3/23/2017 LTB and EC confirmations are within control criteria.
32	Fecal coliform	SM 9222D 3f	EC incubation ending temperature recorded 35.5°C on 3/16/2018 on verification sheet. Incubation temperature should be 44.5 $\pm$ 0.5°C. Correct temperature verified in Temperature Log Book.	T1803814001	**Required:** Ensure that errors in documentation are resolved appropriately.	The analysts have been retrained on the correct temperature requirements for the EC verification step. **Implementation Date:** 2/13/2019	Acceptable

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
33	Fecal coliform	NELAC 5.D.3.8 b)6)i, SM 9020B 4n	On the March 2017 fecal verifications log, recorded waterbath ID is PBD1. No temperature log was provided for water bath ID PBD1.	T1703672001	**Required:** Explain the discrepancy. Check and document incubator temperature twice daily, at least 4 hours apart. Ensure that errors in documentation are resolved appropriately.	Incorrect lab instrument ID recorded. Management made a change in Micro staff since the error and the current staff has been trained on proper documentation procedures. **Implementation Date:** January 2018	Acceptable

Table 3. Findings for the lab systems audit of AEL-Tampa conducted by DEP on September 19-20, 2018.

Finding #	Requirement Reference	Finding	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
1	NELAC 5.5.8.3.1 a)3) and c)2)ii	An improperly preserved drinking water sample was observed in the lab during sample prep, when total residual chlorine (TRC) detected. The analyst records the check results on a copy of the COC transmittal form accompanying the micro samples. This information is transferred to a personal note pad, which is retained in the records archive, and later transferred to the lab bench sheet (form). It is not clear how the TRC check result is propagated through the lab documentation system to the lab report (with Y-code assignment, when necessary).	**Required:** Explain how lab fulfills the following requirement: If sample does not meet the sample receipt acceptance criteria, and the laboratory proceeds with the analysis, the analysis shall be appropriately "qualified" on the final report and a Non-conformance or corrective action report must be created and maintained with the final report.	Going forward the lab will be checking the preservation of samples and entering the data real time electronically to move away from multiple loose forms of documentation. The data will then be qualified in the LIMS with a non-conformance report, based on the electronic bench form being used and reviewed, as required. **Implementation Date:** 2/20/2019	Acceptable
2	SM 9020B 3e	Log entry for monitoring air density for December 2017 was missing.	**Required:** Provide this log if available or develop a plan to prevent errors in record keeping and QC procedures.	Issue was previously resolved. The air density check for Dec 2017 was not completed. Management made a change in Micro staff since the error and the current micro staff has been trained on the proper procedures for air density checks. **Implementation Date:** January 2018	Acceptable

Finding #	Requirement Reference	Finding	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
3	SM 9020B 5j	Expiration dates not recorded in log book for membrane Thermotolerant *E. coli* (m-TEC) media on 7/17/17 and 12/17/17.	**Required:** Record type, amount, and appearance of media received, lot number, expiration date, and dates received and opened in a logbook or computer file; also place date of expiration and date opened on container.	Issue was previously resolved. Management made a change in Micro staff since the errors and the new Micro staff was trained on proper documentation/labeling requirements. **Implementation Date:** January 2018	Acceptable
4	NELAC 5.5.5.2.1 and 5.D.3.8 b)2)iii	Autoclave log does not indicate maximum temperature. Some log pages do not indicate year of entries (2018).	**Required:** Ensure that autoclave records include date and maximum temperature reached.	There is only one temperature for the autoclave documented, the max, which has been documented as required. The analysts have been retrained on the need for properly documentating the entire date as it relates to individual forms. **Implementation Date:** 1/01/2019	Acceptable
5	SM 9020B 4h	December 2017 entry missing for biological (*Geobacillus stearothermophilus*) autoclave check.	**Required:** Biological check shall be performed monthly. Develop a plan to prevent errors in record keeping and gaps in performing QC procedures.	Issue was previously resolved. Management made a change in Micro staff since the error and the QA Officer is now reviewing the Micro QC binder in more detail during the Internal Audits to ensure QC procedures in place are being kept up. **Implementation Date:** January 2018	Acceptable

Finding #	Requirement Reference	Finding	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
6	NELAC 5.5.5.2.1 and 5.D.3.8 b)2)iv	Unclear log entries for annual maintenance, pressure check and temperature calibration for autoclave. Device used to verify temperature functioning also not clear. There is a corrective action indication in the log as of 7/11/18 for thermometer check positions (front, middle, back). The ideal gas equation may be used to verify pressure (by solving for P, using measured maximum temperature), if the autoclave is verified as not leaking. The AEL log has no information about leak checks (see finding #4 above for the maximum temperature question).	**Required:** Indicate which checks are performed and how they are documented. Review with staff the proper procedure for performing and documenting autoclave QC procedures.	A maintenance logbook for the autoclave was created and is in use for documentation of annual maintenance. The unit is checked for visual leaks during use and maintenance is performed when necessary. The annual pressure check is now derived using the temperature and the ideal gas equation on a form that has been updated. The analysts were trained on the updated requirements. **Implementation Date:** 2/11/2019	Acceptable
7	NELAC 5.D.3.8 b)6)i, SM 9020B 4n	The following log book entries were noted for waterbaths: 9/9/2017, only a 3-hour span noted between AM and PM readings; 9/24/2017, a 3.25-hour span between AM and PM noted; 10/30/2017, a temperature of 43.5°C was entered for the AM reading for waterbath ID T1AN.	**Required:** Temperature of waterbaths shall be documented twice daily, at least four hours apart, on each day of use. Develop written procedures for corrective actions when temperature is out of range.	The temperature of waterbaths shall be documented twice daily, at least four hours apart, on each day of use, going forward. Written procedures for corrective actions for when temperatures are out of range have been developed. **Implementation Date:** 2/14/2019	Acceptable

Finding #	Requirement Reference	Finding	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
8	NELAC 5.5.5.2.1 and 5.D.3.8 b)6)	Waterbath did not have a cover. Evaporation observed during audit that left some samples out of the water.	**Required:** This finding was discussed with AEL at audit, and they agreed to purchase a waterbath cover to prevent evaporation. Confirm the cover was purchased or provide expected date.	The water levels are now being checked twice daily and samples weighed down with weights to keep them better submersed. Covers will be made/purchased. **Implementation Date:** October 2018 – weights/water levels and 3/31/2019 – for the covers	Acceptable. Note: ideally, only add water when samples are not in the incubator and allow time for the temperature to equilibrate. If this is not possible, ensure the added water is the same temperature as the incubator.
9	NELAC 5.5.5.2.1, SM 9020B 4n, EPA 1603	No documentation noted for waterbath maintenance and cleaning.	**Recommended:** Empty and clean bath as needed to prevent buildup of salts and microbial growth and disinfect before refilling. Clean and then sanitize incubators routinely. Record cleaning and any repairs in a maintenance log.	Maintenance logbooks are now in use for the waterbaths. **Implementation Date:** 2/11/2019	Acceptable
10	NELAC 5.D.3.8 b)6)i	No documentation noted for completed waterbath temperature uniformity and equilibrium checks.	**Required:** Complete these checks and provide documentation.	The initial uniformity and equilibrium checks are now completed. **Implementation Date:** 2/15/2019	Acceptable, documentation provided.

Finding #	Requirement Reference	Finding	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
11	NELAC 5.D.3.8 b)6)i, SM 9020B 4o, SM 9230C 3b2	The following log entries were noted for incubators: 9/9/2017, only a 3-hour span is indicated between AM and PM readings (T1AJ-1&2, T1AC); 9/24/17, a 3.25-hour span is noted (T1AJ-1) and a 3.5-hour span is noted (T1AC); 4/28/18, a temperature of 42°C is noted for T1AC (1:00 PM).	**Required:** Temperature of incubators shall be documented twice daily, at least four hours apart (morning and afternoon), on each day of use.Develop written procedures for corrective actions when temperature is out of range.	The temperature of incubators shall be documented twice daily, at least four hours apart, on each day of use, going forward. Written procedures for corrective actions for when temperatures are out of range have been developed. **Implementation Date:** 2/14/2019	Acceptable
12	NELAC 5.D.3.8 b)6)i, SM 9020B 4o	March 2018 incubator logs, temperatures not checked in the morning on 3/15/2018, 3/16/2018, and 3/31/2018.	**Required:** Check incubator temperature twice daily, at least 4 hours apart, morning and afternoon.	The incubators will be temperature checked twice daily, at least 4 hours apart, morning and afternoon, going forward. **Implementation Date:** 2/14/2019	Acceptable
13	SM 9020B 4o	Thermometers in incubators are not submerged in water or glycerin.	**Required:** Submerge stem of thermometer in water or glycerin to immersion mark.	The incubator thermometers have been reaplaced with water or glycerin to the immersion mark. **Implementation Date:** 2/14/2019	Acceptable
14	NELAC 5.D.3.6 and 5.D.3.8, SM 9020B 4o	No documentation noted for incubator monthly cleaning and sterilization.	**Recommended:** Complete these checks and provide documentation. Incubators should be cleaned monthly and sterilized periodically.	Maintenance logbooks were created for the incubators and documentation of the cleaning and sterility will be completed moving forward. **Implementation Date:** 2/14/2019	Acceptable, documentation provided.

Finding #	Requirement Reference	Finding	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
15	NELAC 5.D.3.8 b)6)i	No documentation of incubator uniformity checks in 2017. Uniformity checks performed in 2018 for incubator T1AC, but not incubator T1AJ. Equilibrium checks were performed in 2017, but no record for 2018.	**Required:** The stability and uniformity of temperature distribution and time required after test sample addition to re-establish equilibrium conditions in incubators and water baths shall be established. Temperature of incubators and water baths shall be documented twice daily, at least four hours apart, on each day of use.	The incubator uniformity and equilibrium checks were completed initially as required. There is a recommendation in house that they be performed annually, but there is not a requirement to do so. New checks will be completed if major maintenance is required or for the purpose of troubleshooting. **Implementation Date:** N/A	Acceptable
16	SM 9020B 4o	No room thermometer observed to ensure room temperature maintained.	**Required:** Place thermometers in any room with incubators and maintain the temperature between 16 and 27°C (60 to 80°F).	A thermometer is now observed and readings recorded in the Micro room to ensure room termperature is maintained. **Implementation Date:** 2/14/2019	Acceptable
17	NELAC 5.D.3.8 b)5) and 5.5.5.2.2.1, SM 9020B 4c	In some 2018 recent log entries, some pH measured buffer values were recorded as integers (no decimals).	**Required:** Use a pH meter, graduated in 0.1 pH units or less. Record readings to the first decimal place.	The Intranet form settings were adjusted to display 0s after the decimal point. Readings are now recorded to at least one decimal place. **Implementation Date:** 2/14/2019	Acceptable

Finding #	Requirement Reference	Finding	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
18	NELAC 5.D.3.8 b)1)	Documentation of semi-annual calibration check with NIST certified thermometer frequency is not clear. In 2017, entry for thermometer T1AV is missing. In 2018: 2996, P78150, 153414, and 3030 thermometer entries are missing. Traceable certificate for reference thermometer R51427 not provided.	**Required:** Verify calibration for any thermometers that have not been checked in the last six months. Develop a plan to prevent errors in record keeping and gaps in performing thermometer calibration verification procedures.	T1AV was first used in Mar 2018. Thermometers 2996, P78150, 153414, and 3030 were calibrated 10/2/17-11/29/17 for 1 year, as required. R51427 was an in house thermometer previously calibrated by a NIST thermometer for 1 year till 10/2/18. The associated NIST thermometer is 4167102. **Implementation Date:** N/A	Acceptable
19	TNI 2016 1.7.3.7.b.vi(c), SM 9020B 5a2	Inhibitory residue test (IRT) and evaluation not performed in-house.	**Required:** The detergent for washing reusable labware shall be tested for possible presence of residues that may inhibit and promote growth of microorganisms by performing the IRT initially and each time the laboratory changes the detergent formulation or washing procedures. Lab must retain and provide certificate from manufacturer.	The detergent is tested by the manufacturer and the documentation is kept on file by master lot. That documentation was available during the audit. Each batch of cleaned glassware is pH tested. The IRT by the manufacturer includes test comparison results based on rinsing and not rinsing after washing with the product. **Implementation Date:** N/A	Unacceptable. Perform a new IRT whenever a different detergent formulation is used or a change in SOP for washing is made. DEP will verify implementation of corrective actions at a future date.

Finding #	Requirement Reference	Finding	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
20	NELAC 5.D.3.6 c), SM 9020B 5f2	Use test is missing for the fourth quarter of 2017. For Type II water, conductivity was not measured within acceptable range, and SiO2 was not measured. Laboratory must submit certificate of analysis or other supporting documentation from lab water system supplier.	**Required:** Ensure use tests are performed quarterly and passing. Develop a plan to prevent errors in record keeping and gaps in performing QC procedures. Please provide certificate of analysis from lab water system supplier.	Change in Micro personnel completed by management. New staff trained on use test criteria, which has been completed regularly since. The staff has been retrained on conductivity requirements and is monitoring it daily. The QA officer now monitors the conductivity values quarterly for errors. The Silica is tested on a routine basis in metals well below the limit of <0.1ppm. Data will be collected and placed in the Micro binder for easy access going forward. **Implementation Date:** 2/15/2019	Acceptable
21	NELAC 5.D.3.3 a) SM 9020B 1	No documentation of demonstration of capability (DOC) for weekend analyst (initially and annually).	**Required:** Provide documentation that each analyst who is reading samples has a completed Initial DOC.	All analysts will now have DOCs completed and reviewed before analysis of samples can begin per company protocol. The department supervisor has been retrained on the correct DOC procedures for training purposes. **Implementation Date:** 2/14/2019	Acceptable, documentation provided.

Finding #	Requirement Reference	Finding	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
22	SM 9020B 12c	Analyst uses note pads/hand written notes that are not verified to minimize transcription errors before being entered to computer.	**Required:** Data entry process must include a verification step to minimize transcription errors. Confirm documentation of this process. **Recommended:** Analyst should be entering data onto a bench sheet or using a portable electronic device, not scratch pads.	Going forward the lab will be documenting the data real time electronically on a single benchform to move away from additional loose forms of documentation. The data will then be transferred directly to the LIMS from the single benchform. **Implementation Date:** 2/25/2019	Acceptable
23	SM 9020A 5j	Agar plates appeared wet.	**Recommended:** Agar plates should be inverted to prevent condensation inside of plates. Explain lab's process for ensuring condensation does not occur inside agar plates.	Agar plates are now being inverted to help prevent condensation inside of plates when prepared and stored. **Implementation Date:** October 2018	Acceptable
24	EPA 1603	Lab does not have a microscope available to verify counts.	**Required:** Need glass lens with magnification of 2-5X or stereoscopic microscope.	The laboratory has acquired a glass lens with magnification of 2-5X to verify counts going forward. **Implementation Date:** 2/11/2019	Acceptable

Finding #	Requirement Reference	Finding	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
25	NELAC 5.4.12.2.5.3	The auditor observed an analyst pre-filling times on benchsheet and not recording actual times.	**Required:** Enter incubation beginning and ending times exactly, without rounding and without estimating. **Recommended:** Use the same timepiece for all samples to ensure accuracy.	The analysts have been retrained on proper time documentation, are entering incubation beginning/ending times exactly, without rounding or estimating, and have been using one time piece for all samples to ensure accuracy. **Implementation Date:** October 2018	Acceptable corrective action. The implementatino date (October 2018) provided by the lab does not match with the implementation date (2/12/2019) for the corresponding finding from the records audit (Table 2, Finding #6). DEP auditors are unclear as to when the issue was properly fixed, and therefore, are using the later date in their response.
26	Rule 62-160.700, F.A.C.	A benchsheet for fecal coliforms dated 3/7/18 has incorrect qualifier instructions for use of "A" and "B" in the footnotes.	**Required:** Update any qualifier instructions in all lab documents to reflect current rules and methods.	Qualifier instructions in all Micro bench forms have been updated to reflect current rules and methods. **Implementation Date:** 2/15/2019	Acceptable

* Florida Department of Environmental Protection (DEP). Guidance for Microbiological Data Reported to DEP (attached to purchase order), Version 060117.

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