# Florida Department of Environmental Protection

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Rick Scott
Governor

Carlos Lopez-Cantera
Lt. Governor

Noah Valenstein
Secretary


VIA EMAIL
*Read receipt requested*

January 3, 2019

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

**Re: Final Audit Report for Microbiology Lab Records Audit**

Dear Mr. Cantin:

Thank you for responding to the preliminary audit report for the Microbiology Lab Records Audit of the Advanced Environmental Laboratory-Altamonte Springs laboratory (AEL). The Florida Department of Environmental Protection (department or DEP) has reviewed your response and determined that the proposed corrective actions are acceptable, and have been implemented. We are confident that the indicated corrective actions will improve the quality system for AEL.

Attached is the final audit report detailing the audit procedure, audit findings, and the department's audit conclusions. This final audit report also will 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 conform with the DEP purchase order AF315E, the 2003 National Environmental Laboratory Accreditation Conference (NELAC) standards, Chapter 62-160, Florida Administrative Code (F.A.C.), and the relevant methods. The auditors do not recommend any restrictions on DEP use of the data evaluated in this audit.

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 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. 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.

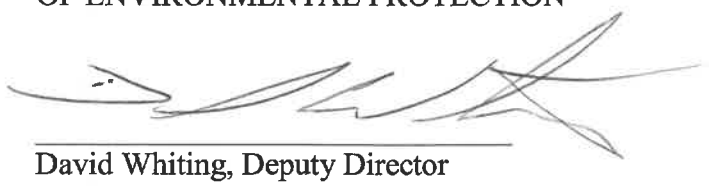
A petition that disputes the material facts on which the department's action is based must contain the following information: (a) The name and address of each agency affected and each agency's file or identification number, if known; (b) The name, address, and telephone number of the petitioner; the 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
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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 January 7, 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.

NP Baino 1/7/19

Clerk Date

# *Final Audit Report*
# *AEL-Altamonte Springs*
# *DOH ID # E53076*
# *Microbiology Lab Records Audit*
# *Conducted August 2018*

**Division of Environmental Assessment and Restoration**
**Florida Department of Environmental Protection**
**January 3, 2019**

## Introduction

This laboratory records audit of the Advanced Environmental Laboratory-Altamonte Springs laboratory (AEL), DOH ID E53076, was conducted by the Florida Department of Environmental Protection's (DEP or department) Biology Program and Aquatic Ecology and Quality Assurance Section (AEQAS). 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 is complying with the quality assurance (QA) requirements of DEP purchase order AF315E 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

DEP staff requested analytical and quality control records for four samples analyzed for fecal coliform under contract during the last year (Table 1). Records were requested on August 28, 2018, and received on September 7, 2018. A team of staff from AEQAS reviewed the records, which included custody chains, laboratory check in logs, analytical runs, laboratory reports, and QA and quality control (QC) documentation. The DEP purchase order No. AF315E, 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.

## Preliminary Audit Report and Implementation of Corrective Actions

A preliminary audit report of findings and deficiencies was sent to Stephen Cantin of AEL on October 24, 2018. Procedures or documentation that did not comply with audit criteria are identified in Table 2, along with the department's suggested or required corrective actions. Mr. Cantin replied on November 26, 2018 with proposed corrective actions for the noted deficiencies, which have been included in Table 2. The AEQAS auditor reviewed and accepted the proposed corrective actions, and the corrective actions have been implemented as of the dates indicated in Table 2. Any additional required corrective actions or other clarifications are indicated in the AEQAS response column.

## Conclusions and Usability Statements

Based on the reported findings for the records audit, the AEL lab procedures for fecal coliforms analysis during the audited period (September -December 2017) adhere to the QA requirements in DEP purchase order No. AF315E, the 2003 NELAC standards, Chapter 62-160, F.A.C., and the relevant methods. DEP recommended some updates to the AEL lab SOP per the findings and

the current versions of published methods used by the laboratory. The auditors do not recommend any restrictions on DEP use of the data evaluated in this audit.

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 conducted by DEP.

| Lab Sample ID | Collection Date | Analyte | Method |
|---|---|---|---|
| A1707094001 | 09/21/2017 | Fecal Coliform | SM 9222D |
| A1708179003 | 10/26/2017 | Fecal Coliform | SM 9222D |
| A1708838002 | 11/20/2017 | Fecal Coliform | SM 9222D |
| A179673001 | 12/21/2017 | Fecal Coliform | SM 9222D |

**Table 2.** Audit Findings for the lab records audit of AEL conducted by DEP.

| Finding # | Analyte | Requirement Reference | Finding | Sample(s) Affected (lab ID) | Required or Recommended Corrective Action | Laboratory Response | AEQAS Response |
|---|---|---|---|---|---|---|---|
| 1 | Fecal Coliform | SM 9020 B, Section 7c | Sample temperature was not verified as ≤10°C upon receipt, or indicated it was received on ice. | A1708838002 | **Required:** Record temperature control measurements performed during laboratory receipt, to link to all corresponding samples. | The sample receiving and PM staff has been retrained on the FDEP COC format and temperature recording requirements. The sample receipt temperatures will be verified by login on the COC, and documentation will be verified by the PM, going forward. **Implementation Date:** 11/16/2018 | Acceptable |
| 2 | Fecal Coliform | Guidance document, page 2* | Only two dilutions for the samples were run instead of the required three dilutions. | A1707094001, A1708179003 | **Required:** Use three dilutions for membrane filtration tests. | The FDEP overflow contract has been re-reviewed by the lab since the time the affected samples were run and are now running the dilutions as required. **Implementation Date:** 11/20/2018 | Acceptable |

| Finding # | Analyte | Requirement Reference | Finding | Sample(s) Affected (lab ID) | Required or Recommended Corrective Action | Laboratory Response | AEQAS Response |
|---|---|---|---|---|---|---|---|
| 3 | Fecal Coliform | SM 9222 D, Section 2a & Guidance document, page 2* | Volumes filtered did not yield results within 20-60 colonies. | All samples | **Required:** Filter the appropriate volume to achieve colony counts within the ideal range, per SM 9222 and guidance document*. | The lab has further reviewed the FDEP contract requirements to determine the correct dilutions and quantity of them to use based on water source and will follow them going forward. **Implementation Date:** 11/20/17-to correct for the amount of dilutions; 11/21/18-to correct for the volumes filtered per contract | Acceptable |
| 4 | Fecal Coliform | NELAC 2003 D, 3.8b 6i | Temperature was not recorded a second time throughout the day, at least four hours following the first temperature check. | A1709673001 | **Required:** Check temperatures twice daily, at least four hours apart. | The analyst began recording the range of the samples in the incubator with a second temperature check, four hours from the initial temperature check, after a previous internal audit finding covered in NCF A18011. **Implementation Date:** 04/23/2018 | Acceptable |
| 5 | Fecal Coliform | SM 9222 D, Section 1a | Media sterility was checked after the sample was run on the media. | A1707094001 | **Required:** Check media sterility prior to analyzing samples on the media. | The analyst was retrained on the verification requirement of sterility check of the media prior to running samples using the media. The lab will run the sterility check and verify criteria have passed before using the media on samples going forward. **Implementation Date:** 11/16/2018 | Acceptable |

| Finding # | Analyte | Requirement Reference | Finding | Sample(s) Affected (lab ID) | Required or Recommended Corrective Action | Laboratory Response | AEQAS Response |
|---|---|---|---|---|---|---|---|
| 6 | Fecal Coliform | Guidance document, page 1* | The "V" qualifier was inappropriately applied to sample. The qualifier was added when the method blank did not have a detection according to the bench sheet. | A1709673001 | **Required:** Review and resubmit data with the appropriate qualifier applied. Only use the "V" qualifier if there was a detection in an associated method blank. | A closing post blank was contaminated, not the initial pre-blanks. The data was qualified for that reason and reported correctly. An NCF, A17047, was previously generated for the post blank failure. **Implementation Date:** N/A | Acceptable. Records reviewed by the auditor when responses were received. Noted the "Post 1" control had 7 CFU. Qualifier was appropriately applied and lab report has adequate description for the qualified samples. |

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

**Other References:**

APHA-AWWA-WEF. 1997. Standard Methods for the Examination of Water and Wastewater, 20th Edition, Part 9000, Microbiological Examination, Section 9020, Quality Assurance.

APHA-AWWA-WEF. 2006. Standard Methods for the Examination of Water and Wastewater, 21st Edition, Part 9000, Microbiological Examination, Section 9222 D, Thermotolerant (Fecal) Coliform Membrane Filter Procedure.

Florida Department of Environmental Protection (DEP). Request for Proposals Contractual Services, Microbiological Overflow Services, Solicitation Number 2017004C, Agency Release Date July 29th, 2016.

National Environmental Laboratory Accreditation Conference (NELAC). 2003 NELAC Standard, EPA/600/R-04/003, Volume 1, Module 5, Quality Systems, Approved June 5th, 2003