FLORIDA DEPARTMENT OF Environmental Protection

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2600 Blair Stone Road
Tallahassee, FL 32399-2400

Ron DeSantis
Governor

Jeanette Nuñez
Lt. Governor

Noah Valenstein
Secretary

VIA EMAIL
Read receipt requested

July 30, 2019

June Flowers
Flowers Chemical Laboratories, Inc., Port St. Lucie, FL
571 NW Mercantile Place
Port St. Lucie, FL 34986
Email: june@flowerslabs.com

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

Dear Ms. Flowers:

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 the Flowers Chemical Laboratories, Inc., Port St. Lucie, FL (Flowers-PSL). 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 Flowers-PSL have met the Quality Control (QC) criteria required by the approved methods, NELAC 2003 standards, Chapter 62-160, Florida Administrative Code (F.A.C.), and/or DEP contract requirements, except for Finding 6, Table 2. The corrective action for Finding 6 is acceptable from 7/18/18, when blanks were implemented for IDEXX tests, going forward. Enterococci and *E. coli* results determined by IDEXX tests performed before this date may be considered by DEP as estimated for certain uses of the data. DEP auditors found other QC deficiencies as well, as outlined in the report. Corrective actions for all findings in this report are acceptable. 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, FCL, 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 Jessica Patronis at (850) 245-8980.

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 Flowers Chemical Laboratories, Inc., Port St. Lucie, FL 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 July 30, 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 7/30/19
Clerk Date

Final Audit Report
Flowers Chemical Laboratories, Inc. Port St. Lucie (DOH #E86562)
Microbiology Lab Records Audit

Division of Environmental Assessment and Restoration
Florida Department of Environmental Protection
July 26, 2019

Introduction

The Florida Department of Environmental Protection's (DEP or department) Aquatic Ecology and Quality Assurance section (AEQAS) conducted a laboratory records audit of Flowers Chemical Laboratories, Inc. located in Port St. Lucie, Florida,(Flowers-PSL), as part of a routine review of laboratories holding contracts or under purchase orders with DEP for microbiological analyses. The audit was conducted in accordance with Rules 62-160.650 and 62-160.670, Florida Administrative Code (F.A.C.), to verify that Flowers-PSL is complying with the quality assurance (QA) requirements of DEP purchase order No. B3508E and correctly implementing approved analytical methods, including acceptable quality control (QC), 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 responses to the corrective actions proposed by the laboratory.

Audit Description

DEP staff requested analytical and QC records for ten samples representing the laboratory's analyses for Fecal coliform, *Escherichia coli* (*E. coli)* and enterococci under contract during the 2017-2018 fiscal year (Table 1). Records were requested on November 19, 2018 and received on December 17, 2018. A team from AEQAS reviewed the records, which included custody chains, laboratory check in logs, analytical runs, laboratory reports, and QA and QC documentation. The DEP purchase order No. B3508E, 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 June Flowers of Flowers Laboratories on March 14, 2019. Procedures or documentation that did not comply with audit criteria are identified in Table 2, along with the department's required or recommended corrective actions. Ms. Flowers responded on April 25, 2019 with proposed corrective actions for the noted deficiencies, which have been included in Table 2. The AEQAS auditors reviewed the proposed corrective actions and added additional responses to Table 2. Several responses to the Preliminary Report required further clarification from the laboratory. AEQAS sent a draft Final Report to June Flowers on June 10, 2019, which included the areas in need of clarification for several findings in Table 2. June Flowers responded on June 14, 2019, with further clarifications to resolve these findings. Responses to clarifications, with date of correspondence notated in bold, are included in Table 2.

Audit Conclusions

Based on the findings for the records audit, DEP has determined that Flowers-PSL has met the QC criteria required by the approved methods, NELAC 2003 standards, and/or DEP contract requirements, except for Finding 6, Table 2. The corrective action for Finding 6 is acceptable from 7/18/18, when blanks were implemented for IDEXX tests, going forward. Enterococci and E. coli results determined by IDEXX tests performed before this implementation date may be considered by DEP as estimated for certain uses of the data.

DEP auditors found other QC deficiencies as well, as outlined in the report. Corrective actions for all findings in this report are acceptable. 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.

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 Flowers-PSL conducted by DEP.

Laboratory ID	Collection Date	Analyte	Method
338292SW6	7/20/2017	Enterococci	Enterolert
343389SW5	9/18/2017	Enterococci	Enterolert
350023SW1	11/21/2017	Enterococci	Enterolert
337907SW7	7/18/2017	*E. coli*	Colilert-18/ SM9223B
339587SW2	8/3/2017	*E. coli*	Colilert-18/ SM9223B
341975SW1	8/29/2017	*E. coli*	Colilert-18/ SM9223B
343824SW2	9/20/2017	*E. coli*	Colilert-18/ SM9223B
345750SW3	10/9/2017	*E. coli*	Colilert-18/ SM9223B
347078SW1	10/23/2017	Fecal coliform	SM9222D
349391SW5	11/15/2017	Fecal coliform	SM9222D

Table 2. Findings for the lab records audit of Flowers-PSL conducted by DEP.

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Required or Recommended Corrective Action	Laboratory Response (Preliminary report response 4/25/2019 unless otherwise noted)	Implementation Date	AEQAS Response
1	Fecal coliform	NELAC 5.4.12.2.5.3; Guidance Document p. 1, 2.	The bench sheet lists a range of times for incubation start time. There are fields for "time in" and "time out" for each sample, but they are not filled out.	347078SW1, 349391SW5	**Recommended:** Clearly indicate a specific time when individual samples went into the incubator.	The routine is to wait for all samples to arrive and have a single filtration series in the afternoon. The way the logbook is being used, the space is insufficient for the analyst to complete the Time In box, so it was being recorded top left following the Date In Incubator. Analyst will now fill in the column alongside the sample with the Time In and Out of incubator.	4/9/19	Acceptable.
2	Fecal coliform	Guidance Document p. 7; NELAC 5.4.12.1.5 and 5.4.12.2; SM9020B	Filtration times are not recorded on the bench sheet. There is no way to reconstruct the filtration process associated with blanks and environmental samples without proper documentation.	347078SW1, 349391SW5	**Required:** Document filtration times so that the process of analysis can be historically reconstructed and understood. **Recommended:** Add "Filtration Start Time" prompt to (all) bench sheets.	Since the Blanks indicate the start and end of a filtration series, the time filtration started and ended is now written alongside each Blank.	4/9/19	Acceptable.

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Required or Recommended Corrective Action	Laboratory Response (Preliminary report response 4/25/2019 unless otherwise noted)	Implementation Date	AEQAS Response
3	Fecal coliform	NELAC 5.5.4.7.1; SM9020B	There is no indication on the bench sheet that more than one person verifies that results are correct and entered correctly.	347078SW1, 349391SW5	**Required:** Perform and document verification of data entry to minimize transcription errors.	With a single analyst, the procedure is to enter results on the Logger (Excel file), walk away, return and review for entry completeness before submitting. Re-counts are also performed by the same analyst with 5% agreement criteria.	4/9/19	**Response 6/10/19:** Ensure that the data result and entry verifications are documented, and result calculations are also checked.
						Response 6/14/19: An effort will be made to have a secondary review of data entered on spreadsheets and that person's initials recorded. The current procedure is to enter, walk away, review then submit. On an annual basis, all FCL spreadsheet calculations are verified by QA.		Acceptable.

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Required or Recommended Corrective Action	Laboratory Response (Preliminary report response 4/25/2019 unless otherwise noted)	Implementation Date	AEQAS Response
4	Fecal coliform	Guidance Document p. 5; SM9020B	A "+" is recorded on the bench sheet for presumptive and confirmed phase tests. There is no indication of how many colonies were used for the tests, or what the + sign means.	347078SW1, 349391SW5	**Required:** Clearly document that the required colonies are carried to the verification phases.	The number of colonies up to 10 from positive plates is now written in the LTB column. The "+" or "-" is now recorded alongside the colony # to indicate presence or absence of gas.	4/9/19	Acceptable.
5	Fecal coliform	FDEP Records Request	The incubator temperature log page that corresponds to the audited sample is missing for the date range 11/16/17-11/17/17, Water Bath ID 1007. The auditor cannot determine if the incubator temperature was properly maintained over the incubation period for the sample.	349391SW5	**Required:** Provide the incubator temperature log book page for 11/16/17-11/17/17, Water Bath ID 1007. An email was sent requesting this information on 3/1/2019, but no response was received.	See attached page 8 of 12 of the Fecal Water Bath Temperature Log for the measurements that corresponds to the audited samples.	4/9/19	Acceptable.

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Required or Recommended Corrective Action	Laboratory Response (Preliminary report response 4/25/2019 unless otherwise noted)	Implementation Date	AEQAS Response
6	Fecal coliform, Enterococci, *E. coli*	Guidance Document, p.1; NELAC 5.4.12.2.1, 5.4.12.2.5.2 a), 5.4.12.2.5.3 l) & n), 5.5.9.2 b); SM9020B	For fecal coliform, the dilution water lot information is missing or not clearly linked to the samples. For IDEXX methods, the sterile water lot numbers are not recorded on the bench sheet or log book cover page. There is no record that contamination checks are being performed.	347078SW1, 349391SW5, 338292SW6, 343389SW1, 350023SW1, 337907SW7, 339587SW2, 341975SW1, 343824SW2, 345750SW3	**Required:** Explain how dilution water lot numbers are linked to the samples. Provide documentation that contamination checks are being performed, including the lots of sterile water, with linkages to the samples. Perform contamination checks on each lot and document lot numbers of sterile water used.	Squirt bottles of "Buff H2O" are recorded in the autoclave log. To link to samples, the date is now added to the record and recorded alongside each Blank in the designated logbook row, i.e., Blank "Buf H2O 4/9/19". DI water straight from the spigot is used for Enterococci and E.coli.	4/10/19	**Response 6/10/19:** "4 Buff. H2O" and "1 squirt" are notated in the autoclave logs. Are these used as dilution water for the fecal coliform test? Are these multiple separate containers of water? How are they uniquely identified and linked to the samples? For Enterococci and E. coli, explain how the DI water from the spigot is sterilized and where/how it is documented. Explain how contamination checks are performed for these tests. Auditor could not find documentation that contamination checks are being performed.
						Response 6/14/19: The 4 Buff H2O and 1 squirt bottles are considered a batch of buffered water prepared together and autoclaved together for Fecal MF dilutions. DI water has not been autoclaved but is free from bugs as indicated by running blanks. The process of autoclaving, checking for sterility with double-strength TSB, positive/negative controls will be performed for future samples.	6/18/19	Acceptable.

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Required or Recommended Corrective Action	Laboratory Response (Preliminary report response 4/25/2019 unless otherwise noted)	Implementation Date	AEQAS Response
7	Fecal coliform, Enterococci, *E. coli*	Guidance document p. 1, 8; SM9020B; NELAC 5.4.12.1.5; 5.4.12.2.2; 5.4.12.2.5.2 a), 5.4.12.2.5.3 l) & n); 5.5.9.2	There are no duplicate samples recorded on the bench sheet, or the system of labelling duplicates is unclear. Precision calculation documentation is not provided.	347078SW1, 349391SW5, 338292SW6, 343389SW1, 350023SW1, 337907SW7, 339587SW2, 341975SW1, 343824SW2, 345750SW3	**Required:** Identify sample duplicates for each run associated with the audited samples (if any). Label individual samples on the bench sheet so that a second party can understand the documentation. Perform sample duplicates for at least 10% of samples and calculate variability according to Standard Methods requirements. Duplicate samples which do not meet the required precision should be qualified with a "J" and accompanied by a comment.	For Fecal Coliform, 1 samples' 10mL filtration is always duplicated. A line is drawn down from the sample ID entry and "Dup" is recorded. IDEXX duplicates began in July, 2018. Precision spreadsheets are completed by the analyst and kept on file. If criteria are not met, data would be flagged "J". Analyst will take more time to clearly document which sample is being duplicated. Example precision chart is attached.	Fecal since contract began Entero and E.coli 7/18/18	**Response 6/10/19:** Are duplicates performed on each run for fecal coliform tests?
						Response 6/14/19: Yes, Fecal Coliform duplicates have always been performed on 1 sample per batch, using the 10mL filtration volume.		Acceptable.

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Required or Recommended Corrective Action	Laboratory Response (Preliminary report response 4/25/2019 unless otherwise noted)	Implementation Date	AEQAS Response
8	All analytes	SM9020B; NELAC D.3.8 b)6)i)	Time entries in the incubator temperature logs are often recorded only to the hour. (Water bath ID# 1007; Air incubator 1005 and 1108)	347078SW1, 338292SW6, 343389SW1, 350023SW1, 339587SW2, 343824SW2, 345750SW3	**Recommended:** Record times to the minute in the incubator temperature log book to determine that the incubator temperature has been checked twice daily, at least 4 hours apart.	Military time, i.e., 4 digits should be used for recording times, but the analyst consistently states "A" or "P", and will now use at least 3 digits to the minute in all records.	4/9/19	Acceptable.
9	Enterococci, *E. coli*	Guidance document page 7,8	Records do not indicate that method blanks are performed following each environmental sample set.	338292SW6, 343389SW1, 350023SW1, 337907SW7, 339587SW2, 341975SW1, 343824SW2, 345750SW3	**Required:** Perform a method blank following each environmental sample set as required by the purchase order (PO).	Since the IDEXX methods do not require a method blank, they were not being performed. We immediately added a Blank to each batch of FDEP samples.	7/18/18	Acceptable.

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Required or Recommended Corrective Action	Laboratory Response (Preliminary report response 4/25/2019 unless otherwise noted)	Implementation Date	AEQAS Response
10	Enterococci	NELAC D.3.1 b) & c); Enterolert	There is no record of media controls being performed for lot numbers HM824 and FM612B.	338292SW6, 343389SW1, 350023SW1	**Required:** Perform media controls for Enterococci or provide records of media controls run on the specified media lots before each of the audited sample dates.	See attached documentation for the positive and negative controls and pH tested for the Enterolert lot numbers in question. **Response 6/14/19:** We prefer not to have multiple strains of virulent organisms in the lab. Pseudomonas aeruginosa is an acceptable negative organism for Enterococcus.	2/20/17, 10/15/17	**Response 6/10/19:** AEQAS has the following questions about the additional attachments: Why is the organism Pseudomonas aeruginosa used for a negative control instead of the organisms recommended in the IDEXX method QC procedures for Enterolert? Acceptable.

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Required or Recommended Corrective Action	Laboratory Response (Preliminary report response 4/25/2019 unless otherwise noted)	Implementation Date	AEQAS Response
11	Enterococci, *E. coli*	Guidance document page 8; NELAC D.3.8 b)3)iii); SM 9020	Records do not indicate that a volume check is performed on one vessel for each lot of IDEXX Quanti-Tray mixing vessels.	338292SW6, 343389SW1, 350023SW1, 337907SW7, 339587SW2, 341975SW1, 343824SW2, 345750SW3	**Required:** Provide mixing vessel volume check records or perform and document a mixing vessel volume check to the regular quality control (QC) performed on each lot of consumables as required by the PO.	Lot #1198795 was checked on 10/9/17. The record is on page 5 of 10 in the Microbiology Receipt Log. The cl2"S1697" and "Vol ok" with analyst initials is written in the right hand margin. FCL has created a dedicated log sheet for clarification of these records. See attached. **Response 6/14/19:** Yes, the sterile bacti bottles that we purchase and verify are used for preparing sample dilutions. All our analysts only use their current lot of sterile containers. The next revision to the SOPs will be specific and state this for assessor review.	4/10/19 New log When new lot is received	**Response 6/10/19:** Are the BactiBottles what the laboratory is using as a mixing vessel for these tests? FCL SOP does not specify the use of a mixing vessel and what type of vessel is used in section XIV. Procedure. Please include information about the mixing vessel in the FCL SOP for each IDEXX method. Acceptable.
12	*E. coli*	NELAC 5.4.12.1; 5.4.12.2.5.2 h); 5.4.12.2.5.3 k); 5.5.4.7.1 a)	The Sample Description number on the lab report is missing a digit.	345750SW3	**Required:** Ensure documentation is reviewed and corrected for transcription errors.	Analyst has been instructed to take the time to properly record the complete sample ID's.	3/15/19	Acceptable.

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Required or Recommended Corrective Action	Laboratory Response (Preliminary report response 4/25/2019 unless otherwise noted)	Implementation Date	AEQAS Response
13	All	NELAC 5.4.12.1.2; 5.4.12.1.5.e),f); 5.4.12.2.3	Handwriting on the records is often very difficult to read and often not entirely complete.	All	**Required:** Ensure handwriting is legible on all documentation and documentation is filled out completely.	Analyst has been instructed to take the time to clearly record all required information so that a complete reconstruction of activity can be made.	3/15/19	Acceptable.
14	*E. coli*	NELAC 5.4.12.2.1 & 5.2.12.2.2, 5.5.8.2.d); Colilert-18 Test Kit insert; SM 9223B	There is no record of a comparator being used for *E. coli* samples.	337907SW7, 339587SW2, 341975SW1, 343824SW2, 345750SW3	**Required:** Use a comparator as indicated in the IDEXX method for *E. coli*. Track comparator lot numbers and expiration dates for use of color comparators for samples analyzed for *E. coli* using the IDEXX method to ensure proper interpretation of results.	The color comparator lot # in use has been added to the cover pages of the corresponding lab test logbooks. **Response 6/14/19:** The expiration date for the color comparators in use have been added to the cover page of the respective logbooks along with the date range of when put in use, and when retired.	3/15/19	**Response 6/10/19:** Document the expiration date and replace the comparator when expired. Acceptable.

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Required or Recommended Corrective Action	Laboratory Response (Preliminary report response 4/25/2019 unless otherwise noted)	Implementation Date	AEQAS Response
15	Enterococci, *E. coli*	Colilert-18 Test Kit insert; NELAC: 5.4.12 (1st par.); 5.4.12.2.1; 5.4.12.2.2; 5.4.12.2.5.3e), g), k); 5.5.4.1.2b)15); 5.5.4.7.1; 5.5.9.2; D.3.5	It is unclear and inconsistent from the bench sheet documentation what is meant by the sample volume recorded, how that relates to the dilution factor, and how an MPN result is determined when a dilution factor is applied. It is unclear when and how rounding and significant figures are used with MPN table values.	350023SW1, 337907SW7, 339587SW2, 341975SW1, 343824SW2, 345750SW3	**Required:** Explain documentation procedures for IDEXX method results and calculations for each of the audited samples. Explain the procedure for applying a dilution factor to the result and the use of rounding or significant figures. Document calculation procedures in the SOP. Clearly label individual sample volumes, dilutions, and results on the bench sheet.	The analyst is not properly completing the logbook, but simply indicating "10%" in the 1:10 Dilution column if only 10mL of sample is diluted to 100mL total sample volume. The logbooks have been changed to indicate "DF" so that value is multiplied by the IDEX chart value. The DF, Large and Small Well numbers are entered into a spreadsheet that is annually verified to calculate the MPN/100mL to 3 significant figures.	4/10/19 New log by 5/3/19	Acceptable.

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.

APHA-AWWA-WEF. 2012. Standard Methods for the Examination of Water and Wastewater, Part 9000, Microbiological Examination, Section 9223, Enzyme Substrate Coliform Test.

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

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

IDEXX. 2018. Enterolert Test Kit, 06-02150-14.

IDEXX. 2017. Colilert-18 Test Kit, 06-02027-24.

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