Florida Department of Environmental Protection

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Tallahassee, Florida 32399-2400

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Carlos Lopez-Cantera
Lt. Governor

Noah Valenstein
Secretary

VIA EMAIL
Read receipt requested

December 12, 2018

Jeremy Bosso, MPH
University of West Florida
11000 University Pkwy
Pensacola, FL
Email: jbosso@uwf.edu

Re: Final Audit Report for Microbiology Lab Records Audit

Dear Mr. Bosso:

Thank you for responding to the preliminary audit report for the Microbiology Lab Records Audit of the University of West Florida (UWF). 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 UWF.

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 UWF conform with the DEP contract No. LAB032, the 2003 National Environmental Laboratory Accreditation Conference (NELAC) standards, Chapter 62-160, Florida Administrative Code (F.A.C.), and the relevant methods.

Under Chapter 120 of the Florida Statutes, UWF, 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

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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Final Audit Report
University of West Florida Laboratory
Microbiology Lab Records Audit
Conducted July 2018

Division of Environmental Assessment and Restoration
Florida Department of Environmental Protection
December 12, 2018

Introduction

This laboratory records audit of the University of West Florida's Laboratory (UWF) 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 UWF is complying with the quality assurance (QA) requirements of DEP contract No. LAB032 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 ten samples analyzed for fecal coliform, *E. coli*, and enterococci under contract during the last year (Table 1). Records were requested on May 31, 2018 and received on June 5, 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 contract No. LAB032, 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 Jeremy Bosso of UWF on August 30, 2018. DEP staff discussed preliminary findings with him by phone on September 7, 2018. Mr. Bosso replied on September 19, 2018 with proposed corrective actions for the noted deficiencies. Procedures or documentation that did not comply with audit criteria are identified in Table 2, with suggested or required corrective actions as well as UWF responses to the findings. The AEQAS auditor reviewed and accepted corrective actions in the department's final response, 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 UWF lab procedures for all audited laboratory analyses (fecal coliform, *E. coli*, and enterococci) during the audited period (July - November 2017) adhere to the QA requirements in DEP contract No. LAB032, the 2003 NELAC standards, Chapter 62-160, F.A.C., and the relevant methods. DEP recommended some

updates to the UWF 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 UWF conducted by the Florida Department of Environmental Protection.

Lab ID	Collection Date	Analyte	Method
17-42816	7/20/2017	Fecal Coliform	SM 9222D
17-42981	8/28/2017	Fecal Coliform	SM 9222D
17-43071	9/25/2017	Fecal Coliform	SM 9222D
17-42922	8/7/2017	*E. Coli*	Colilert 18
17-43154	10/16/2017	*E. Coli*	Colilert 18
17-43287	11/29/2017	*E. Coli*	Colilert 18
17-42811	7/18/2017	*Enterococci*	Enterolert
17-43006	9/05/2017	*Enterococci*	Enterolert
17-43137	10/12/2017	*Enterococci*	Enterolert
17-43280	11/28/2017	*Enterococci*	Enterolert

Table 2. Audit Findings for the lab records audit of UWF conducted by the Florida Department of Environmental Protection.

Finding #	Analyte	Requirement Reference	Audit Finding	Sample(s) Affected (lab ID)	Required or Recommended Corrective Action	Laboratory Response	AEQAS Response
1	Fecal Coliform	SM 9020 Section 10, NELAC QS5 D.3.4	Verification samples were incubated for less than the required time for both presumptive and confirmed phases.	17-42816, 17-42981, 17-43071 (All Fecal Coliform)	**Required:** Incubate verification samples for 24-hours in both lauryl tryptose broth (LTB) and EC broth (per method) **Recommended:** (a) Continue incubation of atypical colonies to 48 hours if no growth and presumptive coliform LTB results are obtained; (b) Verify atypical "suspected" fecal colonies on EC medium.	**Finding 1 Response:** The analyst is checking the samples when the temperature is checked, usually before 24 hours incubation time is up. Most of the time they are positive at this point and the results are recorded (per instructions from assessors). If any happen to be negative, they are left to incubate the full time, but the time the samples are removed from the incubator may not have been updated on the log. **Finding 1 Corrective Action:** Going forward, the analyst will make sure that any negative samples are incubated for the full time prescribed by the method, and that the correct incubation end time is recorded for each sample. **Implementation Date:** 9/7/2018	Acceptable
2	Fecal Coliform	SM 9020 Section 10	It appears that the sample result for 17-42815 was adjusted when atypical colonies did not verify as positive on LTB or EC medium. It is unclear if the atypical colonies were counted as positive in the original sample. The lab SOP (15.1) states that atypical colonies are grey to green, and therefore should not be counted. In sample 17-43232, the atypical colony was negative for coliforms but positive for fecal. This result should be invalid, but the remark reads 90% verification.	17-43132	**Required:** Clarify the procedure for picking colonies to verify. Explain how the % verification was determined for these two samples.	**Finding 2 Response:** The analyst is verifying 10 blue colonies monthly (presumed positive). The ones noted as "atypical" on the log sheet are presumed positive because they are blue, but may have an odd shape or different shade of blue. With this information, the percentage verified was correctly calculated. **Finding 2 Corrective Action:** The percentage verified is calculated correctly; however, going forward, the analyst will not use the term "atypical" in the verification log for colonies that are presumed positive. **Implementation Date:** 9/7/2018	Acceptable. Note: The original finding and corrective actions were based on an incorrect interpretation of the lab's records by AEQAS. After discussion with the lab, AEQAS determined the calculations were correct. The lab's response is acceptable, provided they record any verifications done in the future for presumed negative colonies.

3	Fecal Coliform	SM 9020 Section 7, NELAC Appendix D 5.5.8.3.2	The collection times recorded on the chain of custody and laboratory report do not match.	17-42816, 17-42981	**Required:** Check for transcription errors. Confirm with sampling entity the time of sample collection, and record the correct time of collection. A corrective action report should be generated to correct the time for sample collection.	**Finding 3 Response:** The samples in question are correct; the person who collects the samples uses a slash on the zeros, which can make the number look different. The lab is aware and confirms the time with the sampler if there is any question. The sampler works for DEP, so **no Corrective Action** is needed by the laboratory. **Implementation Date:** N/A	Acceptable