FLORIDA DEPARTMENT OF Environmental Protection

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Tallahassee, FL 32399-2400

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VIA EMAIL
Read receipt requested

July 15, 2019

June Flowers
Flowers Chemical Laboratories, Inc., Altamonte Springs, FL
481 Newburyport Avenue
Altamonte Springs, FL 32701
Email: june@flowerslabs.com

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

Dear Ms. Flowers:

Thank you for providing detailed information pertinent to the final audit report for the Microbiology Lab Records and Quality System Audit of the Flowers Chemical Laboratories, Inc., Altamonte Springs, FL (FCL). The Florida Department of Environmental Protection (department or DEP) has completed our evaluation of the additional records and responses you provided, and we have added detailed content to the findings tables and revised audit conclusions.

Attached is the revised 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 FCL have not met a critical 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 B16975. The critical finding for FCL is that the lab was recording temperatures of incubator 408 as a whole number, leading to an inability to verify incubator temperatures for *E. coli* tests performed by SM 9223B. DEP auditors found other, non-critical 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 will verify the implementation of corrective actions with future requests for QC documentation. Due to the inability to confirm that incubator temperatures were in the acceptable range, DEP may consider *E. coli* data from 5/2/2017 through 9/19/2018 as estimated values for certain uses of the data.

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. 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 FCL 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 July 15, 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 7/15/2019
Clerk Date

Final Audit Report
Flowers Chemical Laboratories, Inc. – Altamonte Springs DOH # E83018
Microbiology Lab Records & Quality System Audit
Conducted July 2018 and September 17, 2018

Division of Environmental Assessment and Restoration
Florida Department of Environmental Protection
July 15, 2019

Introduction

The Florida Department of Environmental Protection's (DEP or department) Aquatic Ecology and Quality Assurance Section (AEQAS) and Biology Program conducted an audit of Flowers Chemical Laboratories, Inc., Altamonte Springs location (Flowers Laboratory) as part of a routine review of laboratories holding contracts or under purchase orders with DEP for microbiological analyses. This audit consisted of two parts: an initial records-only audit and an in-person laboratory systems audit. DEP staff conducted the audit in accordance with Rules 62-160.650 and 62-160.670, Florida Administrative Code (F.A.C.), to verify that Flowers is complying with the Quality Assurance requirements of the purchase order (PO) B16975 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 enterococci and *Escherichia coli* (*E. coli*) under contract during 2017 (Table 1). Records were requested on May 29, 2018 and received on June 27, 2018. A team of staff from AEQAS reviewed the records, which included custody chains, laboratory check in logs, analytical runs, laboratory reports, and Quality Assurance (QA) and Quality Control (QC) documentation.

AEQAS staff Michael Blizzard, Sarah Panek, and Jennifer Claypool, along with Avril Wood-McGrath from Biology followed-up on September 17, 2018, with an in-person systems audit of the Flowers Laboratory facilities and procedures pertaining to the microbiological analyses under contract. June Flowers, Quality Assurance Director, Jeff Flowers, President/Technical Director of Flowers Laboratory, and Cindi LaRosa, Laboratory Manager, were present. The systems audit included verification of laboratory procedures through review of laboratory analytical and QC records for the microbiological tests, the laboratory Quality Manual and Standard Operating Procedures (SOPs), interviews with laboratory staff, and direct observation. The requirements of PO B16975, 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 Laboratory 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. Ms. Flowers replied on January 28, 2019 with proposed corrective actions for

the noted deficiencies, which have been included in Tables 2 and 3. The AEQAS auditors reviewed the proposed corrective actions, along with additional responses and documentation submitted by the laboratory on April 19, 2019, which are also included in Tables 2 and 3. The AEQAS auditors' responses are found in the last column of Tables 2 and 3. Responses to several findings were initially found not to be acceptable, and additional instructions for corrective actions were provided by auditors in the AEQAS Response column. The original final report was issued April 26, 2019. This final report has been revised to include the resolutions for those findings, reflected as additional responses from June 11, 2019, in Tables 2 and 3.

Audit Conclusions

Based on the findings from this audit, DEP has determined that the laboratory has not met a critical QC criteria required by the approved methods, NELAC 2003 standards, and/or DEP contract (purchase order) requirements. The critical finding for the Flowers Chemical Laboratories – Altamonte Springs is that the lab was recording temperatures of incubator 408 as a whole number, leading to an inability to verify incubator temperatures for *E. coli* tests performed by SM 9223B.

To show that the incubator is currently performing within the acceptable range, Flowers submitted a chart showing temperature readings within range from November 2018 through April 2019. AEQAS further reviewed temperature logs from 3/20/2017 through 10/10/2018. Log entries reviewed during this period were not recorded to the tenths decimal place 66.8% of the time. The review also showed the analyst began consistently recording the tenths decimal place in temperature log entries beginning 9/19/2018. Flowers confirmed from their records that the deficiency began 5/2/2017. Due to the inability to confirm that incubator temperatures were in the acceptable range, DEP may consider data from 5/2/2017 through 9/19/2018 as estimated values for certain uses of the data.

DEP auditors determined other QC deficiencies as well, as outlined in the findings tables. 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 will 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 records audit of Flowers Laboratory conducted by DEP, July 2018.

Sample Description	Laboratory #	Collection Date	Analyte	Method
G2CE0088	337920SW1	7/18/2017	Enterococci	Enterolert
G5CE0089	352380SW2	12/18/2017	Enterococci	Enterolert
G1CE0025	337644SW1	7/13/2017	*E. coli*	SM9223B-2012/QuantiTray
G2CE0084	341241SW1	8/21/2017	*E. coli*	SM9223B-2012/QuantiTray
G1CE0023	340278SW1	8/10/2017	*E. coli*	SM9223B-2012/QuantiTray
G1CE0007	342703SW1	9/6/2017	*E. coli*	SM9223B-2012/QuantiTray
G2CE0099	345350SW2	10/4/2017	*E. coli*	SM9223B-2012/QuantiTray
G2CE0099	347046SW1	10/23/2017	*E. coli*	SM9223B-2012/QuantiTray
G1CE0060	347993SW1	11/1/2017	*E. coli*	SM9223B-2012/QuantiTray
G2CE0075	352513SW1	12/19/2017	*E. coli*	SM9223B-2012/QuantiTray

Table 2. Audit findings for the lab records audit of Flowers Laboratory conducted by DEP, July 2018.

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Required or Recommended Corrective Action	Laboratory Response and Corrective Action (CA) Date (if provided)	AEQAS Response
1	All analytes	Guidance document page 7,8; NELAC 5.4.4	Records do not indicate that method blanks are performed following each environmental sample set.	All samples	**Required:** Perform method blanks as required by the PO.	Method blanks are now logged in with samples and reported for each analyte tested. If a value is above 1MPN/100mL, the associated data values will be flagged.	Acceptable. Our records indicate the laboratory began performing method blanks in July 2018. Report data qualifier "V" for all samples where the associated method blank indicates growth of the target organism.

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Required or Recommended Corrective Action	Laboratory Response and Corrective Action (CA) Date (if provided)	AEQAS Response
2	All analytes	Guidance document page 8; NELAC D.3.8 b)3)iii)	Records do not indicate that a volume check is performed on one vessel for each lot of IDEXX Quanti-Tray mixing vessels.	All samples	**Required:** Provide mixing vessel volume check records or add the mixing vessel volume check to the regular quality control (QC) performed on each lot of consumables.	100mL mark is verified for each lot of sample containers received. This is recorded in the "Misc" Logbook. Several pages of examples were reviewed. See Attachment 1.	There is no clear linkage of the container lot numbers in the Misc. Logbook example pages sent or Attachment 1 to the audited samples. Ensure that mixing vessel volume check records are linked to records for individual samples.
						Response 6/11/2019: Attachment l was a copy of page 33 of our "Miscellaneous" QC logbook where a lab sample #323858DW1 was logged into our LIMS to document the necessary QC for new bacteria bottles: Lot# 070416-3A VG. This answered the finding and recommended corrective action. However, the AEQAS Response referred to "linkage" of that bottle lot to the samples tested. To establish linkage, we record a date range for bottle lot numbers in use on the cover of each lab notebook.	Acceptable.

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Required or Recommended Corrective Action	Laboratory Response and Corrective Action (CA) Date (if provided)	AEQAS Response
3	All analytes	SM 9020B; Guidance document page 8.	Records do not indicate that laboratory quality control duplicates were performed during the audited period. Currently, the lab is performing duplicates, but not evaluating the results.	All samples	**Required:** Perform sample duplicates and calculate variability according to Standard Methods requirements.	Sample duplicates are now logged in with samples and variability is calculated for each analyte on dedicated spreadsheets. If lab criteria are not met, the data will be flagged. CA Date: July 18, 2018. In changing from membrane filter to IDEXX QT, sample duplicates were no longer being performed. This error was an oversite. Flowers Central Lab (FCL) immediately began logging in duplicates for FDEP samples when notified. Attached are examples of precision charts. If duplicates do not meet criteria the data values will be qualified with a "J" and a comment will be made in the Narrative Report.	Acceptable.
4	*E. coli*	Guidance document pages 2,3.	The matrix for this sample is fresh, surface water. The sample was run with a 10x dilution, and 52.0 MPN/100mL was the reported result. The undiluted sample result is 14.5 MPN/100mL.	G1CE0023	**Required:** Explain why multiple dilutions were run for the sample. Explain how the result was chosen. Run future *E. coli* at a single dilution. 10X is acceptable for matrix interference or suspected high levels.	Analysts have been informed to set up a single 10X dilution in the 2000 Quanti-Tray. Two dilutions were set up with the intention to obtain the best reportable value similar to the MF criteria, i.e., 20-60.	Acceptable. Freshwater samples do not need the 10X dilution unless there is a known reason to mitigate matrix interference. Samples must be diluted at least 10X for marine samples as required by the IDEXX method.

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Required or Recommended Corrective Action	Laboratory Response and Corrective Action (CA) Date (if provided)	AEQAS Response
5	All analytes	Guidance document pages 2,3.	The laboratory is performing multiple dilutions on each sample.	All samples	**Required:** Explain why multiple dilutions were performed for samples and how the laboratory chooses which result to report. Run future *E. coli* and enterococci at a single dilution. 10X is acceptable for matrix interference or suspected high levels.	See response above. Multiple dilutions had been performed in error and that analyst used the fecal MF 20-60 cfu/mL rule for selecting data the value to report.	Acceptable. For IDEXX methods, use only a single sample volume and only dilute when required by the method. For the audited freshwater samples except for G1CE0023, the result from the undiluted sample was reported consistent with the method.
6	Enterococci	Guidance document page 3; Enterolert procedural notes	This marine sample does not appear to have been diluted as the IDEXX method and contract requires.	G5CE0089	**Required:** Explain why the marine sample was not diluted per IDEXX method and contract requirement. Dilute all marine samples 1:10 or higher.	The analyst was not informed that the sample was a marine matrix. A copy of the chain-of-custody is now given to the analyst for matrix reference. The chain of custody for these samples did not state they were "Marine".	Acceptable. See AEQAS response for finding 4.
7	All analytes	NELAC 5.4.12.1.2; 5.4.12.1.5.f); 5.4.12.2.3	Handwriting is illegible for several entries on bench sheets and log books.	G2CE088 G1CE0060 G2CE0099/ (345350SW2)	**Required:** Ensure handwriting is legible on all documentation.	The analyst with the illegible handwriting is no longer working here. FCL encourages analysts to take their time to document legibly.	Acceptable.

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Required or Recommended Corrective Action	Laboratory Response and Corrective Action (CA) Date (if provided)	AEQAS Response
8	Enterococci	NELAC 5.4.12.1.5 f); 5.4.12.2.3	Bench sheet indicates a time correction from 16:15 to 14:20 for time in incubator with a line drawn down the column. It is unclear if the correction includes subsequent samples on the bench sheet. A correction was not made to the Electronic Data Deliverable (EDD).	G5CE0089	**Required:** Revise the time in incubator to reflect the correct time for this sample on the EDD, as appropriate. Ensure corrections made to documentation are clear.	Judging from the time that DEP samples were received, 15:45, they could not have been incubated at 14:20. The correction only applied to the first two samples. See Attachment 2.	Acceptable.

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Required or Recommended Corrective Action	Laboratory Response and Corrective Action (CA) Date (if provided)	AEQAS Response
9	*E. coli*	Guidance document page 8; NELAC 5.4.12, D.3.1.a)	Sterility check of the Quanti-Trays lists two lots on the bench sheet cover page within the same date range. The auditors cannot tell which lot of trays was used for the sample. Entry for DN007 was used for audit because records were not provided for MM011.	G1CE0025 G2CE0084 G1CE0023 G1CE0007 G2CE0099/ (345350SW2)	**Required:** Provide an explanation of which lot was used for the samples and why two lots were listed for the same date range. Develop a procedure that clearly links each sample to a tray lot number.	The new analyst has been trained not to have multiple lot numbers of consumables in use at the same time. One lot number is exhausted before another package is opened. The sterility check is performed prior to use and the materials are to remain in storage until needed. Recording the lot #'s on the cover page of the logbooks with a date range of use is our procedure for linking the samples to their respective Quanti-Tray lot #.	A clear linkage cannot be established because an assumption must be made that the individual sample falls within that lot number's date range on the cover page based on the date of analysis. There is no way to tell what lot was actually used for a sample. Ensure that the linkage between tray lot numbers and samples is unequivocal for all logbook cover pages and document this procedure in the FCL SOP. Additionally, sample G1CE0025 was analyzed before the sterility check for lot DN007.
						Response 6/11/2019: The clear linkage is assured by training analysts to not have multiple lot numbers of consumables in use at the same time and denoting each consumables lot number and applicable date range of use on the cover pages of test logbooks.	Acceptable.

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Required or Recommended Corrective Action	Laboratory Response and Corrective Action (CA) Date (if provided)	AEQAS Response
10	*E. coli*	NELAC 5.4.12.2 and 5.5.8.2.d)	Comparator lot numbers are not clearly linked to the samples.	All audited samples for this analyte	**Required:** Clearly link all documentation associated with a sample or measurement.	A color comparator is not linked to any sample MPN data value since there is no quantitative determination associated. It is a visual aide.	Acceptable. The IDEXX method requires the use of the color comparator, and tracking is needed to verify that it isn't expired. We recommend tracking 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.
11	*E. coli*	Guidance document page 5 NELAC 5.4.12.2.1	The bench sheet has no number recorded for small cell count. Most Probable Number (MPN) calculation is not verifiable with available data. During the in-person audit, it was determined that the analyst was leaving the small cell column blank when using trays without small cells. There is no way to tell from the bench sheet which type of tray was used.	G1CE0025	**Required:** Develop procedures that clearly link each sample to a tray lot number. Do not leave spaces on bench sheets blank. Either write NA or draw a line through. **Recommended:** Only use Quanti-Tray 2000 for DEP samples.	Now only Quanti-Tray 2000 are used for DEP samples. For non-DEP samples where the 55 trays may be used, a single line is drawn through the small well spaces. FCL began using QT-2000 trays for DEP samples January 19, 2017.	Acceptable. Ensure an unequivocal link is made between individual samples and their associated consumables including trays and document this procedure in the FCL SOP.

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Required or Recommended Corrective Action	Laboratory Response and Corrective Action (CA) Date (if provided)	AEQAS Response
12	All analytes	NELAC 5.4.12.2.5.3 e)	The IDEXX MPN calculation was not recorded on the bench sheet.	G2CE0084 G1CE0025 G2CE0099/ (345350SW2) G2CE0088	**Required:** Consistently record IDEXX MPN calculations on the laboratory bench sheet.	The bench-sheet lab logbook page is the tool for data entry. The MPN reported values are calculated by the LIMS spreadsheet, so logbooks will be revised to remove these columns. (The MPN calculations are verified annually against the IDEXX MPN tables).	Acceptable. Record the results of the annual IDEXX MPN table verifications linked to sample sets. Ensure that all steps and documentation performed with the data reduction process are described in the laboratory's SOP.
13	*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; 5.4.12.1.5 d)	The bench sheet has the sample number recorded as 240278SW1. This appears to be a misprint, but was not corrected on the bench sheet. The other records associated with the sample do not appear to be affected by the mistake.	G1CE0023	**Required:** Ensure documentation is reviewed and corrected for transcription errors.	The sample ID has been corrected. This transcription error did not affect the results, since the incorrect number was no longer active in the LIMS. Correctness of transcribed documentation has been reviewed with all lab staff. See Attachment 3.	Acceptable.

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Required or Recommended Corrective Action	Laboratory Response and Corrective Action (CA) Date (if provided)	AEQAS Response
14	*E. coli*	NELAC D.3.8.b) 6) i) and 5.4.12.2.5.3 c); SM9020B	Incubator temperatures were not recorded for 11/2/2017.	G1CE0060	**Required:** Explain why there is no record of incubator temperature for the date indicated.	Evidently, the back-up analyst failed to perform this duty. We have now installed "SensorPush" thermometers in all incubators so that a constant measurement is recorded 24hours-7days. See an example printout for the air incubator. Attachment 4.	Acceptable. We recommend creating a procedure for monitoring these temperature sensors so that failures of the incubator can be corrected in a timely manner. Attachment 4 does not include which incubator the temperature data goes with. Ensure linkage between "SensorPush" data records and the associated incubator.
15	All analytes	NELAC 5.4.12.1.5; 5.4.12.2.1; 5.5.8.2	Waterbath ID for Enterococci samples (Incubator ID for *E. coli* samples) and media lot numbers are not recorded on the bench sheets. This information is on the coversheet for the date range of the samples. The bench sheets appear to be kept in a bounded logbook with the coversheets.	All samples	**Recommended:** Record the incubator ID or water bath ID and the media lot numbers on the bench sheet to clearly link it with the samples.	All FCL logbooks now clearly define the specific incubator/water bath, media and Quanti-Tray lot #'s on the front page of the document controlled, bound logbook.	A clear linkage cannot be established because an assumption must be made that the individual sample falls within that lot number's date range on the cover page based on the date of analysis. There is no way to tell what lot was actually used for a sample. Ensure that the linkage between media lot numbers, waterbath IDs, incubator IDs and samples is unequivocal for all logbook cover pages.
						Response 6/11/2019: The clear linkage is assured by training analysts to not have multiple lot numbers of consumables in use at the same time and denoting each consumables lot number and applicable date range of use on the cover pages of test logbooks.	Acceptable.

Table 3. Audit findings for the Systems audit of Flowers laboratory conducted by DEP, September 17, 2018.

Finding #	Requirement Reference	Finding	Required or Recommended Corrective Action	Laboratory Response and Corrective Action (if provided)	AEQAS Response
1	NELAC D.3.6d; SM9020B	Analysts perform pH checks on every batch of prepared media. However, there is no indication of corrective actions or discarding of media when pH is outside of the internal laboratory acceptance criteria.	**Required:** Enact procedures for handling and documentation of media that does not meet the acceptance criteria for pH checks.	FCL no longer prepares media for DEP tests. If purchased media tested pH is outside of vender pH measurement, the test would be repeated to confirm the outlier, then returned to the vendor if not within acceptable limits. FCL SOP 5.08 "Purchasing and Storage of Consumable Materials" indicates "All errors/disputes will be brought to the attention of the vendor by the Lab Manager for corrective action and resolution by email or telephone." Enterolert and Colilert-18 were used starting January 19, 2017. There are no acceptance ranges for pH in the IDEXX literature but the pH is measured and recorded on each new lot of media received.	Acceptable. Ensure that corrective actions are documented, including contacting the vendor for a resolution when pH check does not meet the internal laboratory acceptance criteria.
2	NELAC D.3.6d); NELAC 5.5.6.4; SM9020B	Auditors observed that the date opened for media containers, dilution bottles, and pH buffers is not recorded in the log book.	**Required:** Maintain logs to document the opened date for each container of media, dilution bottles, and pH buffers.	The "Microbiology Media / Supply Receipt Log" is a record of all items received with traceability and expiration dates. The individual boxes of media (there may be 100 with the same lot #) have an "Opened" date on them. The logbook cover sheets clearly indicate the lot # of media packets that are in use, and therefore "opened". Likewise, the pH buffer solution containers now have a "date opened" recorded. Our procedure meets the NELAC standard.	Acceptable.

Finding #	Requirement Reference	Finding	Required or Recommended Corrective Action	Laboratory Response and Corrective Action (if provided)	AEQAS Response
3	NELAC D.3.8 b) 2) ii); SM9020B	Auditors observed that autoclave tape used on laboratory glassware appeared to be autoclaved multiple times. The laboratory SOP states that autoclave tape should be razored off the glassware between uses. It was not apparent that the autoclaved dilution water had fresh tape on it at the time of the audit.	**Required:** Autoclave tape should be properly removed from laboratory glassware between uses. New tape must be used for each autoclave cycle.	Flasks used for autoclaving dilution water are re-used. New tape is used to adhere a Diack tube to the flask each autoclave cycle.	Acceptable. We recommend old tape be removed from glassware between uses.
4	NELAC D.3.8b)	It is unclear how the maximum temperature and pressure are measured for the autoclave.	**Required:** Clarify this procedure in the lab SOP or Quality Manual.	FCL SOP 5.35 "Autoclave Verification Recording" is being updated to clarify that the pressure and temperature gauges are read each cycle and recorded in the Autoclave Sterilization Log. The min-max thermometer placed with items sterilized verifies the temperature was reached.	Acceptable. Ensure that results of all checks (maximum temperature, pressure and min/max thermometer) are documented.

Finding #	Requirement Reference	Finding	Required or Recommended Corrective Action	Laboratory Response and Corrective Action (if provided)	AEQAS Response
5	NELAC D.3.8 b) 2) ii) and v); SM9020B	There is no record that a monthly biological (*Geobacillus stearothermophilus*) check or quarterly timer check was performed on the autoclave between January and June, 2017.	**Required:** Consistently perform monthly biological (*Geobacillus stearothermophilus*) checks and quarterly timer checks on the autoclave.	The logbook observed during the inspection contained autoclave records from June 2017 to present. The previous Autoclave Logbook Doc. Control #001130 has the January through June 15, 2017 data recorded. Attachment 5 is the 1st page of this logbook, where the June through December 2017 data from the newer logbook was transcribed. The beginning pages of our Autoclave Sterilization Logbook contains the 12 months of biological indicator checks and quarterly timer checks. FCL SOP 5.35 has been updated to clarify this process. Since the new logbook began mid-year, the old logbook had blank entries for months June through December. Evidently, the analyst at the time thought to complete the summary page so it didn't appear to be missing the records for the full year. The new "Biological Indicator Check / Autoclave Cycle Timing" log prompts for start and end times and Cycle Minutes. The analyst's iPhone timer is used to verify the autoclave timer. In the event that the autoclave timer is different than the iPhone or stopwatch, then we would have to rely on a separate timing device for every autoclave cycle. The SOP updated 1/25/19 now indicates to document the actual time elapsed and the new logbook "Attachment 2" is included. Example attached.	Acceptable. Consistently perform monthly biological (*Geobacillus stearothermophilus*) checks and quarterly timer checks on the autoclave. Ensure that FCL SOP 5.35 is updated to include the corrective action that will be taken when timer checks fail.

Finding #	Requirement Reference	Finding	Required or Recommended Corrective Action	Laboratory Response and Corrective Action (if provided)	AEQAS Response
6	SM9020B	Temperature logs were examined for the date range 6/15/17 – 9/17/18 (Document #12463 and #12864). The incubator was denoted with ID #408, and the thermometer was indicated as ID #N65789. Many temperature entries over this calendar period were recorded to the whole number only (no decimal degree reading). This affects the initial test temperature for *E. coli* as well as verifications for *E. coli* and enterococci tests.	**Required:** Record incubator temperature readings to the tenths decimal place and apply a correction factor if Flowers' review of verification documentation indicates the necessity for correction.	FCL recognized that temperature readings and recordings were inconsistent, so we added the "SensorPush" thermometers in all incubators so that a constant measurement is recorded to the tenth decimal place 24hours-7days. Attachment 4. Our review was of the same records you observed that some entries were whole numbers. The inconsistent "35" degrees record by the analyst (according to her was 35.0), but if considered as a rounded number the lowest reading say 34.6 and the highest 35.4 could be interpreted, which are in the acceptable range. Now the SensorPush doesn't rely on the human recording to the decimal. Our new analyst does not round to a whole number. We have no correction factors to apply to any data.	Acceptable. Ensure that incubator temperatures are recorded to the tenths decimal place. Note: The finding included "verifications for *E. coli* and enterococci tests." This was an auditor error, as those do not apply to IDEXX methods. This finding only applies to *E. coli* results. Flower's corrective action is acceptable going forward. Extended temperature log review showed 66.8% of temperature log entries were not recorded to the tenths decimal place. Temperature logs were reviewed over an approximately 19-month period (date range 3/20/17-10/10/2018). Temperatures were recorded to the tenths decimal place consistently beginning on 9/19/2018. Flowers reviewed previous temperature log records and determined that the deficiency began 5/2/2017.

Finding #	Requirement Reference	Finding	Required or Recommended Corrective Action	Laboratory Response and Corrective Action (if provided)	AEQAS Response
7	NELAC D.3.8. b) 6) i); SM9020B, table I	For the audited calendar period, many daily afternoon incubator log entries were omitted from documentation.	**Required:** Check incubator temperature twice daily, at least 4 hours apart.	See above regarding "SensorPush" thermometers. Attachment 4.	Acceptable. See AEQAS finding 14, Table 2.
				Response 6/11/2019 In addition, per your request via email, we have copied 9 pages from Air Incubator ID 408 Daily Temperature Logs from 1/13/18 through 9/17/18 to demonstrate the consistency of the 35 deg C temperature measurements. These pages were observed during the on-site audit, but since the dates did not correspond to the FDEP samples being observed, copies were not provided. Other than the Saturdays or Sundays when the incubator was not in use, the following dates did not have the temp record posted in the Daily Temperature Log, but records do exist in the Sample logs for P/ A and Quanti-tray for temp/time "out" and "in" on each of these dates: 1. Thurs-Fri 1/18-19/18 record was missed . Single entries for samples put in and taken out are in the Sample Total Coliform Logbook 2. Fri 1/26/18 - both entries missed 3. Mon 5/28/18-only I entry 4. Wed 6/27/18 - both entries missed 5. Tues 9/18/18 - the 2·• entry missed* *The afternoon temperature had not been recorded in the Daily Temperature Log, but FDEP sample #'s 378257SWI, SW2 & SW3 were incubated on 9/18/ 18. On this date, the 35.0 measurement was recorded on the Lab Notebook page, at a time 4 hours apart from the morning entry. To alleviate the possible omission of the 2 temperatures each day in the Daily Logs, the SensorPush digital thermometers are our corrective action backup.	Acceptable. Upon further temp log review (date range 3/20/17-10/10/2018), 20.3% of temperature entries were not recorded. However, most of the missing entries were on weekends or holidays and Flowers was able to retrieve some of the missing week day entries from bench sheet records. Auditor did not investigate whether samples were in the incubator on the weekends and holidays with missing temperatures, but Flowers states that the incubator was not in use on those dates. The percent of missing entries excluding weekends, holidays and instances where Flowers provided an explanation was less than 1%.

Finding #	Requirement Reference	Finding	Required or Recommended Corrective Action	Laboratory Response and Corrective Action (if provided)	AEQAS Response
8	NELAC D.3.8 b) 7) iii); SM 9020B, Table I	The laboratory does not evaluate inhibitory residue tests (IRT) for washing of glassware and supplies, including pre-sterilized disposable plastic ware. The laboratory stated that they were advised by DOH that only the certificate from Liquinox is required.	**Required:** Perform and document the IRT initially and each time the laboratory changes the detergent formulation or washing procedures. Continue to retain the certificate from Liquinox.	FCL performed the IRT 1/5/10 (Attachment 6). Any items washed are checked with bromothymol blue for residue according to SM9020B 5.2). The Liquinox COA is kept on file for every lot purchased.	Acceptable. Perform a new IRT whenever a different detergent formulation is used or a change in SOP for washing is made. Retain detergent vendor IRT reports. Note: Upon discussion with DOH auditors on 5/10/19, the IRT test is not required for pre-sterilized disposable plastic ware as long as it is not being reused.
9	SM9020A	Conductivity and total residual chlorine values for laboratory water quality checks were outside the acceptance criteria on 5/3/2018 for conductivity and 1/11/18, 2/20/18, and 8/6/18 for Total Residual chlorine.	**Required:** Document procedures and implement corrective action for instances where acceptance criteria are not met.	FCL SOP 5.14 "Departure from Policies and Procedures and Corrective Actions" will be reviewed with all lab staff. This document states that when acceptance criteria are not met, to inform management and take action. DI water is not used for preparing media for DEP samples, so these slight outliers did not affect any tests.	This CA is acceptable; however, since DI water is used for making dilution water, these water quality checks would affect DEP samples. Create and maintain a record to document when checks are outside the acceptance criteria. Describe the corrective actions that must be taken when acceptance criteria are not met in the revised FCL SOP.

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10	SM9020A	Conductivity meter calibration frequently exceeded the ± 5% maximum acceptance criterion for verification with standards (Document #12247; 8/31/16 - present).	**Required:** Document procedures and implement corrective action for instances where acceptance criteria are not met for conductivity meter calibration.	The conductivity measurement performed on the Mantech instrument has a +/- 20% criteria for reading the KCL standard. A fresh standard would be used if this criteria was not met. The 5% criteria in 9020B refers to pH meter slope.	The +/- 5% acceptance criteria for conductivity is required by DEP SOP FT 1200. Use this required acceptance criterion for DEP samples to perform any necessary corrective action related to this finding.
				Response 6/11/2019: The ±20% criteria range expressed in our response was taken from Standard Methods. The Mantech instrument is capable of meeting the FDEP Field SOP± 5% conductivity measurements, so our SOP has been changed. The analyst that recorded values above 2 umhos/cm had not been trained to take corrective action. For values in the 200's, it appears that they were not actual conductivity measurements of the DI water, but perhaps of the pH buffer solutions.	Acceptable.
11	NELAC D.3.3.a; SM9020B	Laboratory analysts are not carrying out initial and annual demonstrations of capability (DOC) and proficiency testing (PT) for each analyst. There are no records for DOC or PT demonstration for VLB, BNP, ORS analysts. Analyst CLL is due for annual PT.	**Required:** All current microbiology analysts should complete and document initial and annual demonstrations of capability and twice a year proficiency testing for methods they perform, including updates per TNI 2016 minimum requirements.	VLB, ORS and CLL now have annual DOC records for each method. BNP is no longer working in the microbiology lab. PT's are performed twice a year by a different analyst. FCL performs 2 PTs per year. The primary analyst performs at least 1 study per year. The backup analysts alternate performing the 2nd annual PT study. Continuing DOC is defined in our SOP to be either a single passing PT per year or 4 QT tests using a positive sample with 10% agreement.	Acceptable.

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12	NELAC 5.4.12 SM9020B	Data entry process does not include documentation of a verification step.	**Required:** Include and document a verification step during the data entry process to minimize occurrence of transcription errors.	FCL's data entry review is first performed by the Analyst conducting the data entry, then the Project Manager reviewing the final reports. Data entry errors, e.g., incorrect sample ID's are rejected by the LIMS and would have to be re-entered by the analyst.	Acceptable. Ensure that data entry checks are indicated in the sample documentation. Provide a specific description in the appropriate FCL SOP of what a data review entails and what specific sample information is being verified.
13	NELAC 5.5.1.2	An auditor observed that when pouring samples into the mixing vessel, the analyst is not keeping the mixing vessel flat on the bench, which could cause measurement error.	**Required:** Keep vessels flat on the bench surface when pouring samples.	When performing 10x dilutions, the analyst holds the container at eye level to visually observe the sample is level at the 100mL mark. The liquid lines up front to back.	Acceptable. Keeping vessels steady and flat on the laboratory bench is important to prevent inaccurate measurements.
14	NELAC 5.5.8.4, IDEXX method	An auditor observed that the unsealed Quanti-trays were propped up against the counter in groups after being poured and before being sealed.	**Recommended**: After pouring a sample into a tray, tap the bottom of the tray to dislodge any bubbles and immediately seal the tray before pouring another sample.	FCL will take this recommendation into consideration. Our procedure has proven to be acceptable for large volume of sample output.	Upon further evaluation, auditors determined that this is a requirement in the IDEXX Quanti-Tray/2000 method, User Instruction 4. The method states, “Tap the small wells 2-3 times to release any air bubbles. Allow foam to settle.” Perform this step as the method requires and add it to the FCL SOP.
				Response 6/11/2019: We consulted with IDEXX and they mentioned that language has been added to the 23rd edition of Standard Methods, but the "tapping" of Quanti-Trays is not mentioned in SM 22nd edition that we follow. If a sample foams, or the small wells of a 2000 Tray contains air bubbles, a tap of a finger will be employed and this will be added to our SOP.	Acceptable.

References

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

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